

1 UNITED STATES FOOD AND DRUG ADMINISTRATION
2 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
3
4
5
6

7
8 Scientific Data and Information about Products
9 Containing Cannabis or Cannabis-Derived Compounds
10

11 Part 15 Public Hearing
12
13

14 DATE: Friday, May 31, 2019

15 TIME: 8:00 a.m.

16 LOCATION:

U.S. Food and Drug Administration
White Oak Campus, Building 31
10903 New Hampshire Avenue
Silver Spring, MD 20993

20 JOB No.: 3406507

21 REPORTER:

KeVon Congo
22

1 A P P E A R A N C E S

2 Amy Abernathy, MD, PhD

3 Principal Deputy Commissioner

4 U.S. Food and Drug Administration

5 Nick Alexander

6 Director, Intergovernmental Affairs

7 Office of Policy, Legislation and International
8 Affairs

9 U.S. Food and Drug Administration

10 Dayle Lewis Cristinzio

11 Director, Stakeholder Engagement

12 Office of External Affairs

13 U.S. Food and Drug Administration

14 Jarilyn Dupont

15 Director, Regulatory Policy

16 Office of Policy

17 U.S. Food and Drug Administration

18 Randall Gnatt

19 Regulatory Counsel

20 Center for Veterinary Medicine

21 U.S. Food and Drug Administration

22

1 A P P E A R A N C E S

2 Rebecca Goldberg

3 Associate Chief Counsel

4 Office of the Chief Counsel

5 U.S. Food and Drug Administration

6 Sharon Mayl

7 Senior Advisor for Policy

8 Office of Foods and Veterinary Medicine

9 U.S. Food and Drug Administration

10 Erik Mettler

11 Assistant Commissioner for Partnerships and Policy

12 Office of Regulatory Policy

13 U.S. Food and Drug Administration

14 Timothy Schell, PhD

15 Director, Office of Surveillance and Compliance

16 Center for Veterinary Medicine

17 U.S. Food and Drug Administration

18 Lowell Schiller

19 Principal Associate Commissioner for Policy

20 Office of Policy

21 U.S. Food and Drug Administration

22

1 A P P E A R A N C E S

2 Sherene Sepehri

3 Associate Chief Counsel

4 Office of the Chief Counsel

5 U.S. Food and Drug Administration

6 Ned Sharpless, MD

7 Acting Commissioner of Food and Drugs

8 Douglas Throckmorton, MD

9 Deputy Director for Regulatory Programs

10 Center for Drug Evaluation and Research

11 U.S. Food and Drug Administration

12

13 ORAL COMMENTS WITHOUT SLIDE DECK

14 ACADEMIA

15 Peter Pitts

16 Center for Medicine in the Public Interest

17 Tory Spindle, PhD

18 Johns Hopkins University School of Medicine

19

20 AGRICULTURE (NON-GOVERNMENT)

21 Jason Amatucci

22 Virginia Industrial Hemp Coalition

1 A P P E A R A N C E S

2 Hunter Buffington

3 Hemp Feed Coalition

4 Jonathan Miller

5 U.S. Hemp Roundtable

6 Jonathan Vaught, PhD

7 Front Range Biosciences

8

9 CONSUMERS

10 Susan Cromer

11 LilyHemp

12 Pamela McColl

13 Smart Approaches to Marijuana Canada

14 Sally Schindel

15 Marijuana Victims Alliance

16

17 HEALTH PROFESSIONALS

18 Anne Hassel

19 Holyoke Visiting Nurse Association

20 Russell Kamer, MD

21 Partners in Safety

22

1 A P P E A R A N C E S

2 Ashley Morgan, DVM

3 American Veterinary Medical Association

4

5 MANUFACTURERS

6 Philip Blair, MD

7 Elixinol LLC

8 Charles Jolly

9 Baker Donelson

10 James Shults

11 WMI Consulting - Wildflower Brands

12 David Spangler

13 Consumer Healthcare Products Association

14 Stuart Titus, PhD

15 Medical Marijuana

16 Julian Wright

17 Science & Recreation

18

19 OTHER

20 William Bookout

21 National Animal Supplement Council

22

1 A P P E A R A N C E S

2 Betsy Booren, PhD

3 Grocery Manufacturers Association

4 Aubrey Adams* (for James Childs, MD)

5 Childs Dermatology Clinic

6 Robert Discordia, PhD

7 Corbus Pharmaceuticals

8 Kristina Garcia

9 Women Grow

10 Gabriel Giancaspro, PhD

11 US Pharmacopeia

12 Karen Howard

13 Organic & Natural Health Association

14 Rod Kight

15 Kight Law Office PC

16 Andrew Kline

17 National Cannabis Industry Association

18 Michael McGuffin

19 American Herbal Products Association

20 Megan Olsen

21 Council for Responsible Nutrition

22

1 A P P E A R A N C E S

2 David Rodman

3 The Rodman Law Group LLC

4 Zoe Sigman

5 Project CBD

6 Andy Snyder

7 Manward Press

8 Monica Weldon

9 Bridge the Gap - SYNGAP Education and Research

10 Foundation

11 Anna Williams

12 A2LA

13

14 PATIENTS

15 Keith Fargo, PhD

16 Alzheimer's Association

17 Keith Chapman, MD

18 American Epilepsy Society

19 Kari Rosbeck

20 Tuberous Sclerosis Alliance

21

22

1 A P P E A R A N C E S

2 PUBLIC SAFETY

3 Patrick Bird

4 PMB BioTek Consulting

5

6 RETAILERS/DISTRIBUTORS

7 Crystal Guess

8 NuLeaf Naturals, LLC

9 David Heldreth

10 True Terpenes

11 Peter Matz

12 Food Marketing Institute

13

14 STATE/GOVERNMENT OFFICIALS/ENTITIES

15 Pam Miles

16 Virginia Department of Agriculture

17 Brenda Morris

18 Florida Department of Agriculture and Consumer

19 Services

20 Joseph Reardon

21 North Carolina Department of Agriculture &

22 Consumer Services

1 A P P E A R A N C E S

2 Erin Bubb

3 Pennsylvania Department of Agriculture

4

5 FORMAL PRESENTATIONS WITH SLIDE DECK

6 ACADEMIA

7 Barry Gidal, PharmD

8 University of Wisconsin-Madison

9 Igor Grant, MD

10 Center for Medicinal Cannabis Research, University

11 of California, San Diego

12 Bill Gurley, PhD

13 University of Arkansas for Medical Sciences

14 Rick Kingston, PharmD

15 University of Minnesota; SafetyCall International

16 PLLC

17 Igor Koturbash, MD, PhD

18 Center for Dietary Supplements Research,

19 University of Arkansas

20 Michelle Peace, PhD

21 Virginia Commonwealth University

22

1 A P P E A R A N C E S

2 Ryan Vandrey, PhD

3 Johns Hopkins University

4 Larry Walker, PhD

5 University of Mississippi, National Center for

6 Natural Products Research

7 Elise Wertz, PhD

8 Johns Hopkins Medicine; The College on Problems of

9 Drug Dependence

10

11 AGRICULTURE (NON-GOVERNMENT)

12 Cameron Cane

13 Deutsche Process

14

15 CONSUMERS

16 Jaclyn Bowen

17 International Association for Cannabis Testing

18 David Evans

19 Cannabis Industry Victims Educating Litigators

20 Lisa Gill

21 Consumer Reports

22

1 A P P E A R A N C E S

2 Yael Ossowski

3 Consumer Choice Center

4

5 HEALTH PROFESSIONALS

6 Ann Allworth, PhD

7 Cannabis Education Solutions

8 Jerry Bryant

9 Vyripharm Biopharmaceuticals

10 Najla Guthrie

11 KGK Science

12 Sue Sisley, MD

13 Scottsdale Research Institute

14 Lucille Vega, MD

15 Vega Direct Medical Family Practice

16

17 MANUFACTURERS

18 Justin Blehar

19 Genco Pura Oil Company, LLC

20 Richard Brumfield

21 Full Spectrum Omega, Inc.

22

1 A P P E A R A N C E S

2 Rola Mazloum* (for Guy Chamberland, PhD)

3 Tetra Bio-Pharma Inc.

4 Josh Epstein

5 Socati

6 Bill Grubb* (for Scott Warner)

7 Noramco

8 Deb Kimless, MD

9 Pure Green

10 Douglas MacKay, ND

11 CV Sciences

12 Ray Mannion

13 Zynerba Pharmaceuticals, Inc.

14 Rosemary Mazanet, MD, PhD

15 Columbia Care Inc.

16 Alice Mead

17 Greenwich Biosciences

18 Marwan Moheyeldien

19 Maryland Packaging LTD

20 Stephen Mueller

21 Mile High Labs

22

1 A P P E A R A N C E S

2 Aaron Secrist

3 NOW Health Group, Inc.

4 James Sharkey, PhD

5 Therabis, LLC

6 Priyanka Sharma, PhD

7 Kazmira LLC

8 Pulak Sharma

9 Kazmira LLC

10 Thuy Vu

11 Hammer Enterprises

12

13 OTHER

14 Aubree Adams

15 Moms Strong

16 Susan Audino, PhD

17 S.A. Audino & Associates, LLC

18 James Beck, PhD

19 Parkinson's Foundation

20 Scott Coates

21 AOAC Research Institute, AOAC INTERNATIONAL

22

1 A P P E A R A N C E S

2 Daniel Fabricant, PhD

3 Natural Products Association

4 Jacqueline French, MD

5 Epilepsy Foundation

6 Jeffrey Gitto

7 Vanguard Legal PLLC

8 Garrett Graff

9 Hoban Law Group

10 Shawn Hauser

11 Vicente Sederberg LLC

12 Youn Lee, PhD

13 RTI International

14 Brian Malkin

15 Arent Fox LLP

16 Steve Mister

17 Council for Responsible Nutrition

18 Robert Morgan

19 ASTM International

20 Sheri Orlowitz

21 Artemis Holdings / MPP

22

1 A P P E A R A N C E S

2 Matt Sica

3 ANSI National Accreditation Board

4 David Steinberg

5 Steinberg & Associates, Inc.

6

7 PATIENTS

8 James Werline, PharmD

9 H-E-B

10

11 PUBLIC SAFETY

12 Heather Despres

13 Americans for Safe Access

14 John Redman

15 Community Alliances for Drug Free Youth

16 Denise Valenti, OD

17 IMMAD, LLC

18

19 RETAILERS/DISTRIBUTORS

20 Howard Baxter, PhD

21 Daye

22

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

A P P E A R A N C E S

Craig Brand

Folium Biosciences

Dana McMurchy

Harvard CBD Health Center, Oklahomans for Health

Valentina Milanova

Daye

1			Page 18
2	1	C O N T E N T S	
3	2		PAGE
4	3	Welcome & Overview	
5	4	Dayle Cristinzio	20
6	5	Opening Remarks	
7	6	Ned Sharpless, MD	26
8	7	Oral Comments without Slide Deck	
9	8	Academia	37
10	9	Agriculture (Non-government)	42
11	10	Consumers	
12			53
13	11	Health Professionals	58
14	12	Manufacturers	66
15	13	Other	83
16	14	Patients	135
17	15	Public Safety	145
18	16	Retailers/Distributors	147
19	17	Oral Comments & Formal Presentations with Slide Deck	
20	18	State/Government Officials/Entities	156
21	19	Formal Presentations with Slide Deck	
22	20	Academic	176
22	21	Agriculture (Non-government)	227
	22	Consumers	

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

C O N T E N T S

PAGE

Health Professionals	259
Manufacturers	287
Other	373
Patients	456
Public Safety	461
Retailers/Distributors	481
Closing Remarks	501

1 P R O C E E D I N G S

2 OPENING REMARKS

3 MS. CRISTINZIO: -- to the Food and Drug
4 Administration's scientific data and information about
5 products containing cannabis or cannabis-derived
6 compounds public hearing.

7 I am Dayle Cristinzio, director of
8 stakeholder engagement within the Office External
9 Affairs, and I will be moderating today's hearing.

10 For today's agenda, we will hear from Dr. Ned
11 Sharpless, FDA's acting commissioner, who is right
12 here next to me. And then, we will proceed with the
13 oral comment, without slides, portion of the hearing.

14 Afterwards, we will proceed with a group of
15 state presentations and then finish with about six
16 hours of formal presentations with slides. There are
17 printed copies of the detailed agenda at the back of
18 the room and at the registration desk with more
19 information about the flow of the day.

20 Before we begin, I would like to ask our
21 distinguished panel members seated at this table next
22 to me to introduce themselves, except for Dr.

1 Sharpless. Please state your name, your position and
2 office and center.

3 MR. SCHILLER: Good morning. My name is
4 Lowell Schiller. I'm the principal associate
5 commissioner for policy here at FDA. I also co-chair
6 FDA's internal CBD working group

7 DR. ABERNATHY: Good morning. Amy Abernathy,
8 principal deputy commissioner, and I also co-chair the
9 CBD working group.

10 MS. MAYL: Good morning. My name is Sharon
11 Mayl, and I am the senior advisor for policy in FDA's
12 Office of Food Policy and Response in the
13 commissioner's office and I co-chair the marijuana
14 working group at FDA.

15 DR. THROCKMORTON: And I'm Doug Throckmorton.
16 I'm the deputy director for regulatory programs in the
17 Center for Drug Evaluation and Research at the FDA,
18 and I am the other co-chair for the marijuana working
19 group.

20 MR. METTLER: Good morning. Erik Mettler. I
21 am the assistant commissioner for partnerships and
22 policy in the Office of Regulatory Affairs.

1 MR. ALEXANDER: Good morning. I'm Nick
2 Alexander. I'm the director of intergovernmental
3 affairs in the Office of Policy, Legislation and
4 International Affairs in the Office of the
5 Commissioner.

6 MS. GOLDBERG: Good morning. I'm Rebecca
7 Goldberg. I'm an attorney in the FDA's Office of the
8 Chief Counsel.

9 MS. SEPEHRI: Good morning. Sherene Sepehri,
10 associate chief counsel in the Office of the Chief
11 Counsel.

12 DR. SCHELL: And I'm Tim Schell. I'm the
13 director of the Office of Surveillance and Compliance
14 for the Center for Veterinary Medicine.

15 MS. CRISTINZIO: And now, I have a few
16 general announcements to go over before we begin. In
17 addition to the hundreds of people we are expecting to
18 attend today's session in person, today's hearing is
19 also being webcast and transcribed.

20 Public hearings are public administrative
21 proceedings and are subject to FDA policy and
22 procedures for electronic media coverage.

1 Representatives of the electronic media are permitted,
2 subject to certain limitations to videotape, film or
3 otherwise record FDA public procedures, including the
4 presentations of the speakers today.

5 The hearing will also be transcribed and
6 copies of the transcript can be ordered through the
7 docket or accessed on our website approximately 30
8 days after the hearing. In addition, the webcast of
9 the hearing will be recorded and a copy of that
10 recording should be available on our website by the
11 end of next week.

12 No participant can interrupt the presentation
13 of any other participant and only FDA panel members
14 will be allowed to question the presenters. The press
15 contact for today's meeting is Mr. Michael Felberbaum.
16 If you are media and haven't checked in with him yet,
17 please do so as soon as possible. I believe he is at
18 the back of the room waving his hand at us.

19 I would like to remind everyone that members
20 of the public and the press are not permitted in the
21 panel area, which is the area beyond the speaker's
22 podium towards the front of this room. Please do not

1 approach panelists during the hearing. Also, please
2 silence your cellphones -- mine is silenced -- and
3 other electronic devices at this time and be
4 respectful of the speakers and move outside of the
5 room if you need to have a side conversation during
6 today's session.

7 Lunch and refreshments are available for
8 purchase just outside the Great Room throughout the
9 day. If you are planning to purchase lunch, please
10 consider filling out a lunch form and paying in
11 advance during the morning break in order to help us
12 get lunches distributed to this large number of people
13 as quickly as possible.

14 Restrooms are located just outside the Great
15 Room to the right. Just ask any of the staff outside
16 and they will help direct you to them.

17 For our speakers, please be mindful of all
18 your fellow presenters' time and do not go over your
19 allotted amount. We have an ambitious agenda today,
20 with over 113 speakers, and must stay within the time
21 limitations in order to end on time.

22 Please also pay attention to the agenda which

1 will be projected throughout the day and make your way
2 to the podium before your time slot so that we do not
3 lose valuable time between presentations. In order to
4 help the transcribers identify who is speaking, please
5 be sure to clearly state your name and affiliation at
6 the beginning of your remarks.

7 Also, there is a colored light system on the
8 podium microphone that will guide you through your
9 allotted time. It will change from green to yellow
10 when you have one minute remaining. And when the
11 light changes to red, your time is up.

12 If you have not concluded your remarks by the
13 time the light turns red, I apologize in advance, but
14 I will interrupt you and ask you to stop, very nicely.

15 And I will be emphasizing this throughout the
16 day. Your comments and presentations today will be
17 included in the public docket. But if you run out of
18 time and don't get to complete your remarks, please
19 submit additional information to the public docket for
20 consideration.

21 And with that, I'd now like to introduce our
22 distinguished acting commissioner, Dr. Ned Sharpless,

1 for opening remarks.

2 Dr. Sharpless has been with the agency for a
3 few months now, but is certainly not new to public
4 health or the FDA. He has a long and distinguished
5 career in public service, most recently serving as
6 director of the National Cancer Institute at NIH.

7 He is also a world-renowned oncologist who
8 was the director of the UNC Lineberger Comprehensive
9 Cancer Center and served on the faculty of UNC School
10 of Medicine as well as Harvard Medical School. Please
11 join me in welcoming Dr. Sharpless to the podium.

12 (Applause.)

13 OPENING REMARKS

14 DR. SHARPLESS: Thank you, Dayle. Good
15 morning, everyone. Thank you for joining the FDA
16 today for this public hearing titled "Scientific Data
17 and Information about Products Containing Cannabis or
18 Cannabis-Derived Compounds."

19 I'm pleased to see that there's so much
20 interest in this topic. We have over 500 people
21 registered to attend in person. We expect more than
22 800 people registered to join us remotely and over a

1 hundred speakers on today's very packed agenda and
2 lots of interest from the media.

3 We encourage all stakeholders, presenters,
4 attendees and those unable to participate in today's
5 meeting to submit comments to our docket, which is
6 open and will be open until July 2, 2019. Docket
7 comments will help inform the FDA as we consider the
8 important policy options related to the regulation of
9 products containing cannabis or cannabis-derived
10 compounds.

11 It's important to note that the FDA's role in
12 the regulation of products containing cannabis is not
13 new. Cannabis contains more than 80 biologically
14 active chemical compounds, including the best known
15 compounds, Δ -9-tetrahydrocannabinol, or THC, and
16 cannabidiol, or CBD.

17 If one of these compounds or the plant itself
18 is added to a food or cosmetic, marketed as a drug or
19 otherwise added to an FDA-regulated product in
20 interstate commerce, then it falls within FDA's
21 jurisdiction. As I said, this is nothing new for the
22 FDA.

1 At the same time though, some relevant laws
2 have changed. First, some states have changed their
3 laws to allow for medical use of marijuana or CBD and
4 others have begun allowing for recreational marijuana
5 use or decriminalized recreational marijuana
6 possession.

7 Moreover, certain federal laws have changed
8 as well. Part of the cannabis sativa plant have been
9 controlled under the federal Controlled Substances
10 Act, or the CSA, since 1970 under the drug class
11 marijuana.

12 Marijuana is included in Schedule 1 of the
13 CSA, the most restrictive schedule, due to its
14 potential for abuse, largely attributable to the
15 psychoactive effects of THC and the absence of a
16 currently acceptable medical use in the United States.

17 Last year, the federal scheduling of cannabis
18 changed. The Agricultural Improvement Act of 2018,
19 otherwise known as the Farm Bill, removed hemp,
20 meaning cannabis or derivatives of cannabis with a
21 very low THC content. And that's below 0.3 percent by
22 dry weight -- from -- so hemp was removed from the CSA

1 definition of marijuana. As a result, while marijuana
2 remains a Schedule 1 drug, hemp is no longer a
3 controlled substance under federal law.

4 As these laws have changed, FDA's authorities
5 have therefore become more relevant. The 2018 Farm
6 Bill explicitly preserved the FDA's authority to
7 regulate products containing cannabis or cannabis-
8 derived compounds.

9 In doing so, Congress recognized FDA's
10 important public health role with respect to all of
11 these products that it regulates, including when those
12 products are or contain cannabis ingredients.

13 FDA treats substances derived from cannabis
14 just like we do any other substance and they are
15 subject to the same authorities as any other
16 substance. Under FDA's authorities, the relevant
17 legal requirements vary depending on which type of
18 product we're talking about.

19 For example, if a product is being marketed
20 as a drug, meaning that it's intended to have a
21 therapeutic effect such as treating a disease or
22 affecting the body's structure or function, then it's

1 regulated as a drug and it generally cannot be sold
2 without FDA approval.

3 FDA has approved several products that
4 contain compounds found in cannabis as drugs. These
5 include Epidiolex, which contain CBD for the treatment
6 of certain kinds of pediatric seizures, and Marinol
7 and Syndros, which contain dronabinol, a synthetic
8 version of THC, that's used for the treatment of
9 anorexia, for example, in patients with AIDS.

10 These drugs have important therapeutic value
11 and it is critical that we continue to do what we can
12 to support the science needed to develop new drugs
13 from cannabis.

14 Food, including dietary supplements, is
15 regulated differently, but with the same overarching
16 goals throughout the FDA of protecting consumers and
17 the public health. We know that American consumers
18 depend on FDA to help make sure that the food they eat
19 and that they serve to their families is safe. We do
20 this through a number of requirements.

21 For example, while we don't generally require
22 foods to be approved by FDA before coming to market,

1 we do require that a new food additive be approved as
2 safe by FDA before being put in the food supply,
3 unless that substance is generally recognized as being
4 safe, or GRAS.

5 This requirement applies to cannabis-derived
6 ingredients just as it does to any other substance.
7 Americans deserve to know that substances being added
8 to their food are safe, regardless of the source.

9 I will note that several cannabis-derived
10 substances have already come to market through the
11 GRAS pathway. In December, FDA announced that we
12 completed our evaluation of GRAS noticed for three
13 hemp seed ingredients and had no objection to their
14 being marketed in human foods for certain uses without
15 approval, provided they comply with all other
16 requirements.

17 As I mentioned earlier however, some
18 compounds found in cannabis, specifically CBD and THC,
19 have been studied and even approved as drugs. It's
20 important to note that the federal Food, Drug and
21 Cosmetics Act prohibits adding drugs to human or
22 animal food in interstate commerce. That includes

1 both substances that have been approved as drugs as
2 well as compounds for which substantial clinical
3 investigation have been instituted. Similarly the law
4 excludes these products from the statutory definition
5 of a dietary supplement.

6 Based on the information available to the
7 FDA, we have concluded that these provisions apply to
8 CBD and THC. And while there is an exception when the
9 substance was marketed as a food or dietary supplement
10 before it was studied as a drug, we have concluded
11 that that is not the case for CBD or THC.

12 What that means is that under current law,
13 CBD and THC cannot lawfully be added to food or
14 marketed as a dietary supplement

15 Although the new law says that FDA could
16 issue regulations to create new exceptions to these
17 statutory provisions, FDA has never issued a
18 regulation like that for any substance. So if we were
19 thinking about doing that for a substances like CBD,
20 well, that would be new terrain for the FDA.

21 There are important reasons to generally
22 prohibit putting drugs in the food supply. When FDA

1 approves a drug, we carefully evaluate the risks and
2 benefits of a specific formulation, dosage form and
3 strength for a particular population. Often we
4 conclude that to be safely used, it requires a
5 prescription or other medical supervision to help
6 protect against potential dangerous misuse. THC and
7 CBD are no exception.

8 There are real risks associated with both
9 substances and critical questions remain about the
10 safety of their widespread use in foods and dietary
11 supplements, as well as other consumer products like
12 pet food and cosmetics, which are subject to a
13 separate regulatory framework.

14 And given the new interest in marketing
15 cannabis products across a range of areas that the FDA
16 regulates, we will need to carefully evaluate how all
17 these pieces fit together in terms of how consumers
18 might access cannabis products.

19 Nowhere is this truer than with CBD. While
20 we've seen an explosion of interest in products
21 containing CBD, there is still much that we don't
22 know. Prior to the 2018 Farm Bill, population-based

1 research mostly included cannabis-focused observations
2 in aggregate. There still -- rather than specific to
3 CBD.

4 When hemp was removed as a controlled
5 substance, this lack of research and therefore lack of
6 evidence to support CBD's broader use in FDA-regulated
7 products, including in food and dietary supplements,
8 has resulted in unique complexities for its
9 regulation, including many unanswered questions
10 related to its safety.

11 For example, how much CBD is safe to consume
12 in a day? What if someone applies a topical CBD
13 lotion, consumes a CBD beverage or candy and also
14 consumes some CBD oil? How much is too much? How
15 will it interact with other drugs the person may be
16 taking? What if she's pregnant?

17 What if children access CBD products like
18 gummy edibles? What happens when someone chronically
19 uses CBD for prolonged periods? These and many other
20 questions represent important and significant gaps in
21 our knowledge.

22 To help us evaluate these questions as well

1 as potential pathways for CBD products, FDA has formed
2 an internal working group to address these data gaps
3 specifically, and you will be hearing more from this
4 group in the months to come.

5 FDA is aware that some companies appear to be
6 marketing products containing cannabis and cannabis-
7 derived compounds in ways that violate the law. FDA
8 has issued warning letters to companies selling
9 unapproved CBD products.

10 Our biggest concern is the marketing of
11 products that put the health and safety of consumers
12 at risk, such as those claiming to prevent, diagnose,
13 mitigate, treat or cure serious diseases such as
14 cancer in the absent of requisite approvals.

15 Selling unapproved drug products with
16 unsubstantiated therapeutic claims is a violation of
17 the law and puts patients at risk. Patients and other
18 consumers may be influenced not to use approved
19 therapies to treat serious and even fatal diseases if
20 they're confused.

21 That being said, the agency does not have a
22 policy of enforcement discretion with respect to any

1 CBD products. There are lots of questions we will
2 need to answer to ensure that FDA is taking an
3 appropriate well-informed and science-based approach
4 to the regulation of cannabis and cannabis
5 derivatives, including CBD.

6 We hope that this meeting and the comments
7 submitted in our public docket will help us as we try
8 to approach this in a science-based way. This hearing
9 is an important step in our continued evaluation of
10 cannabis and cannabis-derived compounds in FDA-
11 regulated products.

12 Now, that was a lot to go through quickly.
13 So I will be tweeting the text of this speech as well
14 as a link to where you can submit comments for the
15 docket from the FDA commissioner account later today.

16 I thank you all for taking the time to join
17 us today and your contributions toward this important
18 topic. And as mentioned, we have a very fully agenda.
19 So I'll leave it at that. Thank you this morning.

20 (Applause.)

21 MS. CRISTINZIO: Thank you, Dr. Sharpless.
22 Now we are going to begin the open public comment

1 period, or oral comment period of our program this
2 morning. Those people on the agenda will have two
3 minutes each to present.

4 Hopefully when you checked in outside, you
5 were told that you were given a number. We'll have a
6 numeric order for speakers. And they're organized by
7 segment, how you identified yourself. Some of you
8 identified yourself as academic first, and that is the
9 first category that is up.

10 First, I have Peter Pitts, from the Center
11 for Medicine in the Public Interest, as our first
12 speaker. And if you all know your numbers, please
13 make your way to the line behind him so that we can
14 move quickly in between. Peter, you may begin.

15 ORAL COMMENTS WITHOUT SLIDE DECK

16 ACADEMIA

17 MR. PITTS: Thank you. Good morning. My
18 name is Peter Pitts. I'm the president of the Center
19 for Medicine in the Public Interest. The absence to
20 date of advanced regulatory thinking relative to CBD
21 has resulted in a maelstrom of false claims and shoddy
22 quality standards. Nature abhors a vacuum.

1 What's the relevant messages for the nascent,
2 but swiftly growing CBD industry? First, that
3 aggressive and misleading marketing campaigns need to
4 be put on hold now that the FDA has stepped up to the
5 plate. Next, as with all FDA-regulated products,
6 manufacturing quality and labeling integrity are
7 joined at the hip.

8 Many in the CBD community think this issue is
9 one of regulatory creep on the part of the FDA. But
10 waving away as "Big Brotherism" the important public
11 health role of the FDA doesn't make the agency's
12 position or authority any less real or relevant.

13 It's time for the proponents of CBD,
14 including many highly vocal patients, physicians,
15 pharmacists, manufacturers and distributors to become
16 part of the solution.

17 Some key issues include, one, no current
18 standard in quality of production. We mustn't repeat
19 the tragic flaws of limiting FDA's hand via outdated
20 DSHEA legislation. Quality must always trump
21 corporate convenience. Two, no dosing standard. When
22 patients are prescribed any FDA-approved medication,

1 they are given a dosing schedule by the doctor telling
2 them how much to take, how to take it and how often.

3 When people are told to use CBD by
4 physicians, pharmacists, friends or Internet experts,
5 they are not given any peer-reviewed guidelines about
6 how they should take it or in what amounts, something
7 that should never happen.

8 Three, potential for help and harm through
9 chronic use. What does serious research tell us?
10 Hardly anything. And the plural of anecdote isn't
11 data. We mustn't repeat the mistakes that led to the
12 opioid epidemic.

13 Four, legalization changes public opinion.
14 If you can't measure it, then it doesn't count.
15 Quantifying CBD's therapeutic and manufacturing bona
16 fides for pain treatment isn't the end of the debate.
17 It is only the beginning.

18 Now you must develop ways to measure its
19 effectiveness and develop ways to capture the real-
20 world evidence that must drive evolving best practice
21 and reimbursement policies. Thank you.

22 MS. CRISTINZIO: Thank you. Next up is Tory

1 Spindle from Johns Hopkins University School of
2 Medicine.

3 DR. SPINDLE: Hi, everyone. My name is Tory
4 Spindle, and I'm a cannabis researcher at Johns
5 Hopkins University. I'm not speaking on behalf of
6 Johns Hopkins today, and these are my own views.

7 Although I now specialize in cannabis
8 research, I did my PhD work conducting research to
9 inform product regulations for electronic cigarettes.
10 From this research, I learned there's a lot of moving
11 parts with e-cigarettes that will make it very
12 difficult to regulate nicotine dosage and delivery.

13 But I've grown to realize from my cannabis
14 research that regulating dosage for cannabis products
15 will be exponentially more difficult. If you remember
16 one thing from my talk today, remember that for
17 cannabis, a dose is not necessarily a dose.
18 Importantly, the same dose of cannabis can have very
19 different effects on a person depending on the route
20 of administration.

21 We recently published a paper in JAMA Network
22 Open showing that the same dose of cannabis can

1 produce stronger drug effects and greater impairment
2 if it's inhaled with a cannabis vaporizer compared to
3 with a smoked method.

4 When cannabis is inhaled, users can feel the
5 drug effects within minutes. However, when cannabis
6 is orally ingested, it can take up to 45 minutes for a
7 person to feel a drug effect and often peak effects
8 don't occur until hours after ingestion. This delayed
9 onset of effects makes it difficult for someone to
10 titrate their dosage, which can lead to acute
11 overdose.

12 Beyond these products, there are many other
13 routes of administration that are becoming popular,
14 including transdermal or topical cannabis products,
15 sublingual sprays, lozenges and cannabis
16 suppositories. But given the regulatory barriers to
17 conducting cannabis research, we have very little
18 scientific evidence available to inform regulation of
19 these emerging products.

20 Just like the research currently being done
21 to inform regulations for tobacco products, we
22 desperately need to conduct cannabis regulatory

1 science to inform appropriate product standards for
2 the various forms of cannabis that are available today
3 or that might become available tomorrow. Researchers
4 need a streamlined, regulatory pathway that can
5 facilitate research on the spectrum of commercially
6 available products.

7 Clinical research studies have barely
8 scratched the surface when considering the vast array
9 of cannabis products available to consumers. The risk
10 of retail cannabis products harming public health must
11 be mitigated by swift and evidence-based regulatory
12 action. Thank you all for allowing me to speak today.

13 MS. CRISTINZIO: Thank you. The next speaker
14 is from the agriculture category. Jason Amatucci.

15 AGRICULTURE (NON-GOVERNMENT)

16 MR. AMATUCCI: Good morning. My name is
17 Jason Amatucci. I founded the Virginia Industrial
18 Hemp Coalition in 2012 and since that time I've been
19 assisting with the crafting of legislation and policy
20 for the Virginia and United States hemp industry. I
21 want to thank the FDA for holding this public hearing
22 on the subject of cannabis-derived products.

1 I'd like to begin this morning by making a
2 connection between safe, non-intoxicating hemp
3 products being produced currently throughout America
4 and the relationship to famers and agribusiness in
5 those states.

6 Today, as many of you know, the American
7 farmer is facing some of the toughest times in recent
8 history. In my home state of Virginia, agriculture is
9 the largest private industry by far. Nothing else
10 comes a close second.

11 It has an economic impact of \$70 billion
12 annually and provides more than 334,000 jobs for our
13 state. In neighboring Kentucky last year, hemp
14 processors reported \$58 million in gross product sales
15 and they paid Kentucky farmers \$18 million for
16 harvested hemp materials. Hemp processors also spent
17 \$23 million in capital improvements in the state,
18 while creating many new jobs in the process.

19 I truly believe the United States hemp
20 industry is poised to take off. But to do so, we
21 cannot have legal uncertainty which can hinder the
22 growth in confidence in our industry.

1 Currently farmers who grow crops on land
2 where hemp also does well, such as corn, soybeans and
3 tobacco, are being hit with multiple downward
4 pressures. The recent popularity of hemp products
5 have shown great economic promise in providing some
6 hope for farmers and agribusiness in places where
7 there currently is little hope to be found.

8 It is our request that the FDA strongly
9 considers the new economic opportunities that farmers
10 and agribusiness have when forming regulations. We
11 recommend that you regulate hemp products as food and
12 dietary supplements and give them all GRAS
13 designation.

14 We wholeheartedly agree with the FDA that
15 food and dietary supplement safety for the public is
16 of the utmost importance. And the hemp industry has
17 shown that it will work, as it has already started to,
18 to self-regulate, to provide safe products and
19 consumer products.

20 What we need from the FDA right now is clear
21 communication as quickly as possible so that all
22 stakeholders can get on the same page so that the

1 American hemp industry can thrive to boost the
2 economy, create jobs and give Americans safe and
3 effective products for a better quality of life.
4 Thank you for your time.

5 MS. CRISTINZIO: Thank you. Next, we have
6 Hunter Buffington, from Hemp Feed Coalition.

7 MS. BUFFINGTON: Good morning. I'm Hunter
8 Buffington, program director for the Hemp Feed
9 Coalition, a group of farmers, processors, feed
10 experts, researchers, animal nutritionists from across
11 the United States and Canada.

12 Our goal is the legal approval of hemp as an
13 animal feed ingredient, focusing on hempseeds and
14 their byproducts. However, there is an opportunity to
15 utilize flour grown commonly for CBD as forage and
16 silage and significant interest in the nutritional
17 value of post-extracted cannabinoid pulp material for
18 the animal feed market as well.

19 Preliminary data shows that this is a
20 valuable material with high levels of protein and
21 omega fatty acids, including linoleic acid. This
22 material is currently considered waste and accumulates

1 in warehouses instead of providing a much needed
2 secondary revenue stream for farmers and a high
3 protein feed source for animal, poultry and fish
4 producers.

5 Hemp is one of the oldest crops known to
6 mankind and American farmers must be given the
7 opportunity to have an additional cash crop to replace
8 dwindling commodity prices.

9 Currently China produces 50 percent of the
10 world's cannabis supply, a threat to cannabis
11 interests around the world and particularly the U.S.
12 market, as reported by Forbes. Not only is this a
13 threat to small farmers and livestock producers, this
14 introduces low quality and potentially harmful
15 products into the U.S. market and to American
16 consumers.

17 We need to ensure that the economic benefits
18 of the emerging hemp industry start on the family farm
19 with American-grown and processed feeds. Healthier
20 feeds create healthier animals and in turn leads to
21 healthier Americans.

22 We ask that the FDA and its commissioner do

1 not utilize a lack of data and research, considering
2 we've only had access to cannabis for the last three
3 years, as a reason to implement a ban or incorrectly
4 label it a drug.

5 Instead, we recommend the following steps:
6 include data and research from qualified international
7 sources and open research opportunities to private
8 companies instead of a small group of universities.
9 Identify a pathway for the production of hemp-derived
10 foods and reconsider designation of a dietary
11 supplement for products that contain CBD and other
12 useful phytocompounds.

13 Your agreement to this shows a commitment to
14 help farmers and animal producers to keep American
15 agriculture competitive. Thank you.

16 MS. CRISTINZIO: Thank you. The next
17 speaker, number five, is Jonathan Miller, U.S. Hemp
18 Roundtable.

19 MR. MILLER: Good morning. The U.S. Hemp
20 Roundtable is the hemp industry's leading business
21 advocacy organization committed to fostering
22 regulatory discussions and building an accountable

1 industry. We're comprised of members from more than
2 60 firms from across the country who are involved in
3 each link of the hemp supply and sales chain, as well
4 as grassroots leaders such as the Hemp Industries
5 Association.

6 Over the past several weeks, we have worked
7 with members of Congress on the drafting of
8 legislation that, if necessary, could provide a more
9 efficient pathway for CBD while FDA considers
10 rulemaking to allow the use of CBD in food and dietary
11 supplements.

12 We believe Congress clearly intended on
13 having hemp-derived products available to consumers as
14 foods and dietary supplements when it passed the 2018
15 Farm Bill. There is an urgent need for an efficient
16 regulatory framework for CBD as we continue to see a
17 great deal of confusion among consumers and state and
18 local regulators surrounding the lawfulness of hemp-
19 derived products.

20 The roundtable appreciates the FDA's
21 willingness to work with stakeholders. But we
22 strongly believe that the FDA has all the tools

1 necessary to make a change expeditiously. Multiple
2 reviews, including the World Health Organization's
3 June 2019 critical review of cannabidiol and ones from
4 the FDA itself have found that CBD is safe, with a
5 growing body of scientific research which demonstrates
6 CBD's potential benefits.

7 Although hemp-derived CBD is safe, our
8 members are not just relying on the current scientific
9 literature; but rather, we are also investing millions
10 of dollars to conduct our own safety studies.

11 Moreover, the U.S. Hemp Authority's certification
12 program is our industry's initiative to provide high
13 standards, best practices and self-regulation, giving
14 confidence to consumers and law enforcement that hemp
15 products are safe and legal.

16 This effort, led by the roundtable, HIA top
17 tier testing laboratories and quality assessors,
18 provides comprehensive guidance for growers and
19 processors of hemp to help ensure the safety and
20 quality of hemp-derived products, including CBD.

21 We welcome the opportunity to discuss this
22 important initiative with the FDA and use what we've

1 learned to help the agency establish measures of
2 quality, safety and transparency for the entire
3 industry. Thank you.

4 MS. CRISTINZIO: Thank you. Panelists, do
5 you have any questions? Okay. Our next speaker is
6 Jon Vaught, from Front Range Biosciences.

7 DR. VAUGHT: My name is Jon Vaught. I have a
8 PhD in organic chemistry from the University of
9 Colorado at Boulder and I'm CEO and founder of Front
10 Range Biosciences. We're an agricultural company that
11 supports farmers of high value crops such as hemp and
12 coffee.

13 Before Front Range, I spent 15 years
14 developing technology platforms in human diagnostics
15 that generated validated clinical data supporting the
16 FDA drug approval process. I have a deep
17 understanding of FDA regulations for taking drugs to
18 market and the scientific rigor required to ensure
19 safety and efficiency for consumers.

20 I strongly support the FDA's mission of
21 ensuring public safety when it comes to bringing new
22 products to market and am thankful for the role it

1 plays, despite frequent criticism from the public. I
2 can imagine it's not an easy job to do.

3 There are two key points: first, that
4 cannabis-derived ingredients have an incredible safety
5 profile compared to many over-the-counter products and
6 FDA-approved drugs on the market. Besides its
7 measured therapeutic ratio, cannabis is 400 times
8 safer than caffeine and 200 times safer and aspirin.

9 In published Epidiolex studies, doses as high
10 as 10 mg/kg, or 70 milligrams a day for a normal
11 adult, were well tolerated, with only 2.7 percent of
12 the trial participants discontinuing treatment due to
13 severe adverse events such as mild liver toxicity and
14 sleepiness.

15 Given the last decade of state-regulated
16 legal programs which have not created a public health
17 crisis, in recent clinical data from the Epidiolex
18 trials, there is more than enough evidence showing
19 cannabis is generally at safe limits where it's
20 marketed and regulated at the state level as a
21 supplement or a wellness product, typically 10 to 30
22 mg per dose.

1 Second, the economic impact of cannabis
2 products is massive and it's important that
3 regulations don't create a monopoly for any one
4 segment of the industry. The current market in the
5 U.S. hit over \$10 billion last year, generating a
6 billion dollars in tax revenue for state governments
7 and representing over 200,000 jobs in the United
8 States. That's more jobs than coal or textile
9 manufacturing.

10 It has huge potential impact for agricultural
11 regions in the U.S., providing opportunities that can
12 raise the economic status of many farming communities
13 that have been beaten down economically.

14 It's important we focus on a regulatory
15 framework for cannabinoid-based products that ensures
16 public safety, but provides the opportunity for not
17 just one, but multiple segments of the industry to
18 thrive, pharmaceuticals, dietary supplements, food
19 additives, cosmetics and even animal feed.

20 MS. CRISTINZIO: Thank you.

21 PANEL MEMBER: Quick question. Are you
22 willing to submit your data to the public docket so

1 that it can be reviewed?

2 DR. VAUGHT: Absolutely. I'll do it by July
3 2nd.

4 PANEL MEMBER: Thank you.

5 MS. CRISTINZIO: Thank you. Our next
6 speakers in the consumer category, Susan Cromer from
7 LilyHemp.

8 CONSUMERS

9 MS. CROMER: Thank you for taking the time to
10 address this very important issue. I am Susan Cromer,
11 founder and CEO of LilyHemp, a boutique and gourmet
12 retail, wholesale and e-commerce business, cofounder
13 of Women in Hemp, a 501(c)(3) dedicated to the
14 education and support of women in the industry and I
15 am a board member of the Virginia Industrial Hemp
16 Coalition.

17 As a retailer, it is paramount to me to offer
18 safe, effective, top quality products. This can
19 easily be achieved by following the guidelines
20 currently in place for supplements and for ingredients
21 in foods. Additionally, require clear, truthful
22 labeling, the implementation of good manufacturing

1 practices and determination of shelf stability.

2 These are all systems the FDA already has in
3 place to keep us safe. You got this. Just use them
4 for CBD. Science has proven with the discovery of the
5 endocannabinoid system that CBD is beneficial to
6 humans and animals alike. The World Health
7 Organization has deemed CBD safe. Much credible
8 research and a multitude of anecdotal evidence attest
9 that CBD has many positive effects.

10 Personally I have been privileged, awed and
11 at times brought to ears by the positive changes CBD
12 has brought to my customers' lives. My clients and
13 thousands, if not hundreds of thousands of others,
14 have felt the difference CBD can make.

15 Overregulation will simply drive consumers to
16 the black market, costing our economy and tax base a
17 projected revenue stream of many billions of dollars.
18 The ending of prohibition of hemp with the 2018 Farm
19 Bill was monumental for our country. I ask you not to
20 repeat history by once again demonizing any part of
21 this wondrous plant. We the people deserve and I
22 daresay demand no less than safe and unfettered

1 access. Thank you.

2 PANEL MEMBER: Could I ask, as a retailer,
3 what steps are you taking relating to youth access to
4 cannabis products?

5 MS. CROMER: As to what?

6 PANEL MEMBER: Youth access.

7 MS. CROMER: Youth access? We do not allow
8 anyone under 21.

9 PANEL MEMBER: Within the store premises?

10 MS. CROMER: Correct. Well, I don't -- yeah,
11 I mean, we don't sell to anyone under 21 personally.
12 And I guess if parents decide they want to have them
13 using, that's up to them. But, I mean, I can't
14 control that obviously, nor can anybody.

15 PANEL MEMBER: Okay. Thank you.

16 MS. CROMER: With anyone, any subject -- I
17 mean, any product.

18 PANEL MEMBER: And how was the age 21
19 selected?

20 MS. CROMER: Pardon me?

21 PANEL MEMBER: How did you select the age 21?

22 MS. CROMER: Just because of thinking of like

1 alcohol or something like that, just seemed like the
2 age that people usually use for substances.

3 PANEL MEMBER: Thank you.

4 MS. CROMER: That is just a safety guideline.
5 There is no -- I know there is no set thing. But I
6 know that other states that have -- I'm from Virginia.
7 We really don't have any guideline for that.

8 But I know that other states have used 21.
9 So we just did it as kind of a safety net. No
10 particular -- just think that's a good idea. You guys
11 can tell us. We'd appreciate that.

12 PANEL MEMBER: Thank you.

13 MS. CROMER: Thank you.

14 MS. CRISTINZIO: Thank you. Our next speaker
15 is Sally Schindel, from the Marijuana Victims
16 Alliance, speaker number eight.

17 MS. SCHINDEL: Sally Schindel, Marijuana
18 Victims Alliance. My son was the consumer. My son's
19 suicide note: "Marijuana killed my soul, plus ruined
20 my brain." In the end, Andy understood the dangers of
21 marijuana. And I have to ask do you understand.

22 What we need is our federal government

1 enforcing federal laws. We need limits on THC
2 potency. We need product safety warning labels. I
3 have with me Andy's death certificate, Andy's medical
4 marijuana card, Andy's dispensary frequent purchaser
5 card.

6 And I took all of this to the dispensary and
7 I asked the manager to save the next kid who appeared
8 to abuse the drug. She told me marijuana does not
9 cause addiction or death. I asked that she share
10 Andy's warning with others. She refused, saying Andy
11 must have used other drugs. He did not. His
12 toxicology confirmed that.

13 Andy had been a kid with dreams. Join the
14 army. Go to college. Get married. Have kids. He
15 worked hard. He achieved some of that. He served
16 with the 82nd Airborne. He earned two degrees. But
17 by age 25, he was in a downward spiral of severe
18 cannabis use disorder, serious mental illness, locked
19 up in psych units, multiple suicide attempts, court-
20 ordered mental healthcare.

21 I want you to understand the devastation
22 marijuana brought to our family. And sadly, ours is

1 not an isolated story. I can tell you of other
2 tragedies directly linked to marijuana, a list of
3 stories that goes on and on and keeps getting longer.
4 Many families I work with find it too painful to be
5 public about the harms this drug brought into their
6 lives.

7 And even now, it still hurts me. But I am
8 mad. So I speak for those other families. And I am
9 sad. So I speak for my Andy, that his message and
10 warning will be heard.

11 We need FDA to be more involved and take a
12 leading role in marijuana research and policy
13 formation. Being proactive, we can save other
14 families the agony from a loss that so many of us have
15 had. Thank you.

16 (Applause.)

17 MS. SCHINDEL: Thank you.

18 HEALTH PROFESSIONALS

19 MS. CRISTINZIO: Thank you for your comments.

20 Our next category is health professionals. Our
21 speaker number nine, Corey Burchman, is up next. All
22 right. We will move on to speaker number 10, Nasser

1 Hassan, CanDiscPharma, Incorporated. Nasser? Moving
2 on to speaker number 11, Anne Hassel, Holyoke Visiting
3 Nurse Association.

4 MS. HASSEL: My name is Anne Hassel. I am a
5 physical therapist who was once a strong believer in
6 medical marijuana and also an employee in the
7 industry. I worked as a budtender in a Massachusetts
8 medical marijuana dispensary for a year-and-a-half and
9 learned this has nothing to do with public health,
10 just profit.

11 I witnessed unethical and dangerous practices
12 harmful to patients' physical and mental health. I
13 saw and trimmed moldy marijuana plants at the
14 cultivation center. I saw and sold moldy marijuana to
15 dispensaries -- to patients at the dispensary who
16 truly believed we were taking good care of them,
17 looking out for their health. I was wrong.

18 Management policy was to mask moldy marijuana
19 by dunking it into barrels of caustic hydrogen
20 peroxide, an industry standard, all for the purpose of
21 making a sale and a profit. This industry also has a
22 lack of concern for its employees who work in

1 environments exposed to biological toxins and harmful
2 chemicals.

3 The marijuana industry is self-policing and
4 self-reporting. The state is woefully incapable of
5 effectively regulating marijuana to ensure patient and
6 worker health and safety. Health hazards were
7 reported to the state by a group of concerned workers.
8 After two years, we are still awaiting a response, no
9 response despite the fact I have documents to support
10 my toxic exposure and heavy metal poisoning.

11 My state issued a waiver for testing of heavy
12 metals and pesticides in marijuana products. I was
13 fortunate to wake up to the harms of why marijuana is
14 a medicine, cease consuming it, quit an industry more
15 focused on profit over people and seek medical
16 attention for my exposure.

17 The trusting patient population is assuming
18 that medical marijuana is safe, as I did. What the
19 states are allowing the medical marijuana industry to
20 do is dangerous, wrong and a great threat to public
21 health. The FDA needs to step in. You must create
22 rigorous controls over the purity of marijuana

1 products and especially levels of high potency THC in
2 these products to protect the public. I am willing to
3 provide additional information, answer any health-
4 related questions. Thank you.

5 PANEL MEMBER: May I ask which state was the
6 facility that you worked at located in?

7 MS. HASSEL: Massachusetts.

8 PANEL MEMBER: Thank you.

9 MS. CRISTINZIO: Thank you. The next speaker
10 is speaker number 12, Lily Jin, from DataRevive.

11 Lily? Moving on to number 13, Amy Jones, from the
12 Toxicology and Risk Assessment Consulting. Amy Jones?
13 All right. We're on to speaker number 14, Russell
14 Kamer, Partners in Safety.

15 DR. KAMER: Good morning. My name is Russell
16 Kamer, from Partners in Safety. Despite the lack of
17 FDA approval, this plant-based substance was legalized
18 for medicinal use by 27 states.

19 The FDA associate commissioner, Dr. Stuart
20 Nightingale, wrote, "Unfortunately, the lack of
21 scientific evidence about the drug and the views of
22 responsible orthodox spokespersons were viewed as of

1 no consequence by state legislators and the public.
2 Consumer groups were notably silent on this major
3 public health issue." Of course, I am talking about
4 Laetrile, the bogus cancer cure that swept the nation
5 40 years ago.

6 Once again, the FDA's authority to protect
7 the public is being challenged. This time, it is in
8 the form of cannabis-derived products, both THC and
9 CBD.

10 THC products are sold as medical marijuana in
11 the manner described by Anne, the budtender, this
12 morning. And that is just a small bit of what
13 happened at that so-called dispensary. CBD is sold in
14 even less regulated way, if that's even possible.

15 As a practicing primary care physician, I can
16 vouch for the extent of the CBD craze. Every day --
17 every day, I see a patient who has taken CBD. Some
18 patients get it from drugstores or chiropractors while
19 others purchase it online, at gas stations or even at
20 flea markets. They think they are getting a THC-free,
21 safe product. In two cases, they are providing CBD to
22 their children.

1 Most of these products have no independent
2 lab analysis. Ones that do, for a 20 mg CBD tablet,
3 there was 1 mg of THC. A person taking two or three
4 of these tablets would be getting a significant
5 exposure to THC.

6 As Dr. Nightingale said 40 years ago,
7 experience tells us a successor to Laetrile is almost
8 surely on the horizon, if not in our midst. It is
9 hoped that those of us in medicine and science, in and
10 out of government, would be able to meet the next
11 challenge of quackery.

12 While the role of a drug regulatory agency
13 may be limited, submission of scientific data should
14 be encouraged. Thank you.

15 MS. CRISTINZIO: Thank you. The next speaker
16 is number 15, Ashley Morgan, from the American
17 Veterinary Medical Association.

18 DR. MORGAN: Thank you. Good morning. I am
19 Dr. Ashley Morgan, with the American Veterinary
20 Medical Association. We believe there is therapeutic
21 potential in the development of cannabis-derived and
22 cannabis-related compounds, and we would like to see

1 that potential realized.

2 There are FDA-approved cannabis products for
3 human use that veterinarians may use in an extra-label
4 fashion. However, we ultimately desire products for
5 use in animals that come with the assurance
6 veterinarians need that they are of good and
7 consistent quality and that they are efficacious and
8 safe for use in our patients.

9 Currently products intended for use in
10 animals may be animal drugs, food or feed or food or
11 feed additives. The FDA should clearly articulate
12 where the various cannabis-derived and cannabis-
13 related products fall and what may or may not be
14 included in the promotional and labeling materials for
15 these categories.

16 There are many companies in the marketplace
17 today selling unapproved cannabis-derived products for
18 dogs, cats and horses, some of which make what clearly
19 appear to be therapeutic claims. And while we know
20 that DSHEA doesn't apply to products intended for use
21 in animals, other manufacturers say that they are
22 making no therapeutic claims or are simply selling

1 supplements or nutraceuticals for veterinary use.

2 As justification, they ask rhetorically what
3 is the difference between CBD and a glucosamine
4 supplement intended to support joint health. Given
5 known gaps in quality, limited information about these
6 products' efficacy in veterinary patients and emerging
7 concerns about their safety, AVMA believes FDA must
8 seriously consider the need for efficacy and safety
9 data when therapeutic claims are made or implied for
10 these products.

11 To facilitate the development of such
12 products for veterinary use, it is imperative that FDA
13 provide a pathway that assures regulatory clarity and
14 predictability and the economic viability of the
15 industry.

16 Further the agency must make its enforcement
17 policies known and then consistently and intentionally
18 act on these priorities. Otherwise we will continue
19 to face the Wild West and invariably greater numbers
20 of therapeutic failures and toxicoses in our patients.
21 Thank you for the opportunity to comment.

22 PANEL MEMBER: I have a -- I have --

1 PANEL MEMBER: Do you have views on the use
2 of cannabis products in feed-producing animals and the
3 impact on human food?

4 DR. MORGAN: We definitely have concerns
5 about that and would like to see the data and ensure
6 that those products are safe, particularly, like you
7 mentioned, as they're going to go into the food
8 supply. We are going to be submitting additional
9 comments by the July 2nd date.

10 PANEL MEMBER: Okay. Thank you.

11 PANEL MEMBER: Sorry. One more question,
12 please. Is the veterinary community currently
13 prescribing or using these products?

14 DR. MORGAN: No. Well, not legally.

15 PANEL MEMBER: Okay.

16 MS. CRISTINZIO: All right. Well, we are
17 moving onto our next category of speakers in the
18 manufacturer category. Number 16 is Robert Allen.
19 Robert, from Celtic Wind Crops? Now we're moving on
20 to number 17, Phillip Blair, from Elixinol.

21 MANUFACTURERS

22 DR. BLAIR: Hello. I am Dr. Philip Blair,

1 MD, and I represent Elixinol, a hemp CBD manufacturer
2 out of Colorado. I'm also a retired U.S. Army colonel
3 and a veteran of the Gulf War.

4 I've been helping patients with hemp-derived
5 CBD for over five years in all ages. None have
6 experienced any significant adverse effects. On the
7 contrary, CBD has protected many of my patients from
8 the complications of cancer chemo and radiation
9 therapies.

10 Patients with addictions to opioids and
11 benzodiazepines and THC had no increase in physical or
12 cognitive sedation, but instead rapidly reduced or
13 discontinued these drugs, including Suboxone.

14 With respect to laboratory indicators, no
15 patient has reported any adverse result. Yet many
16 showed striking improvements in MRIs, retinal scans,
17 PSAs and liver function tests, unlike Epidiolex.

18 Despite the concern for drug interactions,
19 full spectrum CBD derived from hemp in my use has not
20 caused any significant adverse effects or injuries. I
21 also want to note that the 2018 WHO expert committee
22 on drug dependence said, in humans, CBD exhibits no

1 effects indicative of any substance abuse. And to
2 date, there is no evidence of any recreational CBD use
3 or any public health-related problems associated with
4 use of CBD.

5 So in summary, high quality, full spectrum,
6 hemp-derived CBD has an absolutely safe for all of my
7 patients over the last five years while providing
8 immeasurable levels of benefit. I'll be submitting my
9 written comments with scientific data to support my
10 testimony forthwith.

11 PANEL MEMBER: Please also include the
12 mechanism through which you collected the data and the
13 protocols or anything else you used. That would be
14 great.

15 DR. BLAIR: Yes, ma'am.

16 PANEL MEMBER: Thank you.

17 PANEL MEMBER: Also, you used the term full
18 spectrum CBD derived from hemp. And I'm wondering if
19 you could elaborate on the term full spectrum and what
20 you meant by that.

21 DR. BLAIR: So a legal hemp plant that fits
22 all the categories that have been designated: less

1 than 0.3 percent THC and deriving the substances from
2 that as a full distillate and derivative. And in
3 fact, there are very, very low levels of THC from the
4 Elixinol products specifically.

5 PANEL MEMBER: In your submitted comments,
6 we'd also appreciate it if you could provide
7 information on how you determine dosing and what
8 amount is safe or unsafe for a particular patient.

9 DR. BLAIR: Yes, sir.

10 PANEL MEMBER: Thank you.

11 PANEL MEMBER: And the characteristics of the
12 patients, including age, would be really helpful.

13 DR. BLAIR: Yes, ma'am.

14 PANEL MEMBER: And --

15 DR. BLAIR: Thank you very much for your
16 time.

17 PANEL MEMBER: Oh, sorry. I was just curious
18 too. You mentioned that you hadn't seen any
19 significant adverse effects. I'm curious if there are
20 lesser, more mild side effects that you sometimes
21 observe in your patients.

22 DR. BLAIR: There are sometimes mild side

1 effects from perhaps too heavy a dosing. The
2 variability of a patient's response to CBD is
3 considerable so that a standard serving that would be
4 on a bottle is too much for some, but far too little
5 for others.

6 PANEL MEMBER: So what sorts of side effects
7 do you see of the milder sort?

8 DR. BLAIR: You may see a mild, temporary
9 headache. You might see -- the most common side
10 effect that I've experienced for my clients has been
11 fatigue.

12 PANEL MEMBER: Thanks.

13 MS. CRISTINZIO: Thank you.

14 DR. BLAIR: Again, thank you -- again, thank
15 you very much.

16 MS. CRISTINZIO: We are now on speaker number
17 18, David Holmes, from Plant Life Group. David?
18 Okay. Moving on to speaker number 19, Charles Jolly,
19 from Baker Donelson.

20 MR. JOLLY: Good morning. My name is Charles
21 Jolly. I'm an attorney with the Baltimore office of
22 Baker Donelson. My firm represents a number of

1 clients interested in various ways in the cannabis-
2 derived compound CBD and dietary supplements.

3 It's beyond debate that hemp and its
4 constituents, including CBD, have been part of the
5 human dietary for centuries.

6 Given the legal status of CBD in this
7 country, there's a surprisingly strong body of
8 information that supports the notion that the
9 digestion of CBD enables the body, utilizing the
10 cannabinoid receptor system, to better cope with
11 inflammation, anxiety, sleeplessness and possibly
12 other circumstances. This is a classic definition of
13 a dietary supplement -- a dietary ingredient impacting
14 on human structure function.

15 If CBD is a dietary supplement can play even
16 a small role in addressing these public health issues,
17 the benefits would be huge. Because CBD is coming,
18 whether as a matter of intrastate commerce or
19 otherwise, with or without FDA, I would submit that
20 the question is simple. Is the public health better
21 served with FDA strongly regulating it or staying out?
22 And I would submit they should strongly regulate.

1 We believe the NDI system with a master file
2 is the proper device for regulating CBD as a dietary
3 supplement. The NDI submission would permit
4 limitations on THC, 3 percent or less, mold, heavy
5 metals, pesticide residues and other issues.
6 Enforcement of the NDI must be extended beyond FDA in
7 order to make it effective. Thank you very much for
8 the opportunity to participate in this important
9 discussion.

10 MS. CRISTINZIO: Thank you. Our next speaker
11 is speaker number 20, James Shults, from WMI
12 Consulting.

13 MR. SHULTS: Hello. My name is James Shults.
14 I'm here representing Wildflower Brands today. We
15 make infused beauty and wellness products.

16 Before I begin, I'd like to thank you all for
17 allowing me to speak at this historic point in
18 American history. It's through efforts like today's
19 hearing that we can begin to take an honest and
20 evidence-based approach to truly understanding the
21 productive potential of this plant. So, thank you.

22 Fundamentally Wildflower is a health and

1 wellness company committed to providing premium
2 holistic products. While we recognize that CBD has
3 demonstrable medical use when highly refined and used
4 in a controlled clinical setting, we also believe
5 there is sufficient evidence to safely regulate plant
6 extracts containing CBD in a dietary supplement or
7 cosmetic.

8 Wildflower understands that the best approach
9 to establishing public safety and trust in our
10 products is through the FDA regulating CBD for use in
11 a dietary supplement or cosmetic.

12 As this industry begins to take shape
13 globally, the public needs to trust that the products
14 they are buying are safe, are made with the
15 ingredients that are promised and don't contain any
16 misleading information about its benefits or uses.

17 To begin this process, I'll be submitting a
18 citizen petition requesting -- or excuse me,
19 requesting a regulation allowing the use of CBD in a
20 dietary supplement or cosmetic and I encourage fellow
21 stakeholders to collaborate and do the same.

22 At Wildflower, we have personally seen the

1 public interest in CBD increase exponentially and it's
2 only through -- and it's only getting started.

3 Through evidence-based regulation and guidance, the
4 FDA can ensure safe and accurate CBD products are
5 available to the public and that the industry can grow
6 with clear expectations of what good manufacturing
7 looks like.

8 Thank you for your time. I truly appreciate
9 the opportunity to speak here today and look forward
10 to being part of this conversation as we develop this
11 exciting new industry.

12 PANEL MEMBER: Could I ask what you view as
13 the functional purpose of CBD in a beauty product?

14 MR. SHULTS: Personally I don't have a
15 collection of the evidence to give you a hard claim on
16 that.

17 We've had a lot of interactions with
18 customers that it's simply more effective as a beauty
19 product when we include that ingredient. I'm not --
20 yeah, I'm just not a hundred percent on the scientific
21 reasoning.

22 PANEL MEMBER: And when you say effective,

1 what do you mean by that?

2 MR. SHULTS: It delivers a more -- a higher
3 sense, you know, of personal attraction, you know,
4 increasing -- it's more desirable to the product, not
5 through clinical definitions but, you know, through a
6 consumer-based opinion.

7 PANEL MEMBER: Can I follow up on that about
8 that? Do you have any information about the
9 absorption of CBD from your products?

10 MR. SHULTS: Personally, no. I am -- so as
11 part of my citizen petition, I'm collecting evidence
12 and presenting it, you know, to the FDA, exactly.
13 Getting additional information about the routes of
14 access, specifically topical or ingested and things
15 like that. We make, you know, both.

16 So yeah, no, that is at root of what we're
17 trying to figure out and present to you to provide a
18 clear grounds for why this is -- you know, why you can
19 safely regulate this as those products. Okay. Thank
20 you very much.

21 MS. CRISTINZIO: Thank you. We are now on
22 speaker number 21, David Spangler, from the consumer

1 Healthcare Products Association.

2 MR. SPANGLER: I'm David Spangler, speaking
3 on behalf of the Consumer Healthcare Products
4 Association. We represent over 65 manufacturers of
5 OTC medicines or dietary supplements.

6 Four points. Point one, FDA speaks
7 frequently about three priorities for both OTC
8 medicines and supplements: public safety, product
9 quality and informed consumers. We share these
10 priorities and agree they apply to hemp-derived and
11 CBD products.

12 Second point, we support the status quo for
13 medicines. The existing new drug approval process
14 provides a pathway for sponsors to develop data to
15 bring cannabis-derived products to market once shown
16 safe and effective.

17 Point three, we all see the intense consumer
18 and commercial interest in CBD and hemp-derived
19 products more broadly. But with little regulatory
20 oversight, the marketplace offers a vast array of
21 products of varying degrees of quality, an array of
22 unapproved drug claims and even fraudulent products.

1 While FDA is charting a course forward,
2 enforcement needs to increase. For instance, more
3 consumer alerts and follow-ups beyond morning letters
4 on enforcement actions would be important steps.

5 Finally, point number four, beyond
6 enforcement, dietary supplements need a path to bring
7 CBD-containing products to market. One way to do that
8 is for FDA to exercise its authority to exempt forms
9 of CBD from the prior IND, prior new drug approval
10 exception in the law's dietary supplement definition.
11 Please do that this year.

12 Supplement makers would still need to file
13 NDI notifications for CBD under this approach. Those
14 NDIs would still need to meet the same legal standard
15 of sufficient information to provide reasonable
16 assurance the ingredient does not pose a significant
17 or unreasonable risk. We appreciate this opportunity.

18 MS. CRISTINZIO: Thank you. Moving on to
19 speaker number 22, Stuart Titus.

20 DR. TITUS: Good morning. My name is Stuart
21 Titus. I'm the chief executive officer of Medical
22 Marijuana, Inc., which was founded in March of 2009.

1 In spite of our name, we are not engaged in the
2 production, manufacture or sale of either recreational
3 or medical marijuana.

4 Instead, we're focused on nutraceutical sales
5 of botanical, hemp-based products containing CBD
6 through our four operating divisions. We brought the
7 first nutraceutical hemp-based CBD products to U.S.
8 markets in 2012.

9 In our view, most American diets do not
10 contain an adequate amount of CBD and other non-
11 psychoactive cannabinoids, leaving most of us
12 cannabinoid-deficient and lacking support for a key
13 system in our body, our endogenous cannabinoid system.

14 Our belief was that fully botanical hemp-
15 based CBD nutraceutical supplements would support
16 health and wellness. The belief appears well-founded
17 within the medical literature. There are 2,281
18 studies available PubMed with the term endocannabinoid
19 in the title and there are another 10,000 other
20 studies that mention the endocannabinoid system in
21 their abstracts.

22 In addition, the National Institutes of

1 Health appear supportive of our viewpoint, having
2 mentioned the benefit of non-psychoactive cannabinoids
3 in its 507 patent awarded in 2003. It also should be
4 noted that on the NIH dietary supplement label
5 database, a CBD product is already listed as a dietary
6 supplement.

7 Accordingly we believe that non-psychoactive
8 hemp products containing CBD and other cannabinoids as
9 they support our endogenous cannabinoid system are an
10 essential nutritional supplement for optimal health,
11 just as is vitamin C. In addition, botanical hemp
12 products containing CBD are safe and extremely well
13 tolerated.

14 Given these facts, there is widespread public
15 and legislative support for botanical CBD. Thank you
16 for allowing this opportunity before you today. We
17 will submit more in our written comments.

18 PANEL MEMBER: Question. What do you believe
19 are the health benefits of hemp and CBD?

20 DR. TITUS: Well, we believe they do support
21 this large self-regulatory system, the endogenous
22 cannabinoid system and that helps move people to

1 overall better levels of health and wellness.

2 Certainly we don't make any medical claims.

3 But I think the anecdotal evidence is
4 overwhelming, the public support. People are just
5 seeing tremendous benefit. Anecdotally we see people
6 less stressed.

7 We see people sleeping better. We see less
8 brain fog, many other great anecdotal evidence that
9 we're slowly accumulating. We'll certainly look
10 forward in our written comments to showing more of
11 this data to you.

12 PANEL MEMBER: A follow-up question. If I
13 understood you, you're saying you believe that
14 cannabidiol is non-psychoactive?

15 DR. TITUS: We have seen in the literature,
16 particularly a U.S. government patent mentioning that
17 it is non-psychoactive. We believe it does reduce
18 anxiety. Thus, it may have anxiolytic effects. But
19 we do believe, unlike THC, it is non-intoxicating. So
20 that may be a better distinction.

21 PANEL MEMBER: If you had evidence to support
22 what you just said, it'd be useful to see that when

1 you submitted your comments.

2 DR. TITUS: Very good. We'll do that. Thank
3 you.

4 MS. CRISTINZIO: Thank you. Moving onto our
5 next speaker, Julian Wright, from Science &
6 Recreation.

7 MR. WRIGHT: Good morning. My name is Julian
8 Wright. I am the founder of Science & Recreation.
9 It's an honor to attend today's proceedings and
10 present the FDA with oral comments regarding products
11 containing cannabis or cannabis-derived compounds.

12 Hemp was made legal at the federal level by
13 signing into law the 2018 Farm Bill, with the FDA
14 retaining control over regulation of products
15 containing cannabis.

16 It is my understanding, based upon publicly
17 available information, that a substance that has been
18 approved by the FDA as an active ingredient in a
19 prescription drug -- in this case, CBD -- is precluded
20 from being a food additive. But in order for a
21 substance to be an active ingredient in a prescription
22 drug, the active ingredient must be a controlled

1 substance.

2 But being that industrial hemp and its
3 derivatives are no longer controlled substances, they
4 should enjoy the same range of use as any other legal
5 commodity.

6 Confusion regarding the status of CBD has
7 negatively impacted responsible and legal uses of CBD
8 post 2018 Farm Bill, resulting in detrimental effects.
9 Grandmothers are being arrested at Disneyworld and by
10 the TSA. National couriers are not accepting lawful
11 shipments, thereby stifling commerce. Distribution
12 and advertising channels are limited due to lack of
13 clarity.

14 Hemp stakeholders need certainty and clarity.
15 Hemp represents potentially the largest boon to the
16 agricultural community since tobacco. The 2018 Farm
17 Bill was passed, banking on that promise. Yet without
18 a vibrant CBD market, American farmers will lag behind
19 the rest of the hemp-producing world.

20 Our competitive advantage is in producing
21 hemp which is high in CBD. This advantage allows
22 farmers to realize crops that can return \$60,000 per

1 acre when compared to hemp sold for fiber at \$750 per
2 acre. This difference is stunning and should be
3 paramount as the FDA considers crafting regulations
4 regarding CBD. A strong CBD market means a stronger
5 American economy. Thank you.

6 MS. CRISTINZIO: Thank you. We are moving
7 onto our next category, which was titled "Other."
8 Sorry for that. Number 24 is William Bookout.

9 OTHER

10 MR. BOOKOUT: Thank you. My name is Will
11 Bookout. I'm the president of the National Animal
12 Supplement council. On behalf of the members of NASC,
13 we appreciate the opportunity to comment regarding
14 cannabis-containing products for dogs, cats and
15 horses. I'll be highlighting key points in the verbal
16 comments. However, a more complete response will be
17 submitted in writing.

18 We have three primary points. First, the
19 regulatory agencies, as well as the industry need
20 clearly defined and viable pathways for marketing of
21 these products. FDA needs to provide clear guidance
22 and definitions delineating compounds that would be

1 considered approved drugs as opposed to compounds
2 extracted from or derived from the whole plant or
3 parts of the Cannabis sativa plant containing broad
4 spectrum constituents, including CBD, terpenes, trace
5 THC and other cannabinoids. We would ask the agency
6 to clearly define the meaning of CBD concentrates and
7 isolates. We fully support THC levels of less than
8 0.3 percent.

9 Risk to animals. Consistent with the
10 agency's risk-based approach, NASC provides visibility
11 to regulators from our database which we believe is
12 the most advanced in the world for animal supplements.

13 In addition to product labels, specific data
14 regarding hemp-derived products are. There are 149
15 products currently in the marketplace. They've been
16 in the market for over 10 years. There have been nine
17 adverse event reports, none serious and over 18
18 million administrations in dogs, cats and horses.

19 While more research is certainly needed, we
20 believe the data at this time suggests these compounds
21 provided by responsible companies do not pose undue
22 risk to animals and the species cited. We support the

1 agency's position of taking regulatory action against
2 companies for egregious violation in terms of claims
3 and irresponsibly marketed products. In fact, we are
4 disappointed that more action has not been taken
5 against irresponsible participants.

6 Finally, solutions taking two to three years
7 are simply not realistic or acceptable. NASC has
8 initiated the formation of a taskforce of industry
9 experts that we believe will provide a clearly defined
10 comprehensive pathway that's both viable and
11 responsible for all stakeholders. We'll be reaching
12 out to FDA CVM for further discussion and we thank you
13 for the opportunity to comment.

14 PANEL MEMBER: I have a question for you.

15 MR. BOOKOUT: Yes, sir.

16 PANEL MEMBER: On the 0.3 percent you
17 mentioned --

18 MR. BOOKOUT: Yes.

19 PANEL MEMBER: -- do you have data that
20 supports that use?

21 MR. BOOKOUT: Yes. Our threshold is less
22 than 0.3 percent. We do have data, and we'll be

1 submitting that to the docket.

2 PANEL MEMBER: Okay. Thank you. And what do
3 you see as the intended use of this?

4 MR. BOOKOUT: We're consistent with intended
5 use with 201(g)(1)(C), non-nutritional benefits,
6 occasional discomfort, cognitive function, immune
7 support, similar structure and function examples.

8 PANEL MEMBER: Thank you.

9 PANEL MEMBER: Just one other question.

10 MR. BOOKOUT: Yes, sir.

11 PANEL MEMBER: Do you have any data also on
12 either swine or bovine as well?

13 MR. BOOKOUT: We don't.

14 PANEL MEMBER: Okay.

15 MR. BOOKOUT: Our focus is on dogs, cats and
16 horses only, not production animals.

17 PANEL MEMBER: All right. Thank you.

18 PANEL MEMBER: One last question. The safety
19 database that you -- it'd be really useful to have a
20 little more information about it.

21 MR. BOOKOUT: Yeah.

22 PANEL MEMBER: I assume it's spontaneous, as

1 opposed to a required reporting and things like that,
2 for instance.

3 MR. BOOKOUT: It is required reporting.

4 PANEL MEMBER: It is required?

5 MR. BOOKOUT: Yes.

6 PANEL MEMBER: So that kind of information
7 would be really helpful to us.

8 MR. BOOKOUT: It's a condition of membership,
9 and we've made the information available to CVM. In
10 fact, we've conducted training sessions with the
11 Division of Surveillance at CVM and we work very
12 closely with the agency. Thank you.

13 MS. CRISTINZIO: Thank you. We are now on
14 speaker number 25, Betsy Booren.

15 DR. BOOREN: Good morning. I'm Betsy Booren.
16 I'm senior vice president for science and technology
17 for the Grocery Manufacturers Association. GMA
18 represents the world's leading consumer packaged goods
19 companies.

20 The CPG industry plays a unique role as the
21 single largest U.S. manufacturing sector, delivering
22 products vital to the wellbeing of people's lives

1 every single day.

2 GMA advocates for rational, uniform
3 regulatory frameworks that are informed by risk-based
4 science, promote choice and build consumer trust
5 across the sectors we represent, which is personal
6 care, to household, to food and beverage.

7 We applaud this effort by FDA for holding
8 this public meeting as the first step of stakeholder
9 engagement. We support the opportunity for additional
10 stakeholder discussions as both stakeholders and FDA
11 and other federal agencies share the common goal of
12 providing consumers safe, trustworthy and reliable
13 products.

14 As consumers' interest for food and beverage
15 and personal care and household products containing
16 cannabis and cannabis derivatives, the necessity for
17 nationally uniform regulatory frameworks that protect
18 public health is of a critical importance.

19 The potential patchwork of laws at the state
20 and local level promotes confusion among consumers.
21 We need clear, simple, consistent, national
22 regulations informed by risk-based science that will

1 enhance the consumer trust in these products and
2 reduce frictions within the supply chain. FDA and
3 other relevant agencies must provide this leadership.

4 We support a transparent regulatory process
5 for stakeholder engagement, including comment and
6 rulemaking, development of risk management strategies,
7 development of any research action plans.

8 This will ensure that all stakeholders have
9 an opportunity to provide insights to agencies during
10 the development of this regulatory framework. Only
11 with this type of transparency will effective and
12 durable, long-lasting regulations be developed. Thank
13 you.

14 PANEL MEMBER: Thanks for your comments. I
15 was wondering if, given your broad representation of
16 food and consumer products, if there are thoughts on
17 how to deal with risks of cumulative exposure across
18 many products if these substances are now allowed
19 outside the drug context.

20 DR. BOOREN: Sure, and thank you for your
21 question. I think that is one of interest whereas the
22 branded national companies that we represent start

1 diving into this space, that they would need to take
2 into that.

3 We don't have any clear evidence at this
4 time. But as we indicated, I think that that's part
5 of the discussions we should have in the stakeholder
6 process to make sure we're collecting the right data
7 to protect public health.

8 PANEL MEMBER: And one other question, which
9 is as other markets, significantly Canada, open up and
10 many of your members sell products in that country,
11 are you thinking about ways to collect additional data
12 and information as those products might be sold
13 legally in other jurisdictions?

14 DR. BOOREN: I think there's some
15 opportunities for that. I think GMA is uniquely
16 positioned to gather a lot of consumer information in
17 our current framework of better understanding what
18 consumers want, need and what they expect of these
19 products. I think that's something that we would look
20 at.

21 The market and the indications of what
22 consumers want from these innovation processes or

1 products is really indicative of the market to grow.
2 Our inherent issue is making sure we have the strong
3 legitimate regulatory framework which you all provide.
4 Thank you.

5 MS. CRISTINZIO: Thank you. We are moving
6 down our agenda to speaker number 26, James Childs.

7 MS. ADAMS: I have a question. He was not
8 able to be here. He couldn't make it. But I have --
9 thoughts to the docket.

10 MS. CRISTINZIO: Approach, so we can hear
11 you.

12 MS. ADAMS: I'm sorry. I'm sorry. I just
13 have a question. Dr. Childs was not able to be here.
14 He did upload his comments to the docket. May I just
15 briefly tell his story?

16 MS. CRISTINZIO: Sure.

17 MS. ADAMS: Okay. Dr. Childs --

18 MS. CRISTINZIO: Two minutes, please. And
19 please state your name.

20 MS. ADAMS: Oh, my name is Aubrey Adams. And
21 Dr. Childs has a son -- had a son named David Childs.
22 He started smoking marijuana at the age of 16. The

1 Internet taught him that marijuana was medicine. This
2 past Thanksgiving, the day after, he found his son
3 cutting his hand. He took him to the hospital. He
4 was admitted into a psych unit and only testing
5 positive for THC and diagnosed with psychosis.

6 He was discharged. His family put him in an
7 outpatient program. On the fourth day of that
8 program, it was December the 5th, David Childs came
9 home. He went to the woods behind his house. He
10 smoked marijuana. Then he came back into the house
11 and he shot himself in the head. David was 19.

12 MS. CRISTINZIO: Thank you for telling that
13 story. Any questions from the panel?

14 MS. ADAMS: Thank you.

15 MS. CRISTINZIO: Speaker number 27, Robert
16 Discordia.

17 DR. DISCORDIA: Thank you. My name is Dr.
18 Robert Discordia. I'm vice president of
19 pharmaceutical development and manufacturing at Corbus
20 Pharmaceuticals, where we are developing medicines
21 that target the endocannabinoid system to treat rare,
22 life-threatening autoimmune and genetic disorders.

1 Under IND from FDA, treatment with our novel
2 oral investigational drug called Lenabasum has been
3 associated with improvement in efficacy outcomes in
4 multiple Phase II studies in diseases such as
5 scleroderma, dermatomyositis and cystic fibrosis. It
6 has been granted both orphan and fast track
7 designations. Two Phase III pivotal multinational
8 studies are underway and over 700 patients have been
9 dosed, some for longer than three years.

10 Lenabasum is not medical cannabis nor is it a
11 cannabis-derived substance and it does not involve
12 cannabis-derived compounds in its synthesis. It is a
13 rationally designed NCE specifically designed to avoid
14 interaction with cannabinoid receptors in the brain
15 and purposefully focuses on immune system outside the
16 brain.

17 And yet, because Lenabasum is categorized as
18 a cannabinoid, we face obstacles that other drug
19 developers targeting the same indications with non-
20 cannabinoid experimental drugs do not because we fall
21 under the Controlled Substances Act as a Schedule 1
22 whose restrictions have delayed our clinical trials

1 only in the U.S., Canada and Australia, but not 27
2 other countries in which our trials are conducted.

3 We're here in the interest of public health
4 as a drug developer that experiences unnecessary
5 delays in this field. It is no exaggeration to state
6 that had we not been obliged to comply with Schedule
7 1, we would be one year closer to completing our
8 studies and potentially closer to making available our
9 orphan drug to patients who have no approved medicines
10 to treat their devastating conditions.

11 We respectfully urge FDA to develop a
12 transparent, consistent, fair and practical framework
13 to support the investigation and development of drugs
14 targeting the endocannabinoid system.

15 Specifically for compounds that are not
16 potent brain-penetrating CB1 agonists, we would like
17 to have a clinical development pathway mirroring as
18 closely as possible that of other investigational
19 drugs without the need for onerous regulatory hurdles.
20 I thank you for the opportunity.

21 PANEL MEMBER: One question. How does the
22 availability of CBD or other cannabis derivatives in

1 the marketplace potentially incentivize or
2 disincentivizes your drug development?

3 DR. DISCORDIA: I don't think it actually has
4 an effect since we're not phytocannabinoids. We're
5 not derived from cannabis. I think that because of
6 the regulations though, mostly DEA, we have to -- we
7 have to follow strict guidelines in accounting for
8 every milligram of the material. I'm sorry if I --
9 did I answer your question or --

10 PANEL MEMBER: You got it. Thanks. That's
11 all.

12 DR. DISCORDIA: Thank you very much.

13 MS. CRISTINZIO: Next on the agenda, we are
14 on speaker number 28, Kristina Garcia.

15 MS. GARCIA: Good morning. I'm Kristina
16 Garcia, former CEO and current board member of Women
17 Grow, an international women's networking organization
18 dedicated to the cannabis industry.

19 I also serve on the advisory board of Green
20 Check, a Connecticut company based on meeting the
21 banking and compliance needs of cannabis companies and
22 the financial institutions that serve them. I'm a

1 cofounder of Magnolia Partners, an agency devoted to
2 providing strong foundations to early stage companies
3 both in and outside of the cannabis landscape. I'm a
4 new mother to a four-month-old baby boy and my husband
5 is an Army vet and an operating engineer in Local 825.

6 Through my role in the industry, I've had the
7 privilege to hear many personal stories from patients
8 whose lives have been transformed and even saved due
9 to cannabis and hemp products.

10 I was also privy to clinical studies of
11 equine, canine and feline patients using full spectrum
12 both cannabis and hemp oils with positive results for
13 conditions from anxiety to skin cancer.

14 I also hear from business owners who make
15 quality products which undergo vigorous testing, yet
16 are frustrated with their cheaper competitors who
17 cannot claim the same exhaustive research.

18 While walking in a grocery store earlier this
19 week, I came upon a shelf of no less than 10 products
20 ranging from cookies to tinctures to gummies and the
21 shelf was directly across from the pharmacy counter.
22 As an expert in the industry, I have the knowledge to

1 differentiate between those products and it's still a
2 challenge. And I know that some of those brands are
3 quality and some of those are not.

4 The consumers that are currently seeking out
5 or stumbling upon these products in the marketplace do
6 not have my expert knowledge or that of a trusted
7 medical professional behind them. They're desperate
8 for help and they don't have anybody to turn to.

9 In May of 2018, then-commissioner Gottlieb
10 said that it was crucial that we provide clear
11 expectations so that the industry can meet them. It's
12 just as important for consumers to be able to
13 effectively use updated labels.

14 And we're launching a major educational
15 campaign for consumers to help them better understand
16 the new information that they'll be seeing in the
17 marketplace. That was regarding the food labels and
18 that same information and application can work here.

19 So I ask that you demand that suppliers have
20 their products tested by reputable labs and that those
21 test results be readily available to consumers prior
22 to purchase. Implement clear and concise labeling

1 rules and encourage businesses to provide educational
2 information for medical professionals.

3 And I ask that you move with purpose, as the
4 marketplace is already active and the federal courts
5 have also, as recently as yesterday, asked the DEA to
6 seriously consider the de-scheduling of cannabis in an
7 expeditious manner. Thank you.

8 MS. CRISTINZIO: Great. We are now on number
9 29 on the agenda, Gabriel Giancaspro.

10 DR. GIANCASPRO: Good morning. My name is
11 Gabriel Giancaspro. I'm the vice president for
12 dietary supplements and herbal medicines at the
13 science division at USP.

14 On behalf of USP, I would like to thank the
15 agency for allocated time for us to offer comments on
16 the value of robust science-based, quality standards
17 for products containing cannabis and cannabis-derived
18 compounds.

19 USP is an independent scientific nonprofit
20 public health organization devoted to improving health
21 through the development of standards for medicines,
22 foods and dietary supplements. The organization

1 publishes two legally recognized official compendia of
2 the United States.

3 Additionally, one of USP's areas of expertise
4 and focus is the development of the standards for
5 articles of botanical origin, including analytical
6 procedures and acceptance criteria to help ensure
7 their identity, purity and strength.

8 Regardless of product category, the purpose
9 of a public standard is to help regulators protect
10 public health and by providing scientifically
11 validated tests to ensure identity, constituent
12 composition and strength of a product. The standards
13 also help monitor product quality so adulterants and
14 contaminants are absent or below the level of concern.

15 Public standards are essential to help
16 prevent harm to patients and consumers. The facility
17 -- they facilitate the production of non-contaminated,
18 non-adulterated trials and help limit exposure to
19 toxic substances, pathogenic microorganisms and
20 harmful additives.

21 A robust standard in this area should
22 therefore include specifications for the content of

1 active constituents and limits for contaminants such
2 as pesticide residue, microbial load, aflatoxin level,
3 elemental contaminants based on reliable scientific
4 information.

5 USP is committed to bringing our public
6 health mission and expertise into this developing area
7 through publications and information sharing. We've
8 made significant progress to define suitable quality
9 specifications for this plant material and we plan to
10 publish our work in a scientific paper to disseminate
11 this knowledge to the community.

12 We look forward to continuing the dialogue
13 for exploration of the science-based standards that
14 help prevent harm and protect public health once the
15 regulatory status and path forward for these products
16 are clear, USP stands ready, as appropriate, to work
17 with the agency and other interested parties to
18 develop reliable quality standards and make them
19 available for use by manufacturers and regulators
20 alike. Thank you.

21 PANEL MEMBER: Could you remind -- do you
22 have -- I believe you've put out some materials on

1 marijuana standards to date separate from cannabidiol.

2 Is that right?

3 DR. GIANCASPRO: Yes.

4 PANEL MEMBER: And do you have a date when
5 you anticipate that the cannabidiol might be released,
6 the product might?

7 DR. GIANCASPRO: Our net process for
8 developing quality standards requires the sponsor for
9 the manufacturer that is approved by the agency. We
10 contacted the manufacturer to supply the information.
11 Unfortunately the manufacturer was not willing to
12 supply the information for us to construct the public
13 monitoring at this time.

14 Should the path forward for dietary
15 supplements is clear or other path forward different
16 from drug approval, we may have alternatives to
17 develop quality standards. Thank you.

18 MS. CRISTINZIO: Thank you. Our next speaker
19 is number 30 on the agenda, Karen Howard, from the
20 Organic & Natural Health Association.

21 MS. HOWARD: Good morning. My name is Karen
22 Howard. I'm the CEO of the Organic & Natural Health

1 Association. We're a trade association whose
2 decisions are rooted primarily in transparency and
3 traceability and the quality of products provided to
4 consumers and their interests.

5 Based on the FDA definition of a drug,
6 Organic & Natural concludes that CBD is not precluded
7 from use as a dietary supplement.

8 Hemp extract is not approved or investigated
9 for the intended use of treating a disease. Hemp
10 extract does not resemble the drug Epidiolex to which
11 it is being compared to. For us, the issue is whether
12 hemp extracts are equivalent to the drug, and it is
13 not.

14 Hemp extracts will be proven safe, are safe
15 and can be demonstrated as such, whether by an NDI or
16 through GRAS. That said, Organic & Natural does have
17 concerns related to enforcement and we appreciate the
18 viral nature of how CBD has hit the marketplace.

19 With that, there are always going to be
20 problems related to things like contamination and
21 toxins, especially as it relates to the presence of
22 any THC or heavy metals, which I believe you will hear

1 more about this afternoon. Those would be our
2 concerns. We remain in support of CBD safety.

3 PANEL MEMBER: A question. You're referring
4 to hemp extract. Could you explain what exactly you
5 mean by that?

6 MS. HOWARD: Well, we do mean CBD. But we
7 also know that there are different derivatives that
8 can be derived from the hemp plant.

9 I think our real issue is that hemp extract,
10 hemp CBDs and all of the derivatives from the hemp
11 plant are simply not related to the product that it's
12 being compared to, which is the pharmaceutical.

13 PANEL MEMBER: You stated that the hemp
14 extract has been demonstrated that it would be safe
15 under the NDI and GRAS standard. And I'm wondering if
16 you're putting in any data and information into the
17 record on that regard.

18 MS. HOWARD: We have members of our
19 organization that are currently working on safety data
20 related to it. Our position is that there has been
21 discussion in the industry as to whether this would
22 require an NDI or whether it would require GRAS. We

1 believe that at the end of the day, either will
2 support those conclusions in recognition that some
3 people will choose to go the NDI route while others
4 will partake in the GRAS process.

5 PANEL MEMBER: Yeah. I would just encourage
6 any safety data that you have be put into the record
7 by July 2nd, if you have it.

8 MS. HOWARD: Thank you.

9 PANEL MEMBER: Thank you.

10 MS. CRISTINZIO: Thank you. I believe the
11 next number on the agenda, Loren Israelsen, was an
12 early cancellation this morning. I just thought I'd
13 check before I move on. Okay. Number 32, Rod Kight,
14 from Kight Law Office, is the next on the agenda.

15 MR. KIGHT: Good morning. My name is Rod
16 Kight. Thank you for allowing me this opportunity to
17 speak. I'm an attorney who represents cannabis
18 businesses.

19 Numerous studies have found that CBD is safe.
20 According to the World Health Organization, it is
21 nontoxic, non-addictive and non-intoxicating. People
22 who use CBD should have helpful guidance and

1 reasonable regulations that will allow them to
2 produce, sell and safely use CBD products.

3 The FDA's approval of a CBD seizure drug last
4 year has created a complex legal scenario under
5 section 301(11) of the Food, Drug and Cosmetic Act.

6 Fortunately there are at least two paths
7 forward. The first path is hemp extract. Section
8 301(11) prohibits a drug being added to food only if
9 the substance is intended to diagnose, cure, mitigate,
10 treat or prevent disease through its use in food, as
11 shown objectively by marketing and labeling
12 representations and is the exact same moiety as the
13 active ingredient in an approved drug and is added to
14 the food in the same dosage range as authorized by the
15 new drug approval.

16 Hemp extract as a food is an exception to
17 this rule, notwithstanding that it contains CBD. This
18 is because CBD is a constituent inherent in hemp which
19 has been marketed and used at least since the Civil
20 War.

21 The prohibition on marketing a drug in food
22 applies only to a substance that is added to food and

1 does not apply to a substance that is in food, even
2 when the substance is identical to an approved drug.
3 Additionally, hemp extract contains dozens of
4 compounds and is not the same moiety as the FDA-
5 approved CBD drug.

6 The second path is for CBD itself. The mere
7 chemical identify of an approved drug does not -- or
8 with an approved drug does not render a substance a
9 drug in the absence of marketing claims.

10 Section 301(11) excepts from its prohibition
11 a drug that was marketed in food before any approval
12 of the drug or before substantial clinical
13 investigations involving the drug were instituted.

14 Marketed in food simply means that the
15 substance has been present in food that has been
16 marketed, regardless of whether or not it has been
17 separately promoted.

18 Once a substance has been marketed in food as
19 an inherent natural constituent, as with CBD, it
20 remains within the marketed in food exemption, even if
21 that constituent is later isolated and added to food.

22 Thank you.

1 MS. CRISTINZIO: Thank you. We are on number
2 33, Andrew Kline, the National Cannabis Industry
3 Association.

4 MR. KLINE: Good morning. My name is Andrew
5 Kline, and I'm the lead -- the lead of public policy
6 of the National Cannabis Industry Association,
7 otherwise known as NCIA.

8 Today NCIA represents nearly 2,000 members,
9 including CBD-related commercial manufacturers as well
10 as cannabis and ancillary business leaders. Recently
11 we formed a coalition of well over a hundred CBD
12 entrepreneurs, scientists, medical professionals and
13 food and drug lawyers to provide comments to FDA.
14 Yesterday that coalition submitted more than 60 formal
15 written pages on FDA's website.

16 We encourage interested parties to review our
17 written submission, which can also be found on our
18 website at thecannabisindustry.org.

19 I'd like to quickly drive home five important
20 points today. The first is that time is of the
21 essence. Hemp-derived CBD is in very high consumer
22 demand and the industry is eagerly awaiting FDA's

1 regulatory framework for these products. We strongly
2 recommend that FDA act quickly to clarify the
3 regulatory environment because there is significant
4 confusion in the market. Businesses don't know who is
5 legally permissible -- what is legally permissible,
6 and some are making health claims in the absence of
7 clear regulatory guidance.

8 Most significantly, banks and payment
9 processors don't currently understand the regulatory
10 landscape and as a result many CBD companies are at
11 risk of losing essential financial services. Because
12 of this, it is critical for FDA to advance regulations
13 in an expedited fashion.

14 The second point I'd like to drive home is
15 the significance of the economic impact of this
16 nascent industry. Current research indicates that at
17 present, about 7 percent of all adult Americans, or 22
18 million people, use CBD as a supplement.

19 The current market size is estimated at
20 upwards of \$2 billion. This current economic activity
21 supports nearly 12,000 direct full-time jobs. A five-
22 year projection shows a multiple of eight. We need to

1 get this right. But we need to get this done as
2 quickly as possible before we lose market share to
3 Canada, China and other international players.

4 The third point I'd like to drive home is
5 that CBD products are safe. There is no higher
6 calling in government service than public safety and
7 we applaud FDA's efforts to make certain that
8 consumers are safe. The bottom line is this. An
9 overwhelming preponderance of evidence indicates that
10 cannabis and cannabis-derived compounds present
11 minimal safety concerns.

12 Sorry. My pages are stuck. To address any
13 potential safety concerns, we believe FDA should
14 mandate that all cannabis products are tested in a
15 licensed analytical laboratory to ensure that
16 dangerous levels of potential contaminants are absent
17 from products that are consumed. In July of 2018, we
18 issued a report on lab testing. That report can be
19 found on our website.

20 A fourth point I'd like to drive home is that
21 we need consensus industry standards to get this
22 right. While we know that CBD is safe, we also know

1 that universal standards have worked in other
2 industries to help protect the public from health and
3 safety risks.

4 MS. CRISTINZIO: Sir, are you almost done?

5 MR. KLINE: Yes.

6 MS. CRISTINZIO: You're beyond your time.

7 MR. KLINE: Finally, of course, it's
8 important that consumers be informed of any potential
9 risks. In February of 2019, NCIA released a report on
10 packaging and labeling. You can also find that on our
11 website. Thank you.

12 PANEL MEMBER: One just quick remark.
13 Anything that you would like us to consider, we would
14 encourage you to put those reports and studies into
15 the docket before July 2nd. Thank you.

16 MR. KLINE: We will. Thank you.

17 PANEL MEMBER: Just one other quick question.
18 You mentioned the domestic industry and you briefly
19 mentioned international. Any data that you have from
20 the international industry would be greatly
21 appreciated as well.

22 MR. KLINE: I can get that for you.

1 PANEL MEMBER: Perfect. Thank you.

2 MR. KLINE: Thank you.

3 MS. CRISTINZIO: Thank you. We are now on
4 speaker number 34, Ken Maciora. I'm sorry. I'm
5 butchering your name, if you're here -- from the
6 Empire Relations Group. Next on the agenda is speaker
7 number 35, Michael McGuffin, the American Herbal
8 Products Association.

9 MR. MCGUFFIN: Good morning. My name is
10 Michael McGuffin and I am president of the American
11 Herbal Products Association, or AHPA. Aside from my
12 statement here, AHPA will submit detailed written
13 comments to the docket.

14 AHPA understands that the 2018 Farm Bill
15 reflected the intent of Congress to allow broad access
16 to hemp and products derived from hemp, including
17 those containing CBD.

18 Even prior to the Farm Bill's enactment, FDA
19 stated its position with which AHPA has neither agreed
20 nor disagreed that provisions of the FD&C Act prohibit
21 marketing CBD dietary supplements and adding CBD to
22 conventional foods.

1 AHPA notes that these provisions should not
2 preclude use of hemp-derived ingredients containing
3 naturally occurring quantities of CBD and urges FDA to
4 -- excuse me -- publicly acknowledge this important
5 distinction.

6 FDA's position on CBD has resulted in
7 significant marketplace confusion, many companies now
8 selling foods and supplements containing CBD have the
9 mistaken impression that FDA does not currently
10 regulate them. Others have chosen to stay out of the
11 market.

12 Based on FDA's position to fully implement
13 the congressional intent to allow access to products
14 that contain hemp-derived CBD and to further AHPA's
15 and FDA's shared goal of ensuring safe and well-
16 manufactured supplements and foods, AHPA requests that
17 FDA promptly take one of the two following actions.

18 FDA should use its authority under the FD&C
19 Act to issue a regulation possibly as an interim final
20 rule with an accelerated effective date permitting CBD
21 as a lawful ingredient in supplements and foods. Of
22 course this regulation would still require compliance

1 with all other applicable federal regulations.

2 Alternately, and especially if FDA cannot
3 issue this requested regulation promptly, FDA should
4 issue guidance to state the agency's intent to
5 exercise formal enforcement discretion with respect to
6 the provisions of the FD&C Act on which FDA bases its
7 position that CBD-containing supplements and foods are
8 unlawful.

9 AHPA would support conditioning this exercise
10 of enforcement discretion also on full compliance with
11 all other regulations applicable to these categories.

12 FDA has previously acknowledged its authority
13 to create a lawful pathway for marketing CBD-
14 containing supplements and foods, and the agency
15 should act promptly to use this authority. Thank you.

16 PANEL MEMBER: Yes. I was wondering, you
17 mentioned products with naturally occurring levels,
18 right, of CBD.

19 Is that -- if you could say a bit more about
20 that, is that like in the proportion that you would
21 usually see within the plant or sort of explain a
22 little bit more what you mean about it --

1 MR. MCGUFFIN: Sure.

2 PANEL MEMBER: -- and also what sorts of
3 levels you tend to see.

4 MR. MCGUFFIN: Correct. That is what I mean.
5 I mean the proportion in a plant. So, for example, if
6 a product came to the marketplace that was simply the
7 plant packaged in a tablet or a capsule, then the
8 naturally occurring presence of CBD should not be
9 interpreted by FDA as the restriction under the
10 provisions of the Food, Drug and Cosmetic Act.

11 I think also simple products, tinctures,
12 extracts that do not deliberately concentrate up the
13 level of CBD, those also should be acknowledged as not
14 affected by those provisions of the Food, Drug and
15 Cosmetic Act.

16 PANEL MEMBER: So what sorts of levels do you
17 tend to see in those products and does it depend if
18 it's a derivative from only part of the plant? Is
19 that still within what you're talking about?

20 MR. MCGUFFIN: I'd have to get back to you,
21 and we will submit comments to clarify that detail.
22 But -- and there is also a range. There are different

1 cultivars that have different levels. I don't know
2 the numbers right now. But we'll make sure that we
3 provide that information in our comments. Thank you.

4 PANEL MEMBER: One other thing that would be
5 useful, when you submit that comment, is you had two
6 proposed solutions.

7 I'm not sure if you're -- if there's a dose
8 of cannabidiol that you believe should be considered
9 safe or were there some higher level of cannabidiol
10 that shouldn't be allowed under one or the other of
11 those proposals.

12 MR. MCGUFFIN: We will definitely address
13 that issue in our comments. Thank you for that
14 question. I think it's a very important element of
15 this whole discussion. Thank you.

16 MS. CRISTINZIO: Great. We are now on
17 speaker number 36, Megan Olsen, from the Council for
18 Responsible Nutrition.

19 MS. OLSEN: Thank you. I'm Megan Olsen. I'm
20 the assistant general counsel for the Council for
21 Responsible Nutrition. CRN, based in Washington, DC,
22 is the leading trade association representing dietary

1 supplement and functional food companies. CRN is here
2 today to present comments about CBD use in supplements
3 and foods, specifically to urge FDA to use its
4 rulemaking authority as quickly as possible to create
5 a legal pathway for CBD use in supplements and food.

6 Despite FDA's current position on the
7 legality of CBD, the CBD food and supplement
8 marketplace is exploding. For dietary supplements
9 alone, hemp-derived CBD sales were over \$200 million
10 in 2018 and are expected to grow to over \$300 million
11 by the end of 2019.

12 Driving these sales is an intense consumer
13 demand in hemp-derived CBD. Research suggests that a
14 third of U.S. adults are current CBD users and nearly
15 half of all U.S. adults have used CBD at some point.
16 Lack of FDA oversight for these products leaves this
17 growing consumer base vulnerable.

18 Without FDA oversight, consumers lack
19 assurance that products labeled as CBD are safe.
20 Consumers cannot trust that the products are
21 manufactured in an appropriate manner or actually
22 contain the amount of CBD listed on the label or any

1 CBD at all. Therefore FDA does not have the luxury of
2 time. They must act quickly to address a market that
3 is out of control. Three to five years at a minimum
4 for rulemaking is too long.

5 In fact, CRN was alarmed by the suggested
6 timeframe and comments by FDA leadership, including
7 former FDA commissioner, Dr. Gottlieb. CRN
8 understands and respects FDA's concerns about safety
9 of CBD products. But as CRN will expand on in further
10 comments by CRN CEO Steve Mister, we do not believe
11 that the safety debate has to impede rulemaking at
12 that stage.

13 There is already a regulatory framework in
14 place that is proven to ensure the safety of dietary
15 supplements in food, one that will automatically be
16 implemented should FDA develop a regulation permitting
17 CBD use in food and supplements.

18 To be clear, FDA is not asking -- or CRN is
19 not asking FDA to abdicate a safety review. Rather,
20 CRN is asking FDA to address safety as the Food, Drug
21 and Cosmetic Act intended. In the fact-specific
22 context of how a product will be marketed, intended to

1 be used, its form, dosage and other unique
2 considerations that apply once a product is considered
3 a supplement or food.

4 Americans deserve access to safe quality
5 supplements and food, as well as protection from
6 supplements and food that pose risk. FDA under
7 current law has the authority to achieve both goals
8 for CBD and we strongly urge the agency to use this
9 authority as quickly as possible.

10 PANEL MEMBER: I'm going to ask you the same
11 question I think that I asked the previous speaker,
12 which is if you have information about safe dosages of
13 these products or use in supplements, that would be
14 very useful, including information about whether those
15 dosages or recommended serving sizes would change
16 based upon the intended effect.

17 MS. OLSEN: Yes, and CRN is intending to
18 submit written comments. And we will take that into
19 consideration with our written comments.

20 PANEL MEMBER: Okay. Thank you.

21 MS. CRISTINZIO: Thank you. We are now on
22 speaker number 37, David Rodman.

1 MR. RODMAN: Good morning. My name is Dave
2 Rodman, and I am here on behalf of The Rodman Law
3 Group. I'd like to thank FDA for hosting this hearing
4 and for having the foresight to address these
5 important issues in a proactive manner.

6 My firm has been representing and advising
7 companies in the cannabinoid space for the past five
8 years and we have seen the industry as a whole grow at
9 a blistering pace.

10 Even with this unprecedented expansion as a
11 baseline, the CBD sector stands out due to its
12 exponential growth. Yet this proliferation has
13 occurred almost entirely outside any well-defined or
14 widely enforced regulatory regime.

15 To my knowledge, no compound has ever been
16 removed from Schedule 1. But CBD achieved mass
17 adoption practically overnight, even before hemp-
18 derived CBD was removed from the CSA. Now FDA is
19 faced with the daunting task of attempting to regulate
20 an unprecedented billion-dollar industry that shows no
21 signs of slowing its growth.

22 Ladies and gentlemen, the genie is out of the

1 bottle here and it is probably impossible to force it
2 back inside. Accordingly, I encourage FDA to take
3 prompt action to address this unique regulatory
4 situation. A more comprehensive exposition of my
5 suggestions are contained in my written comment.

6 But in brief, my suggested actions include,
7 one, allowing low dose CBD products to be sold as
8 dietary supplements and/or food additives. The
9 prescribing guidelines for Epidiolex establish the
10 dose range between 700 mg and 1.4 g per day.

11 Most of the CBD products currently in the
12 customer marketplace have less than 500 mg in their
13 entire container and are generally intended to last
14 about a month. This is a difference of several orders
15 of magnitude.

16 The significant differential in dosages
17 suggests the current consumer CBD products should be
18 placed in an entirely different category than
19 pharmaceutical products. The logical category for
20 this is that of dietary supplements.

21 Two, enact a policy stating FDA will not
22 prioritize enforcement of the FD&C Act against CBD

1 operations that follow established enforcement
2 priorities.

3 Soon after states like Colorado began to
4 legalize cannabis, the Department of Justice issued
5 the Cole memo, which basically stated that the DOJ
6 would not enforce the CSA in states where cannabis has
7 been legalized, provided that the state legal cannabis
8 activities did not violate eight established
9 enforcement priorities.

10 FDA could take a page from DOJ's playbook and
11 issue guidance similar to the Cole memo with respect
12 to the FD&C Act. Suggested enforcement priorities
13 could include, A, strictly limiting claims about CBD
14 to structure or function claims only; B, not marketing
15 CBD to children; and, C, adherence to certain
16 packaging, labeling and testing standards to ensure
17 quality and accuracy of ingredients.

18 I should note that much of the industry has
19 already voluntarily participated in rigorous testing
20 programs and it would not be hard to codify such
21 testing. And much of the industry would support it
22 immediately.

1 I know I'm a little bit over time. My last
2 suggestion would be to expedite the creation of a CBD
3 OTC monograph. And I'm not going to read all of that
4 because I'm about a minute late. Thank you.

5 MS. CRISTINZIO: Please submit the rest of
6 your comments to the docket. Next on the agenda is
7 Zoe Sigman.

8 MS. SIGMAN: Good morning. My name is Zoe
9 Sigman, and I'm the program director at Project CBD,
10 an educational nonprofit focused on cannabis science
11 and medicine. Ten years ago, we introduced CBD to the
12 medical cannabis community in California. It spread
13 like wildfire and has become the hugely popular
14 phenomenon that it is today.

15 There are occasions when public health
16 priorities and pharmaceutical priorities are not
17 equivalent. That is, we believe that this is the case
18 with CBD and cannabis. We urge the FDA to maintain
19 public health at the core of your decision-making
20 process.

21 CBD is a nontoxic, non-intoxicating, non-
22 habit-forming neuroprotective antioxidant. What's not

1 to like? Given CBD's intrinsic safety and many
2 potential benefits, it should be legally available
3 without a prescription.

4 Sensible regulations can assure product
5 safety without going through expensive, time-consuming
6 clinical trials. The goal should be public access to
7 diverse cannabis product options that are subject to
8 rigorous manufacturing and compliance oversight.

9 Towards this end, we propose the formation of
10 a committee for traditional herbal medicinal products
11 to assist in implementing regulations for CBD,
12 cannabis and other medicinal plants. Project CBD will
13 provide a detailed account of the committee's
14 responsibilities in a written submission to the FDA.
15 For those interested, I have a list of the resources
16 that informed that idea here today.

17 A few closing comments. Regarding pregnancy,
18 when confounding variables like alcohol and cigarettes
19 are accounted for, there is no science that
20 demonstrates harm to the fetus from cannabis, as
21 Project CBD documented in a report for California
22 health officials.

1 Contraindications and drug interactions are
2 easily manageable. Project CBD has published an
3 extensive report on cannabinoid drug interactions,
4 noting few problems, except with high doses of CBD
5 isolates.

6 Project CBD advocates banning artificial
7 thinning agents and flavor additives from cannabis oil
8 vape cartridges unless these additives are proven safe
9 when heated and inhaled. None have been. Let's
10 regulate CBD to promote public health. Let's make the
11 most of this historic opportunity. Thank you.

12 PANEL MEMBER: Thank you for your comments.
13 You did again mention a few -- a study on pregnancy
14 and a report on drug interactions.

15 MS. SIGMAN: Yes.

16 PANEL MEMBER: And I'm hoping that you will
17 submit those to the docket before July 2nd.

18 MS. SIGMAN: Absolutely.

19 PANEL MEMBER: I do have a question for you.
20 It sounds like your group is sort of coordinating a
21 lot of efforts on CBD. Have you made any efforts to
22 monitor any adverse events or consumer complaints

1 related to these products? And, if so, are there
2 reports that you could submit to the docket?

3 MS. SIGMAN: Absolutely, yeah. We have a
4 research survey that over a thousand people have
5 filled out. So we will. Thank you.

6 MS. CRISTINZIO: great. Thank you. We are
7 now on agenda number 39, Andy Snyder.

8 MR. SNYDER: Good morning. My name is Andy
9 Snyder. I'm the founder and publisher of Manward
10 Press, and I'm not just here today on behalf of our
11 200,000 readers and their families. I'm here on
12 behalf of my family, friends and every American
13 listening and watching today online.

14 Our nation is at a crossroads, one that
15 should be clear to everyone in this room today. While
16 the evidence supporting both the safety and efficacy
17 of CBD continues to pile up, response at the federal
18 level has been slow at best and nonexistent at worse.

19 Today most Americans are under the impression
20 that the research on CBD is insufficient. But that's
21 merely a projection of the mainstream perception. The
22 truth is there are more than 150 active clinical

1 trials registered with the U.S. National Library of
2 Medicine as I speak to you right now.

3 In fact, multiple published studies in the
4 U.S. National Library of Medicine confirm the safety
5 profile and efficacy of CBD.

6 One recent review of 132 studies found that
7 not only is CBD safe, it's a powerful antioxidant that
8 is more effective than vitamin C or E at protecting
9 the human brain.

10 Make no mistake. This is just scratching the
11 surface of CBD's potential for mainstream, widespread
12 application in human health optimization.

13 I believe that if the folks charged with
14 liberating CBD from its shackles make the right
15 decisions, CBD is just a few years away from being
16 perceived by the average American no differently than
17 vitamin C or any other common drugstore vitamin. The
18 main difference will be that, unlike vitamin C, the
19 average American will be able to experience
20 significant tangible benefits from CBD.

21 For many, CBD has already become the go-to
22 natural solution for a variety of concerns, like one

1 of my readers, Frank B. Frank wrote in to tell me
2 about his experience with CBD.

3 Here's just a short example of what he wrote
4 me: I'm an old guy that still works pretty hard. My
5 friends are all older farmers, loggers and equipment
6 operators that are still working because we enjoy it.
7 We are using CBD oils and rubs to get through the
8 aches and pains that come from that kind of work.
9 This stuff makes it so we can going without the pain.

10 Ladies and gentlemen, we're talking about a
11 safe, natural compound with seemingly endless benefits
12 for users, one with very little, if any, risk of
13 significant downside. For my money, CBD may be one of
14 God's greatest gifts to mankind in the pursuit of
15 health.

16 It's outrageous that corporate greed and red
17 tape have forced most Americans to spend the last
18 eight decades in the dark. Today is our chance to
19 learn from past mistakes, open our eyes to the
20 compelling scientific and anecdotal evidence and
21 harness the power of nature to put our health back
22 into our hands. Thank you.

1 PANEL MEMBER: Are you familiar with data
2 regarding the safety of CBD use in children?

3 MR. SNYDER: Not personally, no.

4 PANEL MEMBER: Are you supportive of that?

5 MR. SNYDER: In children? I'm a publisher.
6 So I don't have the research on that. Based on what
7 I've heard, no, I wouldn't give my son or my daughter
8 CBD.

9 PANEL MEMBER: Would you give your son or
10 daughter vitamin C?

11 MR. SNYDER: I would.

12 PANEL MEMBER: Okay.

13 PANEL MEMBER: I'm curious just to ask you to
14 speculate a little bit about the impact of expanding
15 the availability of cannabidiol in the foods and
16 dietary supplements based on study of cannabidiol
17 formally and in the kinds of trials that you mentioned
18 on clinicaltrials.gov. Do you think that would help
19 that or in any way hinder it by potentially removing,
20 you know, some incentives for that?

21 MR. SNYDER: You're asking if getting rid of
22 the regulations on food supplements would help?

1 PANEL MEMBER: If it was more broadly
2 available in that way. Would that -- what effect
3 would that have on sort of additional scientific
4 research?

5 MR. SNYDER: I think what we need to do is
6 clear up the confusion. Anything -- any regulations
7 we make need to be simple, clear. Our readers -- I
8 hear it every day. They think there's opportunity out
9 there. They just don't know what to do.

10 As we've heard today, there's a lot of shady
11 characters in the market. There's some really good
12 characters out there. And clearing that up with
13 smart, commonsense regulation is what's needed. Thank
14 you.

15 MS. CRISTINZIO: Thank you. We are now on
16 speaker number 40, Ian Spotts. Ian? Okay. We are
17 moving onto speaker 41, Monica Weldon

18 MS. WELDON: Hi. Thank you. Thank you. I'm
19 Monica Weldon, and I'm president and CEO of bridge the
20 Gap, SYNGAP Education Research Foundation. Imagine
21 being told there is no FDA-approved product for your
22 child. Picture watching your children suffer from a

1 rare genetic disorder that physicians barely
2 understand, marked by seizures, mood disorders, the
3 inability for your child to communicate due to their
4 being nonverbal. Put yourself in the shoes of a
5 parent or a caregiver who is disparate for their child
6 -- to treat their child's challenges, even just to
7 find out what's wrong.

8 Now insert CBD. With all its confusing
9 descriptions, derivative products, vague dosage
10 recommendations, the cure-all marketing and then you
11 create a legal environment of ambiguity around it and
12 now you've just created the Wild West of CBD.

13 Like many pediatric rare disease advocates,
14 we are particularly sensitive to new emerging
15 therapies that are going to help our children.

16 Patients and their families look to us for
17 guidance and trusted educational materials on
18 potential treatments, especially as we work closely
19 with researchers to develop targeted therapies for
20 SYNGAP1. We have no approved targeted therapy for our
21 children. So therefore we are focused on short-term
22 repurposing of drugs and natural medications to

1 mitigate SYNGAP1 symptoms.

2 CBD-based pharmaceuticals and OTC CBD
3 products come up in conversations all the time. Our
4 greatest challenge as an organization is how to
5 address them. At this stage, we need further
6 scientific research when it comes to safety, efficacy,
7 product integrity, drug interactions, further CBD
8 research will answer many of our questions.

9 In addition to our patient community, they
10 have expressed appropriate dosing, potential
11 interactions with other pharmaceuticals, where to
12 purchase products free of harsh chemicals and
13 pesticides.

14 In addition, we support regulations on
15 standards of labeling of CBD products so that patients
16 and caregivers can easily understand what they are
17 consuming and compare labels for different products.
18 We need regulatory shielding from predators and
19 opportunists in the consumer product space looking to
20 capitalize off CBD's popularity by peddling
21 substandard and fake products.

22 We need to know exactly what we are

1 consuming, especially if we are feeding it to our
2 children. We need to feel confident that the products
3 we are using are held to the highest safety standards.
4 SYNGAP1 patients, along with other rare pediatric
5 disease patients, need to have access to safe and
6 effective therapies to improve their quality of life.
7 Thank you.

8 MS. CRISTINZIO: Thank you. I just want to
9 note we're running a little bit behind. We're about
10 10 minutes behind schedule. So I'm going to try and
11 stick to the lights a little bit more vigorously. We
12 are on number 42, Anna Williams.

13 MS. WILLIAMS: My name is Anna Williams, and
14 I'm the main point of contact at the American
15 Association for Laboratory Accreditation, otherwise
16 known as A2LA, for their cannabis and hemp programs.

17 Established in 1978, A2LA is a nonprofit,
18 third party accreditation body with over 3,500
19 actively accredited certificates representing all 50
20 states. We offer training and services to public and
21 private testing laboratories, proficiency testing
22 providers, reference material producers and product

1 certifiers.

2 In the U.S., both government regulators and
3 consumers seek assurance that products and commerce
4 conform to specific quality attributes and/or
5 regulatory requirements. This is generally
6 accomplished via testing of the product by a competent
7 analytical laboratory.

8 The same is true for products containing
9 cannabis and cannabis-derived compounds and both the
10 neat, plant and process materials should be testing
11 for unacceptable levels of contaminant and
12 adulterants.

13 The challenges at present are there few
14 multi-laboratory validated test dates or realistically
15 nationally available proficiency testing programs.
16 This circumstance places the requirement on the lab to
17 develop, validate and run their own internal methods
18 without these necessary tools that laboratories in
19 other industries have access to.

20 Assurance of laboratory competence is most
21 often accomplished through ISO 17025 accreditation
22 process. Accreditation uses criteria and procedures

1 specifically developed for the assessment of technical
2 competence of the laboratory and depends on multiple
3 factors including qualifications and training of
4 staff, correct equipment, adequate quality assurance
5 procedures, properly statistical-based sampling
6 practices, appropriate and valid testing procedures
7 and methods, traceability of measurements to national
8 standards, accurate recording and reporting procedures
9 and suitable testing facilities.

10 Expert technical assessors conduct a thorough
11 evaluation of a laboratory's management process,
12 affecting the production of analytical test data and
13 through being accredited laboratories demonstrate that
14 these quality requirements have been and continue to
15 be met.

16 Accreditation bodies themselves are also
17 periodically evaluated and are part of international
18 laboratory accreditation cooperation. It is through
19 this process that assurance is provided to regulators
20 and the public of technical competence of this testing
21 laboratory.

22 In summary, it is the position of A2LA that

1 any outcome of the FDA's request for information
2 inform any future regulations to include language that
3 requires proficient -- or excuse me, participating
4 analytical testing laboratories to be accredited to
5 ISO 17025 by a signatory accreditation body. Thank
6 you.

7 MS. CRISTINZIO: Thank you. We are on number
8 43, Tiffany Wilson. Tiffany? So we are going to go
9 on to the patient category. We have number 44, Keith
10 Fargo.

11 PATIENTS

12 DR. FARGO: Hi. Good morning. My name is
13 Keith Fargo. I'm the director of scientific programs
14 and outreach for the Alzheimer's Association.

15 Although the chemical components of cannabis
16 have been studied in relationship to Alzheimer's and
17 dementia, most of this research has been conducted in
18 in animal models and cell culture and not in people.

19 Furthermore, research findings to date have
20 been inconclusive and contradictory. Accordingly, the
21 Agency for Healthcare Research and Quality, in its
22 recent draft report on the diagnosis and treatment of

1 Alzheimer's, determined that there is insufficient
2 evidence to draw conclusions about the efficacy or
3 safety of cannabinoids for treatment of Alzheimer's, a
4 determination with which the Alzheimer's Association
5 agrees.

6 At this time, cannabis is essentially an
7 untested drug for use in Alzheimer's disease and
8 dementia. And like any untested drug, it cannot be
9 responsibly recommended for human use.

10 Only large, randomized, controlled clinical
11 trials can provide reliable evidence of efficacy or
12 safety of any drug for human use. And to date, this
13 has simply not happened with cannabis in relationship
14 to Alzheimer's and dementia.

15 This lack of evidence creates substantial
16 risks for individuals and their families. Simply put,
17 there is currently no robust consistent clinical trial
18 data to support the use of cannabis for treatment of
19 Alzheimer's or dementia.

20 The Alzheimer's Association believes that
21 more research in this area is needed, and we applaud
22 the FDA's commitment to protecting the health and

1 safety of individuals until such evidence becomes
2 available. Thank you.

3 PANEL MEMBER: How do you view the commercial
4 availability of cannabis and CBD and other cannabis
5 derivatives as affecting incentives for research in
6 Alzheimer's?

7 DR. FARGO: That's a great question. I don't
8 know that it directly affects the incentive to do
9 further research in Alzheimer's. I just don't know
10 that I have a good answer to that question. All
11 right. Thanks.

12 MS. CRISTINZIO: Thank you. We are now on
13 speaker number 45, Kevin Chapman.

14 DR. CHAPMAN: Good morning. Good morning.
15 My name is Dr. Kevin Chapman, and I'm a pediatric
16 epilepsy specialist in Colorado speaking on behalf of
17 the American --

18 MS. CRISTINZIO: Can you speak a little
19 louder, please?

20 DR. CHAPMAN: Sorry.

21 MS. CRISTINZIO: Or move closer to the mic.

22 DR. CHAPMAN: My name is Dr. Kevin Chapman,

1 and I'm a pediatric specialist in Colorado speaking on
2 behalf of the American Epilepsy Society, representing
3 over 4,400 health professionals who focus on the care
4 of patients with epilepsy from neonates to the
5 geriatric population.

6 We have significant concerns about the
7 current status quo for cannabis products and advocate
8 for regulation of cannabis products as drugs under the
9 purview of the FDA.

10 The current patchwork of state and federal
11 regulations has led to an array of products with
12 variable phytocannabinoid content and potential
13 impurities such as pesticides. By classifying these
14 compounds and drugs, the FDA can assure consistency
15 and safety of these poorly regulated compounds.

16 We strongly encourage the FDA and United
17 States Pharmacopeia to create standard assays to
18 evaluate content and purity, as well as quality
19 standards for cannabis-containing products that are
20 currently unregulated yet may be marketed and sold for
21 the treatment of various medical conditions such as
22 epilepsy, pain or migraine headache.

1 Studies of Epidiolex, an FDA-approved
2 prescription CBD product, have raised concerns about
3 hepatotoxic effects of CBD and interactions with other
4 medications if taken outside of medical supervision.

5 Clear warning labeling of cannabis-derived
6 compounds is necessary to educate about potential
7 adverse effects and help offset the common belief that
8 these products are, quote, "more natural," end quote,
9 and therefore safer than pharmaceutical products.

10 Many questions remain regarding the long-term
11 consequences of cannabis compounds whose underlying
12 mechanism of action remains unknown.

13 We have specific concerns about the unknown
14 effects of these compounds on the complex pathways of
15 the developing brain in children. We also have
16 concerns about the potential long-term effects on
17 adults who regularly consume these products.

18 We support reducing regulatory barriers to
19 research of cannabis-derived compounds. We strongly
20 encourage -- we strongly urge the FDA to classify
21 these compounds as drugs under the complete
22 jurisdiction of the FDA. We also advocate for

1 ongoing, well-designed studies into the safety and
2 efficacy of cannabis drugs. We commend the FDA for
3 tackling this complex problem of public safety, and I
4 appreciate your time.

5 PANEL MEMBER: Question for you.

6 DR. CHAPMAN: Yes, ma'am.

7 PANEL MEMBER: Have you found any -- are you
8 aware of patients using unapproved CBD products as
9 opposed to Epidiolex, which has been approved?

10 DR. CHAPMAN: Yes. I am aware of that.
11 There are quite a few.

12 PANEL MEMBER: And do you know why they are
13 doing that?

14 DR. CHAPMAN: At this point, Epidiolex is
15 limited to a very small segment of our population.
16 There's two current approvals, Dravet syndrome and
17 Lennox-Gastaut syndrome, which is a fairly small but
18 serious epilepsy syndrome.

19 And so, all of the patients that are outside
20 of that are not covered. And the cost of the
21 medication is about \$430,000 per year, whereas
22 families can go to a dispensary and pick up something,

1 you know, on the order of \$100 per month or so.

2 PANEL MEMBER: And how are they choosing
3 dose?

4 DR. CHAPMAN: They're making it up as they go
5 along. Sorry. Sorry. They're just sort of making it
6 up as they go along.

7 PANEL MEMBER: I'll just follow up on that,
8 given that answer. Do you find that most of these
9 patients are being monitored in some way by their
10 physicians for adverse events like liver toxicity and
11 others that were identified in the approval of the
12 Epidiolex drug?

13 DR. CHAPMAN: It's an excellent question. I
14 mean, so this has really been kind of an issue for
15 five years. Since this WEEDS program in August of
16 2013, especially in Colorado, we had an influx of
17 patients. And early on, we definitely did not know
18 what to expect from these compounds.

19 We instituted, you know, trying to evaluate
20 drug interactions, hepatotoxic effects, aplastic
21 anemia, those types of things, with sort of
22 standardized -- at least some attempt at

1 standardization of blood testing and things like that.

2 It's a bit variable because, you know, some
3 families were getting -- we felt as physicians within
4 Colorado we could not make recommendations about non-
5 FDA-approved products because, at the time, we were
6 worried for other regulatory reasons whether it may
7 affect our ability to do research and things such as
8 that.

9 So we have really -- there's so much
10 variability within the CBD products and I think that's
11 one of the biggest concerns that we have.

12 MS. CRISTINZIO: Great. Thank you. Our next
13 speaker is Kari Rosbeck, number 46.

14 MS. ROSBECK: My name is Kari Luther Rosbeck,
15 and I'm president and CEO of the Tuberous Sclerosis
16 Alliance, an advocacy organization for people with
17 tuberous sclerosis complex, or TSC.

18 About 85 percent of those with TSC will
19 experience epilepsy. So accessing effective seizure
20 medications is critically important for our community.
21 In fact, a recent Phase III clinical trial reported
22 efficacy of Epidiolex, a purified and standardized

1 formulation of cannabidiol, for treating drug-
2 resistant seizures in TSC, which we hope will lead to
3 an FDA approval for broader use in epilepsy associated
4 with TSC.

5 The TS Alliance recognizes the importance of
6 taking an evidence-based approach to discovery,
7 development and clinical application of cannabis and
8 derivatives. Multiple drug cannabinoid interactions
9 with commonly used anti-seizure medications are well-
10 documented, including clobazam, valproate and others.

11 Risks of unexpected drug-drug interactions
12 may occur if cannabinoid enters the bloodstream due to
13 its inclusion in food, cosmetics and other products.
14 Therefore we believe labeling of identified drug
15 interactions should be required on any cannabis-
16 derived or cannabis-containing products since people
17 may be exposed to these products in multiple ways.

18 Clinical trial results could also be
19 compromised if investigators are unable to control and
20 verify dietary intake of cannabinoids which might lead
21 to increased variability and apparent placebo effects.

22 In summary, without a wide safety margin to

1 avoid accidental exposure of people with TSC to levels
2 of cannabinoids which are known to interact with their
3 medications, we urge the FDA to prohibit the inclusion
4 of cannabis-based additives in any FDA-regulated
5 products other than drugs as defined and approved
6 under the FD&C Act.

7 Please refer to our written public comments
8 for more information. Thank you on behalf of the TS
9 Alliance and the TSC community.

10 PANEL MEMBER: Sorry. Do your written
11 comments include the information you mentioned about
12 drug interactions?

13 MS. ROSBECK: Yes. Yes, they do.

14 PANEL MEMBER: Okay. Thank you.

15 MS. ROSBECK: Thank you.

16 MS. CRISTINZIO: Great. Okay. We are moving
17 on to the next category of public safety. We have
18 number 47, Patrick Bird.

19 PUBLIC SAFETY

20 MR. BIRD: Good morning. My name is Patrick
21 Bird. And I'm the owner of PMB BioTek Consulting,
22 which works to develop analytical methods and rapid

1 detection platforms for analytical testing
2 laboratories. I'm also the co-chair of the
3 microbiology working group for AOAC International's
4 cannabis analytical science program.

5 The complete lack of a federal regulatory
6 scheme for cannabis generally, including both hemp and
7 marijuana, has left cannabis decades behind other food
8 and agricultural testing. And now, the FDA that must
9 bring a plant that has been used by humans for
10 millennia into a 21st century paradigm for food
11 safety.

12 The FDA is responsible for protecting the
13 public health by ensuring the safety of products
14 millions of Americans consume every day.

15 In developing a new regulatory framework for
16 hemp-derived products, the FDA, in partnership with
17 industry groups like AOAC and testing laboratories
18 like Titan Analytical, should look to two primary
19 sources to guide its efforts: state cannabis
20 regulations and federal food safety regulations.

21 First, the FDA should closely examine the
22 regulatory schemes implemented by states with mature

1 medical and adult use cannabis markets; namely
2 California, Illinois and Colorado.

3 Although these states' regulatory structures
4 have different ends, their policy goals are congruent
5 because the same baseline safety issues are present
6 regardless of whether a cannabis plant, hemp or
7 marijuana is grown in accordance with or in
8 contravention of federal law.

9 The cannabis plant is a bioaccumulator,
10 acting as a sponge for a wide range of environmental
11 and microbiological contaminants. By establishing
12 baseline regulations for pesticides, metals,
13 bacteriological agents and other key target analytes
14 in hemp-derived products for human consumption, the
15 FDA can continue to fulfill its responsibility to
16 protect public health.

17 Second, the FDA should incorporate aspects of
18 federal food safety regulations like FSMA such as
19 HACCP, FSVP and preventative control planning that
20 will adequately ensure product safety. Consumers
21 should expect, if not demand the same levels of
22 safety, traceability and recall readiness that the FDA

1 already requires of food manufacturers. Hemp products
2 should be treated no differently. Thank you.

3 MS. CRISTINZIO: Thank you. We are on a new
4 category, retailers and distributors. Number 48,
5 Crystal Guess.

6 RETAILERS/DISTRIBUTORS

7 MS. GUESS: Good morning. My name is Crystal
8 Guess, and the comments that I am making today are my
9 own and do not represent the company or any
10 individual. I would like to speak to the 2018 Farm
11 Bill, being that it now regulates hemp as any other
12 agricultural crop, just like corn, wheat, rye, barley,
13 potatoes.

14 I can walk into a Safeway and I can buy
15 potato chips and buy those potato chips with a credit
16 card. I can then -- Safeway can then deposit those
17 funds into a national bank. We are having some very -
18 - we are having some issues with now in the industry
19 where there are a lot of people that are trying to
20 provide this medicine to consumers.

21 But they are being held and their hands are
22 being tied because they have no ability to take

1 payment, whether it's online or face-to-face. The
2 banking -- so we just -- we're asking for more clarity
3 from the FDA to give -- to make these people feel a
4 little bit more confident in approaching the banks and
5 being able to get those approvals.

6 When it comes to labeling, I think, you know,
7 when we have -- we're hearing some stories of people,
8 that -- you know, when it comes to labeling, they
9 don't know what they're getting when it comes to full
10 spectrum versus isolate. We're getting questions
11 about what is this, what's the clarity on that.

12 There are companies out there that are saying
13 we're full spectrum, and yet it's 99 percent CBD
14 spiked with 1 percent terpenes and they're putting
15 these out there.

16 And so, there needs to be a little bit more
17 clarity, I think maybe some sort of seal on the label
18 saying this is full spectrum and a table of
19 definitions as to what full spectrum means, what is
20 isolate so that consumers are educated and they're not
21 left in the dark as to what is this, what is this.

22 When it comes to dosing, this is a very

1 complicated topic because everybody is different and
2 every body is different. There's no magical chart
3 that we can point to that says, oh, a woman aged this
4 to this that has this condition takes this much CBD.
5 We don't have that.

6 We have to educate the public as to how to
7 titrate themselves and so on and so forth. And a lot
8 of these things can be addressed I believe through
9 labeling, through obviously education.

10 And we need to also have the ability to hold
11 companies and individuals that are making these false
12 promises to the public, we need to have a place to go
13 where we can hold these people accountable, so that we
14 can raise the flags and so that we aren't having
15 people come up and saying my -- you know, this
16 happened to my son or my cousin and they didn't know.

17 So it really does boil down to consumer
18 education, labeling as well as opening the doors to a
19 little bit more clarity we are asking from the FDA in
20 regards to --

21 MS. CRISTINZIO: Your time is up.

22 MS. GUESS: -- states that -- yeah, that are

1 a little confused as to what they can and cannot do.

2 MS. CRISTINZIO: Sorry for the interruption.
3 We're running behind.

4 MS. GUESS: That's okay.

5 MS. CRISTINZIO: Thank you. Next we have
6 David Heldreth from -- I'm not even going to try and
7 pronounce it.

8 MR. HELDRETH: I'll handle that for you.
9 Good morning. My name is David Heldreth. I'm the
10 chief -- excuse me, chief science officer for True
11 Terpenes. With a little bit of time, let me get to
12 the heart of the matter.

13 While the majority of this hearing is
14 focusing on things related to CBD, I believe there are
15 other issues that we can address with less
16 controversy. CBG, CBC, CBN, these are cannabinoids
17 which are legalized under the Farm Bill, but don't
18 require the regulatory hurdles that CBD and THC face
19 with the drug approvals.

20 Even easier would be things like terpenes and
21 products like hemp leaf foods which will provide low
22 hanging fruit for the FDA to create allowances while

1 avoiding again CBD and other issues.

2 Imagine hemp leaf salads and terpene
3 dressings, hemp and terpene-flavored sodas or your
4 favorite beer with a skunky hemp note. Terpenes are
5 responsible for the taste and aroma of cannabis, in
6 addition to hops, lavender and almost every scented
7 plant on Earth.

8 When these compounds are found in hops or
9 lavender, they're considered generally regarded as
10 safe by the FDA. However, these identical molecules,
11 when sourced from the hemp plant, are not allowed to
12 be used in food, drinks, supplements or even alcohol
13 due to TTB and FDA regulations.

14 True Terpenes is considered the industry
15 expert by those sourcing terpenes from non-cannabis
16 plants and we would relish the opportunity to help the
17 FDA and Congress establish the safety and
18 manufacturing requirements for hemp terpenes to enter
19 our food system.

20 In fact, True Terpenes has our own such
21 system that we deemed True Grade that we would love to
22 provide you information on. As I previously stated,

1 terpenes as an entire class have been demonstrated
2 safe in GRAS panels and are used in innumerable
3 household foods, drinks and other products.

4 Further, there are manufacturing techniques
5 such as steam distillation that are able to
6 selectively pull terpenes while leaving behind things
7 such as cannabinoids that are creating these
8 difficulties.

9 In closing, True Terpenes and myself hope the
10 FDA can see an easy way forward to create more access
11 for safe, sane hemp food products. Please, I
12 recommend you visit our website for more information,
13 trueterpenes.com, and I would love to provide some of
14 this information for you in the future.

15 PANEL MEMBER: Just a quick follow-up
16 question about your comment about selectively I assume
17 concentrating specific terpenes. Any data you have
18 available on the safety of those higher concentration
19 of individual terpenes found in hemp would be really
20 useful to have submitted to the docket.

21 MR. HELDRETH: We would love to. And again,
22 most of that data has also been shown safe in GRAS

1 panels. But we would love to provide that for you.

2 MS. CRISTINZIO: Great. Thank you. Our
3 final speaker in this category is Peter Matz, from the
4 Food Marketing Institute.

5 MR. MATZ: Good morning. I'm pleased to be
6 closing out the first batch of comments and I
7 appreciate the opportunity to provide comment today on
8 behalf of the Food Marketing Institute, the trade
9 association for the supermarket industry, including
10 roughly 33,000 grocery stores and 12,000 pharmacies
11 across the country.

12 I am here first and foremost to convey the
13 seriousness of the regulatory ambiguity facing our
14 member companies and their customers each day as
15 consumer demand for products containing hemp and hemp
16 derivatives continue to grow, along with the
17 commercial availability of such products, especially
18 those which count CBD as an ingredient.

19 While most of the stakeholders participating
20 today understand the Farm Bill did not alter FDA's
21 authority over the use of such ingredients in FDA-
22 regulated products, there is mass confusion in the

1 marketplace for the public, for suppliers and
2 retailers and also for state regulators.

3 From ingestible products including foods,
4 beverages and dietary supplements to topical items
5 such as creams and lotions, the demand for CBD
6 products for both human and animal use is already
7 staggering and growing rapidly.

8 In fact, just last month, a Consumer Reports
9 survey found that more than a quarter of Americans say
10 that they've tried CBD, while one out of seven of
11 those people said they use it every day.

12 Because of the consumer interest in this
13 emerging market and the desire of our members to
14 provide products which their customers are seeking,
15 we're fielding more and more questions from companies
16 that are understandably seeking clarity about the
17 current regulatory framework for the sale and labeling
18 of products containing CBD in particular.

19 And while we want to be in full compliance
20 with all of FDA's requirements, we also want to ensure
21 our members have appropriate assurances that the
22 products they're merchandising are both safe and being

1 sold appropriately.

2 Having said that, FMI sees the regulatory
3 challenges surrounding the legal and appropriate sale
4 of hemp and hemp-derived products as a critically
5 important policy issue. And given the prevalence of
6 these products in the marketplace, we respectfully
7 urge FDA to move swiftly to provide additional clarity
8 and establish a pathway forward.

9 In conclusion, please know that our industry
10 would welcome the opportunity to be a resource to the
11 agency throughout this regulatory process and we look
12 forward to working with FDA, USDA and Congress as
13 things move forward. Thank you very much.

14 MS. CRISTINZIO: Thank you. Now we are
15 moving onto our next panel of speakers that are
16 representatives from state and government officials
17 and entities. Our first speaker is Pam Miles, for two
18 minutes.

19 ORAL COMMENTS & FORMAL PRESENTATIONS WITH SLIDE DECK
20 STATE/GOVERNMENT OFFICIALS/ENTITIES

21 MS. MILES: Good morning. I'm Pam Miles, and
22 I'm the past president of the Association of Food and

1 Drug Officials, AFDO. AFDO has been working toward
2 uniformity in food and drug laws since 1896. AFDO
3 represents federal, state and local food and medical
4 products regulators primarily in the United States.
5 Thank you for the opportunity to present at this
6 public hearing.

7 Across the United States, state and local
8 regulators have been confronted with the huge
9 onslaught of CBD in food products and cosmetics being
10 sold in all types of venues, from farmers markets,
11 convenience stores up to some of the largest retailers
12 and we also have standalone CBD stores opening in many
13 states.

14 Recently a national quick service restaurant
15 chain served CBD-infused sandwiches as part of a
16 promotion. Currently states are struggling with a
17 lack of sound, scientific research available on CBD
18 and long-term health impacts of ingestion, including
19 those to children.

20 Nearly all peer-reviewed research has been
21 based on the usage of CBD as a drug. Most
22 manufacturers are approaching CBD as if it is as safe

1 as food ingredients that have had substantial amounts
2 of long-term research.

3 Further, new reports across the United States
4 have documented that food products purporting a
5 specific quantity of CBD frequently are not adequate.
6 Further, with the widespread distribution and usage of
7 CBD across the U.S., it's making it very difficult for
8 state and local regulators to continue with our stance
9 that CBD cannot be used in food products.

10 AFDO is hopeful that FDA will begin to
11 provide significant leadership as it relates to CBD,
12 including research related to its health impacts.
13 Thank you again for the opportunity to participate
14 today. AFDO looks forward to collaborating with FDA
15 on this important regulatory issue. Thank you.

16 PANEL MEMBER: Hi. Also I think AFDO is in
17 sort of a unique position with state governments. And
18 I'm wondering if there's -- if you're aware or have
19 submitted to the docket any systematic collection of
20 adverse events associated with cannabis products or
21 CBD products specifically.

22 MS. MILES: We do not have that right now. I

1 believe we did do a national survey with all of our
2 states and we're collecting the information that we
3 are going to be making comments, written comments.

4 PANEL MEMBER: Any idea of when that might be
5 finished or available?

6 MS. MILES: It is finished.

7 PANEL MEMBER: Oh, it is finished?

8 MS. MILES: I'm not sure. And I don't know
9 if Brenda has -- Brenda's going to speak next. I
10 don't know how many states have replied.

11 PANEL MEMBER: Okay.

12 MS. MILES: And we've been reaching out. But
13 we have quite a few replies. And we're actually
14 putting together that information right now.

15 PANEL MEMBER: Okay.

16 MS. MILES: And our executive director will
17 be sending written comments.

18 PANEL MEMBER: All right. Thanks, Pam.

19 MS. MILES: Thank you.

20 MS. CRISTINZIO: Thank you. Next up is
21 Brenda Morris.

22 MS. MORRIS: Thank you. I'm Brenda Morris,

1 and I'm president-elect and representing the
2 Association of Food and Drug Officials. Currently a
3 patchwork of laws exist for CBD across the nation,
4 with very little consistency or uniformity in
5 regulations, which is creating a Wild West type
6 atmosphere where nothing -- anything is allowed.

7 CBD products in foods and cosmetics are being
8 shipped in interstate commerce and this is clearly
9 within FDA's regulatory authority. As of last week in
10 a survey that AFDO has conducted in which we had 33
11 responses, 13 of the states that responded have legal
12 CBD sales.

13 Over half are using 21 CFR 117 as their
14 primary regulatory authority with a portion of those
15 also applying parts of the dietary supplement
16 regulations. The remainder states are using the
17 retail food code and a few relying on GMPs under
18 either 110 or 117.

19 For states that are not allowing CBD, most
20 all acknowledge they have insufficient resources to
21 effectively end the sales of CBD in food and cosmetics
22 in their state. Of the 20 responding states where CBD

1 sales is not legal, only eight states were considering
2 any sort of enforcement action on those with clear
3 health claims and even when there are clear health
4 claims, many states are not taking any action.

5 Many of the states noted they are struggling
6 with the appropriate approach given the lack of
7 federal participation in this process.

8 FDA began hosting 50 state meetings in 1998
9 and two key statements that were made by FDA at those
10 early meetings were the vision for the future is an
11 integrated food safety that focuses on preventing harm
12 before it happens and food safety reform at the
13 federal level will be incomplete and insufficient
14 unless it strengthens state and local roles and builds
15 true partnerships across all levels of government.

16 With the legislation of hemp as part of the
17 Farm Bill, most every state legislature in this
18 country considered and many will enact some type of
19 state hemp growing bill in 2019, increasing CBD
20 production. AFDO looks forward to collaborating with
21 FDA on this very important regulatory issue. Thank
22 you so much for allowing us to speak.

1 PANEL MEMBER: And the results of that survey
2 of the states you'll be putting on the docket?

3 MS. MORRIS: Yes, we will.

4 PANEL MEMBER: Thanks so much.

5 MS. CRISTINZIO: Great. Thank you. Next, we
6 have Joseph Reardon, speaker number 53.

7 MR. REARDON: Thank you very much for the
8 opportunity to be here today. Again, my name is Joe
9 Reardon. I serve as the assistant commissioner for
10 consumer protection at the North Carolina Department
11 of Agriculture and Consumer Services. I want to thank
12 FDA today for this opportunity to bring these comments
13 forward.

14 North Carolina, like many other states, has a
15 rapidly growing industrial hemp industry. As of this
16 year, we have over 1,000 growers licensed in the state
17 of North Carolina, 12,000 acres of product that is
18 being grown and 4.9 million square feet that's being
19 grown in greenhouses. We have 601 registered
20 processors just in the state of North Carolina alone.

21 The farmers in North Carolina have invested
22 over a hundred million dollars in this current crop.

1 We know that CBD is being sold across the nation in
2 dietary supplements in food and drink and there's no
3 regulatory framework for that to be done.

4 Due to the availability of these products in
5 the marketplace, we've done some survey work to better
6 understand the availability of these products in the
7 marketplace. We've also sent letters out to our
8 industry in our state informing them of the
9 information that Dr. Gottlieb provided last year and
10 earlier this year of FDA's position on these products.

11 We have done some market survey to understand
12 the prevalence of these products in the marketplace to
13 give us a more informed position here.

14 And in doing so and better understanding the
15 prevalence of these products in North Carolina and the
16 future production of those products, North Carolina
17 will be seeking and will now ask our state legislature
18 to give us the authority to have a regulation in place
19 for the production of these products.

20 We will use the FDA's 21 CFR 111 as the
21 foundation of writing those regulations. We believe
22 with the support of our industry there and the input

1 of our industry, we will be able to put a regulatory
2 framework in place for the production of those
3 products to ensure the suitability of those products
4 going into the marketplace.

5 We believe a uniform and consistent approach
6 is critical to consumer safety and long-term viability
7 of this emerging industry. Consumers and industry
8 alike benefit from a regulatory framework we believe
9 to ensure the identity, the purity, the strength and
10 the composition of those products.

11 The one thing I do want to say though, to be
12 clear, without the FDA's guidance and leadership,
13 individual states may carve out their own regulatory
14 exceptions for CBD, creating a patchwork approach
15 which will hinder the nationwide growth of this
16 industry and endanger consumers.

17 We urge FDA to resolve the statutory issues
18 and properly establish a legal pathway for CBD
19 products to enter the marketplace. I want to thank
20 you for the opportunity today to provide these
21 comments.

22 We are hearing from some states that they

1 would like to extend the written comment period from
2 July to August. We think with the amount of people
3 here today and the interest in this, you want to get
4 all the feedback you can. So it may be in the FDA's
5 interest to extend that written comment period. Thank
6 you very much.

7 PANEL MEMBER: I have a question about your
8 market survey.

9 MR. REARDON: Yes.

10 PANEL MEMBER: I know it's a big agricultural
11 crop, particularly in your state. But when you did
12 the market survey, do you have a sense of the
13 synthetic market as well? There's a lot of synthetic
14 CBD products out there as well.

15 MR. REARDON: We didn't look at that in our
16 survey. We looked at the prevalence of it being sold
17 in foods, what types of foods. Are they the
18 traditional gummies that are being marketed to
19 children? We wanted to understand the prevalence of
20 health claims on those products as well, understand
21 the prevalence of smokables, which is wide in the
22 market today.

1 So we really wanted to understand what was in
2 the marketplace, what the compliance level was on that
3 and what information they need from the federal
4 government or others to better understand what the
5 legal framework is.

6 PANEL MEMBER: Yeah. That would be great to
7 see that data if you could submit that to the docket.
8 That would be great.

9 My other question is when you're
10 contemplating a regulatory scheme at the state level,
11 are you thinking about restrictions on retail, age
12 limitations or labeling or other types of
13 restrictions?

14 MR. REARDON: We're not. We're simply
15 looking for a regulatory framework on the extraction,
16 production and reconstitution of CBD or cannabinoid-
17 related compounds, including terpenes and other
18 constituents that may be in the hemp plant.

19 We are really, like other states, looking for
20 that guidance, and the industry in our state is as
21 well from FDA to show that we have a uniform and
22 consistent platform. What we're hearing from our

1 industry, and you've heard it today, is they want a
2 legal pathway to bring these products to market. So
3 we look forward to partnering with you. Thank you.

4 MS. CRISTINZIO: Thank you. Our next speaker
5 is William Tilburg, number 54. William? William's
6 not here? All right. I'm going to welcome to the
7 podium Erin Bubb, number 55, from the Pennsylvania
8 Department of Agriculture. Erin is our first speaker
9 to present for five minutes with slides.

10 MS. BUBB: Good morning, and thank you. I'm
11 here today to represent the Association of American
12 Feed Control Officials, known as AFCO.

13 AFCO is a voluntary membership organization
14 of the states and federal government agencies, as well
15 as government agencies from other countries,
16 responsible for the execution of laws and regulations
17 pertaining to the production, labeling, distribution
18 and sale of animal feed and feed ingredients.

19 Many states' laws or regulations reference
20 the official terms and definitions of the AFCO
21 official publication. This is the most comprehensive
22 list of approved feed ingredients. There are three

1 ways for an ingredient to make its way into the
2 publication: through a food additive petition, a
3 definition request to AFCO or a generally recognized
4 as safe, also known as GRAS, voluntary notification to
5 FDA.

6 All three routes include a safety and utility
7 review done by FDA's Center for Veterinary Medicine.

8 All three routes result in the ingredient being
9 published in the AFCO official publication and
10 accepted by the states as ingredients in animal feed
11 and pet food products.

12 Let's see. I'm not advancing. But I'm going
13 to continue. Okay. AFCO and FDA have a longstanding
14 MOU that allows FDA to accept animal feed ingredients
15 that have come through the AFCO ingredient definition
16 process.

17 During this process, CVM reviews the
18 ingredient submission packet to ensure the new
19 ingredient has a standard of identity and has been
20 evaluated for safety and efficacy for its intended
21 use.

22 This route has served regulatory officials,

1 the regulated industry and the public well by
2 providing consistency to the animal feed ingredient
3 approval process.

4 AFCO's and CVM's primary concern is the
5 safety of the ingredient. AFCO awaits the industry's
6 scientific evaluation of the safety of hemp-derived
7 products in order to bring these ingredients legally
8 into the market.

9 The AFCO process does take time. If
10 additional resources could be allocated to CVM to more
11 quickly complete their technical review, the entire
12 process could be completed sooner.

13 Hemp seed oil, hemp seed meal or seed cake
14 and whole hemp seeds are products expected to be
15 reviewed by AFCO and CVM for use in animal feed when
16 industry completes the safety studies. Materials and
17 products that are CBD or phytocannabinoid-infused need
18 to be treated as drugs and kept separate from other
19 hemp products used in animal feed or pet food as there
20 is currently no nutritional basis for these compounds
21 to be allowed in animal feed or pet food.

22 AFCO is ready to participate in getting hemp

1 products into the animal feed market as nutritional
2 sources. We are waiting on the industry to complete
3 the safety studies.

4 Lastly, I also respectfully request a 30-day
5 extension for written comments to August 1st. Ah,
6 there's my last slide. If there are any questions,
7 folks are welcome to visit the afco.org website,
8 generalinquiries@afco.org and those that are
9 interested in ingredient definitions and providing a
10 submission through AFCO can use the general email of
11 definitions@afco.org. Thank you.

12 PANEL MEMBER: A quick question. When you do
13 your evaluation of feed ingredients, do you consider
14 residues that might be left in the tissues of food-
15 producing animals?

16 MS. BUBB: That is absolutely one of the
17 evaluations that would be conducted. And that is the
18 information that is needed in a submission,
19 absolutely.

20 PANEL MEMBER: Can you characterize for me
21 what you see on the state level in the use of these
22 products in animals?

1 MS. BUBB: Currently states are not
2 recognizing the legality of hemp-derived products in
3 animal feed. What we are seeing personally, in
4 Pennsylvania, we are seeing CBD-infused products, pet
5 treats especially. And we are issuing regulatory
6 actions on such products in the marketplace. We are
7 issuing stop sale orders, withdrawal from marketplace.

8 We do have a burgeoning, growing hemp
9 industry in Pennsylvania. We want to see it succeed.
10 They're very, very interested in hemp-derived products
11 for the use in animal feed.

12 And we are educating them and supporting them
13 in their efforts for study and research so that hemp-
14 derived products such as hemp seed oil, hemp seed
15 cake, meal could be used for nutritional purposes in
16 animal feed. Okay.

17 PANEL MEMBER: To what extent are you seeing
18 the use of CBD in the feed of food-producing animals?

19 MS. BUBB: Could you repeat that?

20 PANEL MEMBER: To what extent are you seeing
21 CBD in the feed of food-producing animals?

22 MS. BUBB: We have not seen anything like

1 that yet. We do look for that type of product in the
2 marketplace through inspections. We have not come
3 upon that yet. The CBD-infused products are mainly
4 being found -- wholly being found in pet treats and
5 more of the treat/supplement world, maybe even for
6 horses.

7 But right now, food production animals, they
8 have not really crossed that line to put CBD into
9 those food-producing animals at this time, although
10 there's talk about it. There's interest. They would
11 like to do it.

12 PANEL MEMBER: Okay, and one other question
13 sort of on that regard. Are you seeing -- because we
14 have heard and seen news stories about this, sort of
15 the stalks of cannabis and hemp plants being used for
16 animal feed like other grains are being used.

17 MS. BUBB: Okay. Have not seen anything like
18 stalks, leaves or anything like that as forage or as a
19 fiber ingredient yet in animal feed. I do know that
20 again there's been some limited research. I know Penn
21 State and University of Pennsylvania have been
22 involved in some limited studies. They've talked

1 about them on some different podcasts and some
2 different outlets. There's been, you know, not a lot
3 of information released yet.

4 PANEL MEMBER: Right. But not sort of
5 widespread usage of those parts of the plants that
6 might be used for other areas?

7 MS. BUBB: No. I am not familiar with that
8 at all, no.

9 PANEL MEMBER: Okay. Thank you.

10 MS. BUBB: Okay.

11 MS. CRISTINZIO: Great. Thank you, Erin.
12 And sorry for the technical difficulties. We have now
13 a break on the schedule and we are still going to take
14 the break, even though we are running a little bit
15 behind because I know everyone could use a little
16 stretch. We will begin again at 10:45. Thank you.

17 (Whereupon, the foregoing went off the
18 record.)

19 MS. CRISTINZIO: Please sit down. We're
20 about to begin. We have someone joining us via phone
21 for a two-minute presentation. Thank you, everyone.
22 Hopefully you had a nice break. We have one person

1 who has joined us via phone for an oral comment. She
2 is a consumer. Her name is Pamela McColl and she is
3 on the line. Pamela, you are up for two minutes.

4 MS. MCCOLL: Hi. Thank you. Good morning,
5 everyone. I am a social historian and I've been
6 active on the marijuana file in Canada for over seven
7 years and I have the following to say.

8 The public is up against a narrative that is
9 at war with science. The marijuana lobby deceives by
10 saying consuming has no lasting negative impacts.
11 They deceive by denying cannabis hyperemesis syndrome
12 and addiction. The DSM-5 establishes clearly
13 marijuana is highly addictive.

14 Every week, patients on MJ enter the Denver
15 Health Center ER and must be restrained so as not to
16 harm themselves or others. In casual users, THC can
17 disrupt working memory and focus for 24 hours, says
18 Harvard researchers. The true believers of
19 cannabinoids, there can be placebo effect.

20 But it is critical that all be informed with
21 the risk associated with CBD and THC. This includes
22 pregnant women and the risks to the fetus, including

1 developmental damage and DNA damage.

2 In 20 years of research on human cells, I
3 have never found any other drug, including heroin,
4 which comes close to the DNA damage caused by
5 marijuana, Dr. Hugh Davis, at Health Canada. Even
6 minuscule amounts of THC are not safe for human
7 consumption.

8 Health Canada warns men not to use MJ if they
9 wish to have children. MJ products put young adult
10 males at risk of the most aggressive type of
11 testicular cancer. The FDA must respond to the
12 malevolent billionaire's marijuana experiment that has
13 medical professionals and states in extreme anxiety
14 over the damage industry profiteering has inflicted on
15 the public.

16 For Epidiolex, the only FDA-approved CBD
17 product approved for Dravet's and LGS, package
18 warnings include suicidal ideation, driving impairment
19 and hepatocellular injury, requiring liver function
20 testing before starting. Are there such warnings for
21 CBD products being sold at Walgreen's today? Are
22 consumers buying Whoopi Goldberg and Maya's CBD THC

1 rubs informed of these risks?

2 With 30,000 marijuana studies and high
3 potency product research enter biomedical literature,
4 reclassification is but an attempt to access the U.S.
5 banks. We changed the conversation. Now we've
6 changed the laws, boast the lobbyists. The FDA must
7 take back this conversation and protect the public.

8 I would encourage you to call Dr. Hugh Davis
9 from Health Canada, who in the late 1990s did a risk
10 assessment of THC and found that even minuscule
11 amounts were not safe. He was fired. That science
12 was shredded. And the Canadian government lied to the
13 United States government in saying that they had no
14 risk assessment on this drug.

15 The subversion of truth and science and
16 what's gone on in North America should cause everyone
17 great concern and reason to pause and do risk
18 assessments on these drugs and analyze the influence
19 of the billionaires and the industry that have
20 influenced public sentiment and dictated a very
21 deceitful campaign. So with that, I conclude. I
22 applaud the FDA for looking into this and I beg them

1 to not reclassify THC or CBD. Thank you very much.

2 MS. CRISTINZIO: Thank you, Pamela. All
3 right. I want to make just one brief announcement. I
4 think we have a number of people waiting for seats in
5 overflow. And I believe that we have enough space to
6 pull them into the room.

7 I just want to make people aware, if you have
8 a bag on a seat or you're saving a seat, that we would
9 like everyone have a seat in the room. Thank you.

10 All right. Our next speaker represents
11 academia. We're moving onto the formal presentations
12 with slide deck part of the day. And we have Barry
13 Gidal.

14 FORMAL PRESENTATIONS WITH SLIDE DECK

15 ACADEMIA

16 DR. GIDAL: Good morning. Barry Gidal,
17 University of Wisconsin School of Pharmacy. My theme
18 today is to discuss potential unintended consequences
19 that may arise from our gaps in our knowledge base.

20 Now, as has been alluded to by other speakers
21 this morning, CBD is a complicated molecule. It has a
22 complicated biotransformation pathway, as you can see

1 from my slide, being metabolized by a variety of
2 cytochrome P450 enzymes to at least one active
3 metabolite, at least active in a seizure model.

4 CBD also has a complicated pharmacokinetic
5 profile. We've talked about dosing and the
6 variability of dosing this morning. CBD exposure can
7 vary by route of administration, whether or not this
8 drug is taken with food or on an empty stomach and may
9 vary by other patient-specific variables such as liver
10 function.

11 Now, one of the things that I want to talk
12 about some knowns and unknowns. And I first need to
13 emphasize that we've known for a while, looking at the
14 scientific and the metabolic literature, the enzyme
15 literature for a while, that CBD as well as some other
16 cannabinoids such as THC have the potential to cause
17 drug interactions, specifically enzyme inhibition of a
18 variety of different important drug-metabolizing
19 enzymes.

20 But I want to emphasize it really wasn't
21 until the Epidiolex clinical development, the FDA-
22 approved preclinical and clinical development program

1 that we began to really appreciate and understand the
2 clinical ramifications of these potential drug
3 interactions.

4 Now, we know again, if you harken back to my
5 previous slide, because of the metabolism of CBD,
6 there may be impacts of other enzyme-inducing drugs
7 that may alter the exposure of this drug. We simply
8 don't know enough yet.

9 And there's more importantly perhaps the
10 effect of CBD on other drugs that may be used that
11 maybe go beyond the anti-seizure drugs that have been
12 studied so far and that's what I hope to emphasize
13 today.

14 Now, let me talk about some knowns that came
15 out of the Epidiolex clinical development program. We
16 know that an important drug, clobazam, which is used
17 in epilepsy, part of its metabolism can be inhibited
18 by CBD. Clobazam is active. It's metabolized by
19 cytochrome P450 3A4.

20 Interestingly enough, clobazam levels don't
21 really change. I'll get back to why I think that's
22 important in a few moments. But the active

1 metabolite, the N-desmethyloclobazame levels, have been
2 shown quite consistently to go up. And this may in
3 fact be responsible for some of the adverse effects
4 that we see such as sedation in the clinical trial
5 program.

6 Now, let me talk about some other things that
7 maybe are less well recognized. This graph may be a
8 little bit difficult to read. This is some work from
9 a few years ago of looking at the effect of not just
10 CBD but also THC and other drug-metabolizing enzyme
11 systems such as cytochrome P450 2C9.

12 Now why am I telling you? Why is this
13 important? Let's go beyond the anti-seizure
14 development program or anti-seizure co-medication. I
15 think many in this room are familiar with the drug
16 warfarin. Warfarin also has a complicated
17 pharmacokinetic profile. The more active enantiomer
18 of warfarin, the s-warfarin, is extensively
19 metabolized by P450 2C9.

20 Why is this important? Data that came out of
21 the University of Alabama group recently showed again,
22 as we broadened our use of CBD, in a patient receiving

1 warfarin, which is a very narrow therapeutic index
2 drug, in fact the anticoagulation potential of this
3 drug as measured by INR went up dramatically when CBD
4 was added. Now, this could have serious health
5 implications.

6 Now, one of the other things, I want to get
7 back to what I mentioned about clobazam. Clobazam is
8 metabolized by an enzyme called cytochrome P450 3A4.
9 We know from the clinical development program of
10 Epidiolex that there was no interaction with clobazam.

11 We also know from published literature that
12 there is no inhibition of metabolism of a probe drug
13 for at least one isoform of P450 for midazolam.
14 However, a report that just came out in the clinical
15 literature from Rita Alloway and colleagues at
16 University of Cincinnati looking at tacrolimus, which
17 is an important and potentially toxic
18 immunosuppressive drugs. It's used in a variety of
19 regimens, including transplantation.

20 In fact, if you look at this data, a patient
21 had been stabilized on tacrolimus, was part of also
22 this CBD, the Epidiolex program. And within the label

1 doses of Epidiolex, had a dramatic increase in the
2 plasma levels of tacrolimus, necessitating drug
3 reduction.

4 So again, why is this important? There's a
5 lot of things we know. There's a lot of things we
6 don't know. There is the potential for multiple drug
7 interactions from CBD. The exposure-concentration
8 relationship is still unclear. And in fact, some
9 patients may be at risk if we don't have adequate
10 oversight and involvement of healthcare practitioners
11 when using this drug. Thank you.

12 MS. CRISTINZIO: Thank you. Our next speaker
13 is number 58, Igor Grant.

14 DR. GRANT: Thank you very much.

15 MS. CRISTINZIO: Give us one second to pull
16 up your presentation.

17 DR. GRANT: Sorry about that. I didn't hear
18 what was just said. Okay. My name is Igor Grant.
19 Thank you very much for allowing me to speak. I'm
20 professor of psychiatry and director of the Center for
21 Medicinal Cannabis Research at the University of
22 California. That center was established about 20

1 years ago by the legislature of the state of
2 California as perhaps the first of the national
3 centers to actually address medicinal cannabis per se.

4 There are a couple of points I would like to
5 make today beyond the fact that there is emerging
6 science suggesting that THC, CBD and potentially other
7 cannabinoids may have medicinal value.

8 We have some challenges facing us, including
9 research that is limited by the availability of the
10 increasing number of products that patients are
11 consuming in states where cannabis or medicinal
12 cannabis laws exist.

13 We also have some viscosity, shall I say, or
14 I use the term barriers. It's not really barriers.
15 Nobody's trying to prevent research obviously. But
16 there is a kind of slowness in the process of doing
17 research that perhaps could be improved. And that
18 includes the fact that many federal agencies need to
19 opine and regulate this research.

20 This is consequential because, in our view,
21 we are rapidly getting behind the curve in terms of
22 what is happening in the real world and what patients

1 are utilizing. And we need to take steps to catch up
2 and to provide the public with correct scientific
3 information, including positives and negatives.

4 Now, as far as the CMCR center, we early on
5 completed a number of studies, mostly focused on
6 neuropathic pain and these used the NIDA's THC-based
7 products. These all showed in the short term, in
8 limited studies, positive results and these findings
9 have been also confirmed many times by other
10 investigators and by the National Academies report. I
11 don't have to go through that again.

12 Just by way of summary as far as THC-based
13 products and neuropathic pain, the efficacy seems to
14 be comparable to other used drugs and the toxicities
15 certainly are no worse.

16 Currently the CMCR is moving in new
17 directions and these include, first of all, in the
18 case of THC-based products, to look at modes of
19 administration, in particular because these do
20 influence how patients are able to tolerate these
21 drugs. The other is expanding to the range of
22 conditions and the third is to focus much more on

1 cannabidiol, which is a focus of this meeting.

2 We know that the route of administration
3 matters. People have seen these curves before. I
4 won't dwell on them.

5 One thing that was very interesting in some
6 of our early studies with the THC-based products from
7 NIDA is that actually rather small doses of THC seem
8 to produce benefit in neuropathic pain.

9 And these were doses that were much, much
10 less than people would typically consume if they
11 wanted to get a high. So this idea of the therapeutic
12 window needs to be explored further, and that may bear
13 also on safety considerations such as for driving.

14 So I'd like to spend the last minute on just
15 suggesting some paths forward to consider. One of
16 course is that we obviously need more studies and
17 including, as I've mentioned, routes of
18 administration, different kinds of products people are
19 using, products to put on their skin and so forth. We
20 have no idea if these products are absorbed or are
21 affected by those routes.

22 I said before we need to get ahead of the

1 curve of what's going on in the public. Otherwise,
2 the public will continue to use these products without
3 appropriate information. But we need to get the
4 information out in a more nimble fashion.

5 So what does that nimbleness suggest?
6 Perhaps permit research exemptions such as envisioned
7 in the Schatz-Feinstein bill, not requiring detailed
8 pharmacology for all new cultivars if DEA approves
9 manufacturing and if the FDA still requires all these
10 toxicology studies, we'll be in a problematic area.
11 And I've listed some of the other factors that I think
12 should be considered. Thank you very much for your
13 attention.

14 PANEL MEMBER: I have a question. I saw that
15 you had -- you talked about how routes of
16 administration matter and you talked about inhaled
17 versus edible. And I wondered if there was any data
18 on sort of absorption through the skin as would be
19 received through a cosmetic.

20 DR. GRANT: I am not aware of it. Maybe
21 there are data out there. But that's exactly the
22 point I was trying to make, that we need to look at

1 these modes of administration.

2 People claim that, you know, putting some
3 kind of salve on your elbow helps with arthritis.
4 Maybe it does. Maybe it doesn't. But we just don't
5 know. An that's the kind of study that needs to be
6 done.

7 PANEL MEMBER: And in addition to differences
8 in efficacy with different routes of administration,
9 have you found any differences in safety?

10 DR. GRANT: No, because we are now doing an
11 actual comparison of an oral product, which is
12 dronabinol, to a NIDA THC product. So we'll know more
13 about that.

14 What we know from the literature of course
15 is, because of the different pharmacokinetics, the
16 onset of action is much delayed through oral
17 administration and so forth. But in terms of long-
18 term tolerability, I don't know that we have data on
19 that.

20 PANEL MEMBER: Has your program found value
21 in looking at real-world datasets to support some of
22 your questions? So electronic health records, claims

1 data, any other aspects?

2 DR. GRANT: We are in fact moving in that
3 direction and particularly wanting to work with
4 institutions within California itself to do that. But
5 as of yet, we have not don't that.

6 MS. CRISTINZIO: Great. Thank you so much.

7 DR. GRANT: Thank you.

8 MS. CRISTINZIO: continuing in the academia
9 category, we have number 59, Bill Gurley.

10 DR. GURLEY: Thank you very much for the
11 opportunity to speak this morning at this public
12 hearing.

13 MS. CRISTINZIO: Can you move the microphone
14 up a little?

15 DR. GURLEY: Yeah, that's a -- us tall guys
16 have a tough time with this. That's about it. Sorry.
17 I'm taking up all my time playing around with the damn
18 microphone. All right. So can you hear me now? All
19 right. Very good.

20 All right. Again, thank you for the
21 opportunity to speak. My name is Bill Gurley. I'm a
22 professor of pharmaceutical sciences at the University

1 of Arkansas for Medical Sciences College of Pharmacy
2 and I'm also a principal scientist at the National
3 Center for Natural Products Research. I've also been
4 doing research in botanical dietary supplements for
5 the past 23 years.

6 My talk this morning is entitled "Content v.
7 Label Claim: A Survey of CBD Content in Commercially
8 Available Products from the State of Mississippi."
9 And in short, this study provides a snapshot of CBD
10 product quality or lack thereof and is likely
11 representative of the fraudulent nature of many, if
12 not most CBD products currently sold in the U.S.
13 market. I'll skip that slide.

14 Now, for conventional medications regulated
15 by the FDA, product labels must accurately reflect the
16 content of active ingredients within a container. For
17 dietary supplements however, especially botanical
18 dietary supplements regulated by the FDA under the
19 dietary supplement Health and Education Act, it's not
20 uncommon for a product's contents to differ markedly
21 from its label claim.

22 Content versus label claim discrepancies are

1 especially prevalent for dietary supplements marketed
2 for weight loss, exercise performance enhancement and
3 sexual performance enhancement. And so, the question
4 is are CBD-containing products also subject to
5 significant discrepancies between actual content and
6 label claim.

7 All right. So a survey of CBD-containing
8 products was conducted by investigators in the
9 National Center for Natural Product Research to
10 compare CBD as well as THC content to label claims for
11 CBD. And there's 25 various CBD-containing products
12 that were purchased from retailer vendors in the state
13 of Mississippi and submitted for analysis by law
14 enforcement officials from the Mississippi Bureau of
15 Narcotics.

16 Product label claims ranged from either no
17 label claim to as much as 1,500 mg per container. And
18 products were analyzed by gas chromatography with
19 flame ionization detection as well as mass
20 spectrometry for both CBD and THC content as well as
21 the presence of synthetic cannabinoids.

22 Now the data from the first 13 products

1 represented in this table and the second column is the
2 product label for CBD. Column three is the quantity
3 of CBD detected within the product. The fourth column
4 is the percent label claim. The fifth column
5 indicates those products whose THC content exceeded
6 0.3 percent and the last column indicates products
7 containing synthetic cannabinoids.

8 Now, in most instances, product label claims
9 misrepresented the actual CBD content within the
10 product. Percent label claims ranged from
11 indeterminate values -- in other words, there was no
12 claim for CBD -- to products that contained very
13 little CBD to others that far exceeded the label
14 claim.

15 In one instance, the CBD content was almost
16 23 times greater than the quantity claimed on the
17 label. In three instances, THC content exceeded 0.3
18 percent, with one product containing 45 percent THC.
19 An even more disconcerting finding was the fact that
20 one product was adulterated with synthetic
21 cannabinoid.

22 The second table depicts results from the

1 next 12 products. Once again, percent label claims
2 ranged from indeterminate values to values that were
3 either far below label claim or, thankfully, in one
4 case, exactly matched the label claim. In four
5 instances -- in four instances, little to no CBD was
6 detected. Yet three of these products, all of which
7 were vaping oils, were adulterated with synthetic
8 cannabinoids.

9 So in summary, a small sampling of CBD
10 products acquired from retailers in the state of
11 Mississippi demonstrated marked variability in actual
12 CBD content versus product label claims. Several
13 products had no CBD while others contained
14 significantly more than label claims.

15 One product contained only THC while others
16 exceeded the 0.3 percent limit on THC. Several vaping
17 products contained CBD but were adulterated with
18 synthetic cannabinoids. So clearly many CBD products
19 have little or no relation to any potential benefits
20 of CBD itself and pose a range of risks to consumers
21 from both fraud to serious health dangers.

22 The public demand and potential abuses in

1 this unique market sector warrant special attention to
2 regulation of such products in terms of label claim
3 restrictions, good manufacturing practice enforcement
4 and monitoring for potential adulterants. Thank you.

5 MS. CRISTINZIO: Thank you. Our next speaker
6 is number 60, Rick Kingston.

7 DR. KINGSTON: Good morning. My name is Rick
8 Kingston, and I'm a clinical professor of pharmacy at
9 the University of Minnesota, an adjunct professor at
10 the University of Mississippi in the National Center
11 for Natural Product Research and lastly I'm president,
12 regulatory and scientific affairs at SafetyCall
13 International. My comments today will dovetail
14 comments made by my colleagues, Drs. Gurley, Koturbash
15 and Walker at the University of Mississippi.

16 At SafetyCall, we have the distinction of
17 being the only academically affiliated,
18 multidisciplinary healthcare practice providing third
19 party post-market surveillance for both human and
20 animal product categories. That includes conducting
21 post-market surveillance for medical cannabis programs
22 in multiple states, including Minnesota, where we are

1 the sole provider of safety surveillance for all
2 medical cannabis companies and the dispensaries in the
3 state.

4 First, I wanted to comment on the pet side of
5 the cannabis safety issue and echo some of the
6 concerns raised by Dr. Gurley regarding issues of
7 product integrity for many CBD-containing products in
8 the marketplace.

9 Our pet poison helpline has documented
10 cannabis exposures in pets for over a decade and more
11 recently for CBD-containing products where adverse
12 effects reported after pet exposures to such products
13 is oftentimes resulted in clinical effects that are
14 uncharacteristic for what we would expect for CBD such
15 as significant ataxia, lethargy, vomiting and, in some
16 cases, significant cardiovascular effects.

17 In fact, for CBD exposures, up to 45 percent
18 of the incidents require veterinarian intervention.
19 This suggested to us many of these exposures may be
20 secondary to adulterated CBD products that contain
21 other potentially toxic compounds.

22 As for information regarding properly

1 manufactured cannabis products such as those found in
2 medical cannabis products in the medical cannabis
3 program in Minnesota, I believe components of that
4 program could be considered as part of a framework for
5 an FDA-regulated program for CBD.

6 This would include establishing GMPs, sharing
7 of consumer clinical experiences and implementing
8 robust mandatory adverse event reporting -- monitoring
9 and reporting such as required in Minnesota.

10 In fact, in the Minnesota program, there are
11 requirements for 24/7 access to medical professionals
12 for fielding any safety issues, including reports of
13 adverse events.

14 Regarding post-market surveillance for other
15 cannabis products, we are already providing standard
16 of care pharmacovigilance to best practice companies
17 that manufacture both CBD, THC and CBD combination THC
18 products.

19 In these circumstances, these companies have
20 us provide 24/7 access to medical professionals to
21 field any safety issue, including reports of adverse
22 effects and documentation of such data for analysis

1 and benchmarking to aid in safety profiling and
2 conducting surveillance for safety signals.

3 Quite simply, in a market where such products
4 are not currently regulated at a federal level, these
5 companies seek to distinguish themselves from
6 companies that do not adhere to best practices to
7 protect their consumers.

8 We also have worked very closely and
9 collaborated with the National Center for Natural
10 Product Research at the University of Mississippi
11 regarding investigations into botanical adulterants
12 where proper characterization of botanicals including
13 cannabinoids. This includes our mutual efforts to
14 support the American Botanical Council and their
15 botanical adulterants prevention program, known as
16 BAPP.

17 So in summary, the question is what would be
18 a path forward for FDA to gather or develop solid
19 safety information for CBD. We believe tapping into
20 the programs mentioned here would be a good start and
21 also allow access to safety data and clinical
22 experience with cannabis-containing products,

1 including CBD-only products.

2 We would specifically recommend initiating
3 data-sharing with the Minnesota program, where there
4 are currently more than 16,000 patients enrolled in
5 their program where clinical experiences are being
6 prospectively documented.

7 As for a potential regulatory framework for
8 CBD, we think a model with components similar to
9 Health Canada's natural health product regulatory
10 framework might be considered, which would include GMP
11 development, product registration and a post-market
12 surveillance process including submission of adverse
13 event data along with comprehensive adverse event data
14 analysis for signal detection and investigation into
15 any potential safety issues.

16 This could also include a conditional
17 registration process for companies that adhere to a
18 variety of best practices for safety confirmation and
19 product stewardship. Thank you very much.

20 PANEL MEMBER: Excuse me. Just a follow-up
21 question. I hope that you submit some of the details
22 about the Minnesota experience to the docket. This is

1 a rich source of information and I think we'd really
2 appreciate that help. Just I wanted to clarify, these
3 are data on both pet exposures and human exposures?

4 DR. KINGSTON: That's correct. We have two
5 sides of our practice. One is our human toxicology
6 staff and then we have a whole veterinary team of
7 experts. And so, our pet poison helpline collects
8 information from the general public as an animal
9 poison control center.

10 But we also do it for companies that actually
11 market products. So we have information from both
12 areas to compare and contrast. And maybe in comment
13 to your question about access to the Minnesota data, I
14 would strongly encourage FDA to reach out to Minnesota
15 where we could share information with the patients
16 that we're collecting that clinical experience because
17 the spontaneous reporting of adverse events which
18 we're documenting is then integrated within their
19 system of clinical experience. So I think it's a very
20 rich program and we'd certainly like to see some
21 collaboration there.

22 PANEL MEMBER: Thank you. So you're

1 contributing data to that other system now too?

2 DR. KINGSTON: Yes. We're the sole supplier
3 of all the spontaneous reported adverse events from
4 our 24/7 call center.

5 That information is then given to the state
6 of Minnesota and the medical cannabis program within
7 the Minnesota department of health. And so, we
8 collaborate on conducting safety surveillance and
9 signal detection.

10 PANEL MEMBER: Thank you.

11 PANEL MEMBER: So I just have one more
12 question for you. Sorry. Do you have any estimate on
13 the relative size of the market related to the
14 frequencies that you're seeing these experiences?

15 DR. KINGSTON: The size of the market?
16 You're talking about in general?

17 PANEL MEMBER: Yeah, and you mentioned that -
18 - you mentioned that you have the data for specific
19 companies. So I would suspect that you would know
20 relative to their marketing amount how much -- what
21 the frequency is for reporting.

22 DR. KINGSTON: I'd say the frequency for

1 reporting in the general market is pretty small, to be
2 honest with you.

3 PANEL MEMBER: Okay.

4 DR. KINGSTON: I think that there's a small
5 number of companies that are ahead of the curve and
6 are actually engaging organizations like ours to do
7 third party assessment and investigations into
8 potential adulteration and monitor the experience of
9 their products.

10 PANEL MEMBER: But I guess my question is
11 more on the actual adverse events related to a
12 particular product.

13 Would it be -- you know, you mentioned 50
14 percent of these need veterinary care and I guess I'm
15 thinking if I'm a company and I have a product and
16 you're taking all my adverse events for it, then I
17 know how much I'm marketing and you know how many
18 adverse events I have. So I know what that frequency
19 is.

20 DR. KINGSTON: Right. Okay. So there's a
21 couple of answers to that. One is if you look at it
22 big picture and having the experience from the public

1 poison center perspective, as previously being a
2 director in that area, it's probably got one of the
3 lowest incident rates that I've seen for a marketed
4 product. It's rare that we get significant adverse
5 effects, especially for these companies that engage
6 us. So I think they have a higher quality product.

7 PANEL MEMBER: Okay. Thanks.

8 MS. CRISTINZIO: Thank you. Our next speaker
9 is number 61, Igor Koturbash.

10 DR. KOTURBASH: Ladies and gentlemen, it's
11 both a pleasure and honor being here today. My name
12 is Igor Koturbash. I'm a faculty at the University of
13 Arkansas for Medical Sciences and I'm also co-director
14 of the Center for Dietary Supplements Research.

15 The mission of our center is actually to
16 provide industry, regulatory agency and public with
17 credible information, assessments and experts opinions
18 about the safety of dietary supplements and various
19 phytochemicals.

20 As cannabidiol falls into the category of
21 phytochemicals, it is of our interest and especially
22 because there is, as you know, about -- based on

1 clinical data, about 5 to 20 percent of patients who
2 receive Epidiolex during the clinical trial develop
3 elevated liver enzymes. And if you pay attention to
4 the warning label on Epidiolex, it clearly states the
5 potential for hepatocellular liver injury -- for
6 hepatocellular injury.

7 Therefore, we performed a series of studies
8 within the last few years at our center and I would
9 love really to share some of the highlights of our
10 studies.

11 First of all, aspect number one, that
12 cannabidiol, or we use cannabidiol rich cannabis
13 extract that had 57.9 percent of cannabidiol in it.
14 It cannot really cause liver injury. If for single
15 administration case, you really need relatively high
16 dose to achieve it.

17 In the context of repeated dose, then you
18 have to use very low dose actually to cause liver
19 injury evident as elevated liver enzymes, spiking
20 levels of bilirubin and histomorphological changes.

21 Aspect number two I would like to point your
22 attention to is a very high potential for CBD drug

1 interaction, as has been mentioned today by various
2 speakers. Of particular concern of course is CYP2B10
3 in mouse, which is CYP2B6 in humans, responsible for
4 metabolism of the majority of endostatins as well as
5 CYP2E1 which is a major cytochrome for metabolism of
6 mostly frequently used make human antibiotics like
7 ethanol and acetaminophen.

8 Furthermore our concern is in regards to the
9 so-called biphasic response when various doses of
10 cannabidiol can cause differential gene expression.
11 For example, high dose will cause downregulation but
12 low dose will cause upregulation, right? So that's
13 why you may face really very differential responses on
14 cannabidiol.

15 And the third concern of course is the
16 potentiation of drug-induced liver injury. In the
17 study, when we used the nontoxic doses of cannabidiol
18 and mice received up to that one single administration
19 of acetaminophen which was capable only to cause
20 transient elevation in liver enzymes, when you could
21 administer them, we observed significant liver injury.

22 It was a so-called sinusoidal obstruction

1 syndrome like if you would pay attention to the slide
2 and we did 10 mg/kg CBD + APAP. It is a classical
3 picture of the toxic destruction of sinusoidal and
4 endothelial cells with further hemorrhage into the
5 liver tissue.

6 We published some of our data. There are
7 several more manuscripts at various stages under
8 review to preparation and we certainly continue
9 working in this field.

10 The three major points once again that
11 cannabidiol, at least in the form of the cannabidiol-
12 rich cannabis extract, can cause liver injury. It has
13 a very significant potential for drug interaction and
14 can further exacerbate other agents inducing
15 hepatotoxicity.

16 So in my understanding, we just really are
17 only scratching the top of the surface and it's like
18 we're really just observing the tip of the iceberg.
19 Our call is that clearly further research is needed to
20 further understand the safety and drug interaction
21 potential for CBD and CBD-containing products.

22 And we are looking forward to working with

1 the regulatory agencies, with the industry and
2 certainly with public to further understand this.
3 Thank you for your attention.

4 MS. CRISTINZIO: Thank you. Next we have
5 speaker number 62, Michelle Peace.

6 DR. PEACE: All right. Good morning. First,
7 thank you for the opportunity to present our findings
8 on the analysis of CBD products intended to be used in
9 electronic cigarettes. I will also be submitting
10 comments to the docket regarding laboratory testing
11 standards before the deadline.

12 My name is Michelle Peace. I'm associate
13 professor in the department of forensic science at
14 Virginia Commonwealth University. My subject matter
15 expertise is forensic toxicology and I do have a
16 relevant scientific story for you.

17 I have been funded by the National Institute
18 of Justice since 2014 to study the manipulation and
19 use of electronic cigarettes to vape drugs other than
20 nicotine and the impact on the criminal justice
21 system.

22 We have certainly seen an increase in the

1 submission of e-cigarettes and e-liquids into crime
2 labs for analysis as evidence in criminal justice
3 cases. With regards to CBD products, law enforcement
4 is generally very confused about what they need to do
5 about these products in terms of confiscating them and
6 submitting them to crime labs. And there is deep
7 concern about clogging the system that is already has
8 tremendous workload.

9 To set the stage here, what is an e-liquid.
10 The predominant components are the humectants that
11 create the cloud, propylene glycol and vegetable
12 glycerin mixed in some kind of ratio. We know that
13 there are thousands of flavor profiles and that the
14 most predominant drug is nicotine.

15 However, my lab focuses on drugs other than
16 nicotine. We have evaluated herbal substances like
17 blue lotus and kratom and dietary supplements. But
18 our main focus is on designer drugs, legal novel
19 psychoactive substances and drugs scheduled by the
20 FDA.

21 What most people say about vaping drugs other
22 than nicotine is that people know what they're vaping

1 or they know they're vaping something that will make
2 them high. We have been monitoring this website and
3 similar websites for years. Companies do not list
4 what drugs the e-liquids contain. But the
5 descriptions in the user reviews will say this will
6 get you high or this will create hallucinations for
7 you or it will make you mellow.

8 The e-liquids are usually generally very
9 expensive compared to nicotine e-liquids. In some
10 cases, like you see here, they range from \$30-ish to
11 \$2,000. You can also see the shoddy product
12 packaging. In this particular instance, we found a
13 dangerous synthetic cannabinoid, MDMB-FUBINACA and
14 frankly nobody was surprised.

15 Shortly after publishing this finding, I
16 received a call from a young man who was vaping CBD
17 products and he had a really hard high that scared
18 him. He wanted to know if CBD is supposed to do that
19 or if he just had a bad reaction. We told him to send
20 it to us for analysis and also purchased a number of
21 the same e-liquid products directly from the
22 manufacturer.

1 You can see here that the products appear
2 professionally produced and the website is high
3 quality and they proclaim 100 percent CBD extracts.
4 Upon analysis, we found CBD in all of the products.
5 We also found 5-fluoro ADB in the young man's sample
6 and in what we acquired from the manufacturer. 5-
7 fluoro ADB has sent thousands of people to the
8 emergency rooms and been attributed to overdose deaths
9 in the United States and Europe.

10 Several CBD samples we purchased from the
11 manufacturer also contained dextromethorphan, the
12 active ingredient in over-the-counter cough syrups. A
13 consumer wanting to purchase CBD because they want to
14 relieve pain or manage seizures has no idea of the
15 chance of buying something that also contains
16 dangerous drugs.

17 This is the case whether someone purchases
18 from the Internet or walks into a brick-and-mortar
19 store. We have seen a rash of reports nationwide of
20 people being poisoned from taking CBD products that
21 they purchased. In these particular headlines from
22 North Carolina, dozens of soldiers went to the

1 emergency room after taking CBD products purchased in
2 brick-and-mortar stores outside of their military
3 bases.

4 We began monitoring drug forms specifically
5 regarding consumers who had bad reactions after taking
6 CBD products. They don't know where to turn for help.
7 They are embarrassed or afraid to report having had a
8 bad reaction.

9 We have received more than 50 emails from
10 consumers after we reported the adulteration of CBD
11 products purchased directly from the manufacturer. In
12 all cases, the consumer purchased what they believed
13 was CBD.

14 Mostly people are afraid of the short-term
15 and potential long-term symptom. They are afraid of
16 losing their jobs and/or embarrassed to admit they
17 took something that made them high. Convincing them
18 to send me the sample is difficult. But many have.

19 To highlight this problem, just two weeks
20 ago, we received two CBD samples from the family of a
21 79-year-old woman who was convinced to take CBD by her
22 grandchildren to relieve pain from rheumatoid

1 arthritis. After not hearing from her for a few days,
2 they did a wellness check. They found her
3 hallucinating and still trembling days after taking
4 it. Seventeen of the 18 samples we received contained
5 a dangerous synthetic cannabinoid.

6 This unregulated industry with no -- with
7 high public demand and no requirements in oversight
8 for quality that is skirting the edge of legality has
9 ample room for nefarious activity. Clinics will not
10 find these kinds of drugs when they just do drug
11 testing.

12 So we have significant concern with those who
13 are reporting hallucinations or adverse effects are
14 probably just going to say it was just THC when it was
15 likely something else. Thank you for your time.

16 (Applause.)

17 MS. CRISTINZIO: Thank you. Our next speaker
18 is number 63, Ryan Vandrey.

19 DR. VANDREY: Okay. Good morning. So I want
20 to just try to highlight a couple of things that I
21 think are important and I want to note that although I
22 work for Johns Hopkins, I'm here representing myself

1 and not the university.

2 So from a regulatory perspective as a
3 researcher, we know that CBD is the predominant
4 byproduct of hemp and that's what most people have
5 been talking about today.

6 From a research standpoint, it's confusing
7 from a regulatory perspective because CBD is both
8 currently unscheduled if it's derived from hemp. It's
9 Schedule 5 under the CSA at Epidiolex. And it's
10 Schedule 1 if it's synthetically derived. So that
11 causes problems for us doing research.

12 Also, as mentioned by the gentleman from true
13 Terpenes earlier today, it's not just CBD that can be
14 derived from hemp. There are a number of other
15 cannabinoids and non-cannabinoids that can be
16 extracted. And those products can come to market.
17 There are some on the market already. Minor
18 cannabinoids like CBG, CBN, we have no controlled
19 research on what these do pharmacologically in humans.

20 MS. CRISTINZIO: Can you move your microphone
21 up a bit?

22 DR. VANDREY: Yes. Sorry. So in addition to

1 CBD and some of these other minor cannabinoids, THC is
2 an important constituent that is allowable in hemp
3 products. Hemp is defined as 0.3 percent THC. But
4 that's a percentage and not a total amount in a
5 product.

6 A study conducted by my friend and colleague,
7 Marcel Bonn-Miller, found that CBD oils sold on the
8 Internet contained up to 6.4 mg of THC per milliliter
9 of liquid.

10 And to kind of put that in perspective,
11 laboratory studies that we've done at Hopkins have
12 shown that oral doses of 10 mg of THC can produce mild
13 to moderate drug effects and can impair cognitive
14 performance. So the data there show 10 in a 25 mg
15 dose orally administered and showing significant
16 impairment on a working memory task.

17 In addition, route of administration is
18 important. And so, we've conducted a number of
19 controlled administration studies and showed that
20 vaporization of cannabis produces a stronger drug
21 effect and a greater impairment compared with smoking
22 it. Smoking and oral dosing produce comparable peak

1 drug effects. But the time course is very different.

2 We found that the blood cannabinoid
3 concentration correlates poorly with subjective drug
4 effects and impairment and that's important as a
5 consideration for evaluation of these products. And I
6 want to also highlight -- and things got wonky with
7 the transition from Mac to PC again these days.

8 But even though these figures are a little
9 bit hard to see, I'll describe an ongoing study that
10 we have where we're acutely administering cannabidiol
11 as a pure substance as well as cannabis containing a
12 high concentration of cannabidiol and a low
13 concentration of THC.

14 What we found is that when CBD by itself is
15 orally administered, we don't see much in the way of
16 subjective drug effects or impairment. When it's
17 vaporized, we see a discriminable drug effect. It's
18 not THC-like and does not produce cognitive
19 impairment. But to consider CBD non-psychoactive I
20 think is inappropriate.

21 Additional research -- this is with 100 mg
22 dose of CBD. Higher doses administered at the

1 University of Wollongong in Australia by Nadia Solowij
2 have shown some mild cognitive impairment with a
3 higher dose of CBD.

4 We found no THC in blood after administration
5 of pure CBD, which kind of addresses the potential for
6 conversion there. What we do see is difference in CBD
7 in blood when THC is co-administered.

8 I also want to point out that when we did
9 urine drug testing, two of our six participants had
10 positive drug tests with a dose of about 4 mg of THC
11 in this product. So the amount -- again, the amount
12 of THC in the product is going to be important as
13 these retail products come out.

14 So points that I want to make outside of the
15 laboratory studies we've done is that standards for
16 quality control testing and contaminants is urgently
17 needed and while we know a lot about acute effects, we
18 don't know much in terms of systematic evaluation of
19 long-term health effects of chronic use of hemp or CBD
20 products.

21 We need to have better data on special
22 populations such as pregnancy, psychiatric

1 populations, elderly and other at-risk populations.
2 And I encourage the FDA to engage in a formal
3 pharmacovigilance program as these products come to
4 market. Labeling should clearly disclose the amount
5 of THC, CBD and any other detectable cannabinoids.

6 And so, what I would encourage the FDA to do
7 is to establish regulations immediately for content,
8 for quality control and for labeling and to consider
9 the use of existing cGMP regulations for drugs and
10 supplements but also to urgently fund cannabis
11 regulatory science and provide a pathway for
12 researchers to better do what we need to do to help
13 inform you guys. Thank you.

14 PANEL MEMBER: I have a question. You said
15 that CBD has a drug effect, a psychoactive drug effect
16 but not like THC. Can you elaborate on what you mean
17 by that?

18 DR. VANDREY: Sure. So when we've
19 administered pure CBD in the laboratory, people report
20 discriminable drug effects. They on a drug effect
21 scale report feeling a drug effect. But when we look
22 at adjectives that are THC-like effects, do you get

1 the munchies, do you feel impaired, do you feel high,
2 and they say no to that. So the things that we
3 typically see with THC administration we don't see
4 with CBD.

5 PANEL MEMBER: So what do they describe as
6 the drug effect?

7 DR. VANDREY: They've had a difficult time
8 articulating exactly what they feel and it's been
9 different from different people. The most common is
10 relaxing, calm, somewhat sedating.

11 PANEL MEMBER: Excuse me. One other thing.
12 I just -- just to clarify, I assume those studies were
13 done in healthy volunteers.

14 DR. VANDREY: These were healthy adults who
15 were non-cannabis -- non-frequent-cannabis users at
16 the time. So they were all -- had tested negative for
17 THC.

18 PANEL MEMBER: But had used it in the past?

19 DR. VANDREY: They had used it in the past,
20 but not in the prior month.

21 PANEL MEMBER: Okay, and second, like many
22 other comments that have been made, we'd really

1 appreciate any data that you could submit to the
2 docket or make available, you know, in that way to us.
3 Thanks.

4 DR. VANDREY: Certainly.

5 MS. CRISTINZIO: Thank you. Our next
6 speaker, number 64, is Larry Walker.

7 DR. WALKER: Thank you very much for the
8 opportunity. I represent the University of
9 Mississippi. And just some -- it's a little off-
10 center, but just a quick pointers on some background,
11 we've had a program for several years with CFSAN for
12 botanical ingredients research, a center of excellence
13 there, not cannabis-related.

14 We also have been the contractor for many,
15 many years for the NIDA drug supply program for
16 cannabis and cannabinoids. We're a partner in the
17 botanical adulterants prevention program of the
18 American Botanical Council and have now ongoing a
19 current expanded access IND for CBD extract in
20 refractory childhood epilepsy at the University of
21 Mississippi Medical Center with Dr. Ingram as the PI.

22 It's been touched on already here that in

1 addition to the risk with cannabis smoking and
2 presumably THC-related that there are also a number of
3 potential CBD safety issues, product quality issues
4 particularly, but maybe others as well that need to be
5 considered.

6 In our program in Mississippi, which is just
7 a small extended access IND, but I believe the first
8 that was done in the, quote, "restricted" THC states
9 on a CBD extract and the findings were, you know, so
10 far generally it's well tolerated and the patients and
11 the families seem to be happy.

12 But we have had, even with fairly low doses,
13 significant side effects and especially in the drug
14 interaction realm. So these are certainly things that
15 need to be further studied and monitored.

16 A possible path forward it seems to us is
17 prudent to have a multitrack approach with these
18 products that are cannabis-related. In fact, we
19 already have in some respects some of these programs
20 existing. Dr. Sharpless mentioned the GRAS program
21 already existing.

22 Our thinking would be that in the supplement

1 world, some type of program with a special focus,
2 limits on CBD and special focus on the NDI
3 notifications, GMPs, adverse event surveillance, that
4 we need to be able to gather this data and maybe some
5 type of conditional registration for manufacturers
6 that might participate in a quality stewardship --
7 safety and quality stewardship program.

8 There's also also ready the track for the
9 development of botanical drugs under the botanical
10 drug route or single chemical entity. And we're very
11 much proponents and very much in favor of this.

12 But one of the key issues is how do we relax
13 the restrictions on the availability of plant-derived
14 material for clinical research. This has been a major
15 issue for us in Mississippi and all other state
16 programs that I'm aware of, how do we work under the
17 federal guidelines with those types of materials. How
18 do we source those? Even though we are the contractor
19 for NIDA for this, it's not been easy for us.

20 And then, I think just it's been touched on
21 by my colleagues, but about these state medical
22 marijuana programs, although this is obviously out of

1 the FDA bailiwick, so to speak, but I really think
2 gathering data from those programs in some type of
3 coordinated national way would really be very helpful
4 for us in the future going forward.

5 And so, I would just mention these in
6 summary. We need a lot more clinical research. We
7 need a lot more clinical research on well-defined
8 products, whether they're under controlled substances
9 or not. This necessitates some relaxation of the
10 restrictions for producing these materials for
11 legitimate clinical researchers.

12 It would be outstanding I think if the FDA
13 could conduct some basic studies in this realm. It's
14 a national need. It impacts so broadly that I think
15 it's very unique. We need to extend some of the
16 animal work that's been presented here to look at
17 NOELs, you know, very carefully.

18 We need I believe a national testing program
19 for cannabinoid quality and standardization. You can
20 see what the product picture looks like. A national
21 adverse event reporting program for whatever products
22 are out there and rapid response program for products

1 where there are serious incidents. We need analytical
2 backup on many of these things where serious incidents
3 have occurred. And then, finally, if possible, to
4 gather research outcomes in these state medical
5 programs. Thank you very much.

6 (Applause.)

7 MS. CRISTINZIO: Great. Finishing out our
8 academia category, we have Elise Weerts.

9 DR. WEERTS: I'm actually here on behalf of
10 the college on the problems of drug dependence. And
11 this is one of the longest standing scientific
12 organizations focused on the problems of drug abuse
13 and dependence and empirical data for its treatment.

14 I'm presenting also for Margaret Haney, who
15 is the acting president this year, and I am the
16 incoming president. Both of us study cannabis in
17 laboratory studies.

18 So medical cannabis -- important in the
19 discussion, is it marketing or science. This slide
20 shows you the proliferation of advertising that's out
21 there and convincing people that there's some medical
22 benefit. It's very polarizing.

1 At the same time, the states have enacted
2 laws that have so-called approved medical conditions.
3 Up to 51 so far have been approved in the different
4 states. And they're not even consistent in which
5 things are being approved. So, for example, like New
6 York could approve an antibiotic for the treatment of
7 an infection and then Kansas could approve it for
8 epilepsy.

9 We need science to inform policy. Is
10 cannabis good or bad? The answer is actually it's a
11 little of both. So it's pharmacologically complex.
12 It has multiple constituents. And it can have medical
13 benefit in some cases and then also have problematic
14 use.

15 The cannabinoid receptor in the brain is
16 widely spread. We're just starting to learn about
17 what it does for your health. It was only discovered
18 in the 1990s. The plant itself has over a hundred
19 unique cannabinoids. Unfortunately research has been
20 limited primarily to two of them, THC and cannabidiol.
21 And that's because of access.

22 We're in a vacuum right now. We really do

1 need randomized placebo controlled trials of testing
2 products that have known composition. Right now, they
3 are marketed and they're not tested under FDA-approved
4 strategies for safety and efficacy. The public
5 opinion is guiding how we're treating a number of
6 disorders.

7 There's also little regulatory oversight.
8 Recent testing of compounds that are obtained online
9 or from dispensaries of edibles and other things that
10 are cannabinoid-based have shown that they're not
11 accurately labeled and that less than a third actually
12 contain even some of the products that they say they
13 do.

14 What about the GMP and purity and how about
15 dose? And how do we take it? This all effects
16 whether it's going to do anything.

17 And then, the big question, is cannabis
18 addictive? Yes. There's a lot of data in the
19 scientific literature showing that 30 percent of
20 regular users will come to have a cannabis use
21 disorder and about 300,000 treatment admissions occur
22 each year. And why do people seek treatment? They've

1 having problems with functioning. They're having an
2 inability to stop using. They're smoking more than
3 they intend. They have memory deficits. They go
4 through withdrawal and they have other health
5 concerns.

6 Few patients that seek treatment actually are
7 able to abstain, only about 20 percent. The treatment
8 options are not that good.

9 So what does withdrawal look like? Well,
10 typically you see increase in anxiety, irritability,
11 craving and restlessness. They have decreases in food
12 intake and sleep quality.

13 This withdrawal emerges after 24 hours when
14 you stop and it continues for weeks. And a really
15 important point is that women seem to be more
16 vulnerable. They have an accelerated trajectory for
17 developing problems and they also experience more
18 withdrawal and have worse outcomes, even when they're
19 using the same amount as men.

20 Now, to switch sides, Margaret Haney has done
21 a number of laboratory studies looking at benefit. So
22 she did some studies in HIV-positive patients and

1 showed that these individuals who often have problems
2 eating and lose weight, when you give cannabis, it
3 actually improves those symptoms. So there's reduced
4 GI distress and the increase of caloric intake.

5 She also did a laboratory pain model where
6 smoked cannabis and oral THC dose dependently reduced
7 pain sensitivity and then load opioids that don't
8 produce any amount of analgesia or pain relief when
9 combined with small amounts of cannabis actually do
10 have a benefit.

11 However, again, women appear less sensitive
12 to these effects than men. So it may not be
13 beneficial for women.

14 There's also the National Academy of Sciences
15 review that covered a lot of the different literature
16 that's out there to look for medical benefit. Only
17 three of the things that were examined actually proved
18 to be beneficial.

19 So more research is needed. We need to
20 increase research because legalization and acceptance
21 is increasing use. So there's an escalation that's
22 well documented in adolescents and adults, including

1 pregnant women, that's rising. We need to understand
2 how this is affecting health.

3 There's also no regulatory pathway for all
4 these constituents and we really don't know anything
5 about them. The idea that they've been said to be
6 safe is ridiculous. It hasn't been done. And then
7 also we need to evaluate the health claims. But we
8 can't do that if research can't access these
9 compounds.

10 And then, I give you a list of things that we
11 need to research and, you know, you can look at that
12 online. But we need to understand the risks and
13 benefits. There's clearly both. And then, there's
14 some recommendations here for the regulatory outcomes,
15 about streamlining the process, particularly for
16 interactions between the DEA and the FDA because
17 that's very long.

18 And INDs, we need to accelerate the INDs so
19 we can actually study these things in clinical trials.
20 If you would like copies of the slides or you want
21 more information, well, that was my email that was up
22 there that went away. Thank you. Questions?

1 MS. CRISTINZIO: Thank you.

2 PANEL MEMBER: I have a question for you, for
3 just -- so you comment about the need to have a
4 streamlined availability of products for
5 investigation. Could you comment what you think the
6 impact of the Farm Bill removing cannabidiol --

7 DR. WEERTS: For a researcher --

8 PANEL MEMBER: -- and other hemp-based
9 products --

10 DR. WEERTS: For a researcher --

11 PANEL MEMBER: For research purposes, yeah.

12 DR. WEERTS: It has no impact.

13 PANEL MEMBER: Please elaborate just a little
14 bit.

15 DR. WEERTS: So I have a DEA Schedule 1
16 license to study cannabinoids. My 21-year-old son can
17 walk into a store and buy it and I cannot. That's
18 really it in a nutshell. I cannot purchase, store or
19 test that product. It is illegal for me to do so
20 because I am following the regulations of the DEA and
21 I'm following the regulations of the FDA, which
22 anything that I test has to go through an IND and meet

1 all those requirements and go through our IRB.

2 It's a very circular process and can take
3 months and months. But it does bother me that my 20-
4 year-old kid can now get it and, you know, take it and
5 I can't even touch it, unless I was a consumer. Any
6 other questions?

7 MS. CRISTINZIO: Thank you.

8 (Applause.)

9 MS. CRISTINZIO: We are now onto a new
10 segment called agriculture. And we have Cameron Cane
11 up next, number 66.

12 AGRICULTURE (NON-GOVERNMENT)

13 MR. CANE: How are we doing? My name is
14 Cameron Cane. I'm with Deutsche Process. We are a
15 largescale industrial scale sanitary process equipment
16 company.

17 We work in a variety of different food,
18 beverage-related industries as well as nutraceuticals,
19 pharmaceuticals, cosmetics, a lot that deal with the
20 general cannabis and CBD space. We work with majority
21 of the largescale LPs out of Canada as well as some of
22 the major producers here domestically for CBD

1 production.

2 We're here to talk about a little bit today
3 about some of the misinformation on just general
4 compliance in the agricultural community as well as
5 the general processing capabilities in order to
6 hopefully, you know, create a more compliant product
7 and a more simple pathway for compliance in the
8 industry.

9 So, you know, that being said, obviously
10 there's -- in the agricultural community, there has
11 been a lot of information as far as, you know, the
12 federal tolerance for THC and the actual plant itself.
13 You know, in certain states, in certain varieties of
14 the plant, it's kind of irrelevant of the actual
15 content of the THC.

16 States like -- we're in North Carolina. And
17 the state of North Carolina, we almost had full
18 compliance last year for THC products or CBD products
19 devoid of THC in there. In states like Nevada, same
20 plant varieties, almost 40 percent compliance, a 60
21 percent noncompliant product. But Nevada has a gray
22 market where, you know, they can push their products

1 to. There was no real reason other than just grow
2 mediums and the actual locations and the timing of
3 harvest of that compliance that actually had that.

4 If that was the case in North Carolina, you
5 would have had farmers who unfortunately would have
6 been forced to burn their crops, submit insurance
7 claims, which currently there are no federal crop
8 insurance for that.

9 But what is unknown about the process,
10 regardless of what the THC content is in the field,
11 once you go through a processing facility, you process
12 this stuff and you concentrate the full spectrum
13 extract down to a concentrate, as you can see from the
14 pictograph here.

15 Through the concentration process, nearly
16 all, 90 percent plus of all the concentrate itself
17 will be federally noncompliant. There are processes
18 in order to mitigate that, in order to effectively
19 delete THC from those compounds. You know, as you see
20 on here, you go through a purification step once you
21 pass through that concentration.

22 You know, purification is the crystallization

1 of the CBD compounds, generated in an isolate product.
2 You'll then be left with a high THC, what is called
3 the mother liquor. In that product, you will have a
4 variety of other compounds in there as well.

5 And you can take that through several
6 different steps, whether that's hydrogenation or
7 reduction of that THC compound to essentially
8 effectively delete the lucid chemical that is
9 obviously the stigma in the industry.

10 By taking these very simple steps, which are
11 readily available -- you know, we are not the company
12 that created, you know, isolate production or
13 hydrogenation processes. There are multiple
14 hydrogenation processes that have patents out there
15 currently.

16 We are also creating multiple other
17 hydrogenated processes in conjunction with one of our
18 partners, Canopy Growth, in order to, you know,
19 develop more products that are marketable for a, you
20 know, mainstream use down -- you know, without the
21 problem of THC in the marketplace.

22 You know, how do we regulate this and how do

1 we make sure, you know, this is kind of the pathway?
2 You know, in our opinion, again, what's being
3 regulated right now is the agricultural community.
4 It's not processing. It's not the white label CPG
5 manufacturers.

6 The simple choke point here is absolutely
7 from a compliance standpoint. Is our process in
8 compliance? And speaking with our clients, they want
9 to be a compliant, a regulated industry that has
10 transparency and, you know, has the ability to make
11 all of us feel very safe in what we're doing.

12 You know, being able to have an audited --
13 you know, a federal audited compliance checkpoint, you
14 know, through our processing facilities is certainly
15 the way to make it easy from a capacity standpoint
16 from federal regulators and so we know what is going
17 into -- you know, when I listened to the lady from VCU
18 and you see these products, it's scary. You know,
19 there's no need for that.

20 If we had an audited choke point being the
21 processing facilities, you don't have to worry about
22 THC. You don't have to worry about mycotoxins. You

1 don't have to worry about pesticides because when it
2 comes out of these audited facilities, you know it is
3 100 percent compliant and there is no question in the
4 industry and there goes the stigma as well. I
5 appreciate your time.

6 (Applause.)

7 PANEL MEMBER: I have one question for you.
8 What other byproducts would come out of this process?
9 Is there a waste stream that comes out?

10 MR. CANE: There is. And that's -- you would
11 hydrogenate the waste stream or you'd take that
12 through another purification process or you'd throw it
13 away.

14 You know, there are -- the isolation process,
15 the crystallization and isolation process is roughly,
16 you know, 50 to 60 percent effective, you know, as far
17 as an efficiency standpoint. And you take that
18 byproduct, the waste stream from that, which is the
19 mother liquor that has THC in it, and you take that
20 through a hydrogenation process in order to
21 essentially reform that molecular compound that was
22 THC.

1 PANEL MEMBER: Quick question for you. In
2 North Carolina, what do you think the proportion of
3 hemp growers are moving then their hemp for CBD
4 specifically versus other purposes for hemp growth in
5 North Carolina?

6 MR. CANE: I'm not sure I understood the
7 question.

8 PANEL MEMBER: Among farmers who are farming
9 hemp in North Carolina, how many of them are farming
10 hemp for CBD production versus for other purposes?

11 MR. CANE: Nearly all. There is -- you know,
12 when you talk about an economic driver, another
13 gentleman said it today, you know, you can make
14 \$30,000 to \$60,000 an acre on CBD product. You can
15 make \$700 an acre on fiber. Nearly all of it is CBD
16 production. That's globally.

17 PANEL MEMBER: Thanks.

18 PANEL MEMBER: Can I ask a question real
19 quickly? I want to follow up on the waste stream. So
20 we heard this morning about full spectrum
21 phytocannabinoids and things like that. Do these --
22 they come out of this same process as the

1 hydrogenation change what ends up in what you would
2 call full spectrum or --

3 MR. CANE: So your full spectrum, you would
4 take that through the isolation process, first and
5 foremost.

6 And that would isolate the CBD compounds and
7 leave out the rest of your other compounds, fats,
8 waxes, lipids, amino acids, your THC, the mycotoxins,
9 anything else that might -- you know, some of the
10 pesticides, heavy metals, things like that. You know,
11 they don't get crystallized during that process.

12 And, you know, once that happens, you know,
13 you take that through the hydrogenation process. We
14 have done testing on selective hydrogenation. They
15 have been varied results, not very good. It is more
16 of a blunt force trauma of hydrogenation where we're
17 hydrogenating all of the compounds that are in that
18 mother liquor stream.

19 And you know, we're still very actively
20 testing in real time. But there are, you know, THC
21 compounds that are patented -- hydrogenated compounds
22 that are patented out there with, you know, good

1 results that do have ancillary revenue streams or you
2 just take it down and reduce that down to CBN. Thank
3 you.

4 MS. CRISTINZIO: Thank you. Our next
5 speaking category is consumers. And we have Jaclyn
6 Bowen, number 67.

7 CONSUMERS

8 MS. BOWEN: Hi. Thank you. I'm Jaclyn
9 Bowen. I'm the executive director of Clean Label
10 Project, the international association for cannabis
11 testing is a division of Clean Label Project.

12 I'm a food safety and quality systems
13 engineer. So before coming to Clean Label Project,
14 for 15 years I worked on different activities related
15 to standards development, certification, compliance
16 and enforcement mechanisms within food and consumer
17 product safety.

18 Specifically for us at Clean Label Project,
19 what we do is we're a consumer advocacy organization
20 focused on bringing truth and transparency to consumer
21 product labeling. More specifically, what we concern
22 ourselves with is what's not on the labels. Marketing

1 departments can do an effective job at selling comfort
2 and security. So for us, in data and science we
3 trust.

4 So what we do is we go out to the marketplace
5 and I simulate the consumer shopping experience. I go
6 out. I actually buy the products from the -- be it
7 websites or local, national retailers. The only
8 difference is instead of taking them and putting them
9 in my pantry, I take them to an analytical chemistry
10 lab to see what's actually inside.

11 So why did we test the CBD category? Really
12 because of a lot of the great work that FDA has
13 already been doing over the past several years.
14 You've already called it. There have been systemic
15 quality control issues that have been identified. And
16 we see this coming out in other media, academic
17 studies that have been taking place.

18 So for us, we also wanted to validate that.
19 The samples that we selected were the ones that were
20 out in the marketplace between January and February of
21 this year.

22 So a little bit more about the study. How

1 did we test the study? We were inspired by the
2 Amazon.com bestseller's list as well as an Internet
3 search of different types of consumer blogs of popular
4 CBD products that consumers were buying.

5 We used, like I mentioned before, consumer
6 chain of custody rather than relying on certificates
7 of analysis as disclosed by brands. We went out into
8 the marketplace, procured the samples ourselves just
9 like a consumer would and took it to an analytical
10 chemistry lab. Had it validated by another lab as
11 well.

12 What did we look at? Over 400 analytes --
13 heavy metals, pesticide residues, plasticizers,
14 potency, THC as well as mycotoxins. And we tested
15 America's bestselling CBD products.

16 So three key findings that we found. The
17 first one is highly variable potency and
18 contamination. We tested for over 400 analytes. The
19 average of top 10 brands based on what they disclose
20 on their website is about 14 different tests. What we
21 found within our testing, and I'll show more details
22 to this, is that you see over 30 percent of products

1 are plus or minus 20 percent of the CBD value that's
2 listed on the label.

3 We see on average 34 parts per billion of
4 lead, which is the highest amount of any consumer
5 product or food category that we've ever tested. The
6 pesticides that we see, the total pesticides, nearing
7 41 parts per million. The most common pesticide hits
8 listed here. Average phthalates, which I was really
9 surprised about, nearly 1,100 parts per billion. I'm
10 not exactly sure where that's coming from.

11 Overall what we see is a general disconnect
12 between brand-reported certificates of analysis and
13 what's actually showing up on retail store shelves.
14 What happens is this elevated level of detection
15 coming from certificates of analysis listing a bunch
16 of non-detects results in unsuspecting brands and
17 consumers getting a false sense of comfort, security
18 and compliance.

19 So, number two key finding, the CBD content
20 varies widely based with the values listed on the
21 label. What's I think so interesting here and aligned
22 with my friend over in Arkansas is I think that's the

1 same product we tested that was exactly 100 percent
2 accurate with the other one.

3 We see products that had zero CBD. We had
4 another one that I didn't include on here that had 700
5 percent of the claim. But it wouldn't fit on my
6 chart.

7 And then, you know, another question is, you
8 know, I see a fair amount of CBD washing. To be able
9 to kind of command this market premium, it's almost
10 something where it has very, very low levels of CBD,
11 but it's still really marketing that.

12 Finally another question would be we see a
13 lot of THC-free claims. So what exactly does it mean
14 to be THC-free? It's interesting because, for me, I
15 look at words like FDA-provided guidance on gluten-
16 free. And that meant if you chose to make a claim of
17 gluten-free, then that means that you have to be less
18 than 20 parts per million.

19 If someone chooses to make a THC-free claim,
20 well then what exactly what does that mean? In terms
21 of my sensitivity, we tested down to 0.2 parts per --
22 or sorry, 0.2 parts per million. So it was one where

1 we did not see anything that exceeded this 0.3
2 percent.

3 But I think what's important to note is the
4 0.3 percent THC is based on dry weight in hemp and the
5 limit is being applied to manufactured products. But
6 there's no rule or regulation as to how much THC can
7 be present in a concentrate or manufactured product.
8 Thank you.

9 (Applause.)

10 MS. CRISTINZIO: Thank you. Our next speaker
11 is David Evans, number 68.

12 MR. EVANS: And how do I advance the slides?

13 MS. CRISTINZIO: You should be able to do it
14 with your clicker?

15 MR. EVANS: That's the advance? Oh, okay. I
16 am the senior counsel to the Cannabis Industry Victims
17 Educating Litigators. We are a legal education
18 organization that trains lawyers in how to sue the
19 marijuana industry. We've spent the last year doing
20 research on that. This year we're rolling it out.

21 So if a lawyer wants to sue somebody in the
22 marijuana industry, we give them a suit to nuts legal

1 guide on how to do it, the law, the science, a model
2 complaint, model responses to motions, model
3 interrogatory questions and so forth.

4 Right now, we have about a thousand lawsuits
5 against the opioid industry. And if our dreams come
6 true, we'll have the same thing going against the
7 marijuana industry in a year or two or maybe a little
8 bit more.

9 Now, who are the marijuana industry?
10 Basically it's anybody that's selling marijuana as a
11 medicine or as a food that has been approved by the
12 FDA. They have set themselves up in various
13 associations and industry associations.

14 The reality is these people are criminals.
15 They are doing this in violation of the federal
16 Controlled Substances Act and also the criminal
17 penalties within the Food, Drug and Cosmetic Act.
18 They're criminals. And the federal government has
19 allowed this to go on for a long, long time.

20 I have no sympathy for them. I don't respect
21 them. I have seen the widespread damage that they are
22 affecting on this country. We advocate for the

1 victims of the marijuana industry, children with birth
2 defects, developmental problems. We'll provide you
3 all the science on it. We've got a lot of science.

4 Talk to Dr. Howard (ph) at the National
5 Institute on Drug Abuse. She's written papers on the
6 damage to unborn children.

7 We also advocate for marijuana consumers.
8 Marijuana products are full of contamination. We have
9 papers documenting all this, even in the so-called
10 regulated states such as Massachusetts and California.

11 Colorado is now a narco-state. The state
12 government there has been grossly irresponsible in
13 dealing with this issue. And if somebody from one of
14 those states wants to give you a tour, come to us and
15 we'll give you our tour. We'll show you what's really
16 going on there in the ERs and every place else.

17 Marijuana is very dangerous. I have given
18 three copies of a book by Alex Berenson, a New York
19 Times reporter, who has looked into marijuana-induced
20 mental illness and violence. A great deal of violence
21 is being caused by high-potency marijuana. Read his
22 book. You've got three copies of it there.

1 Mental illness, physical disease and
2 addiction to marijuana. Now, is there a demand for
3 marijuana products? You bet your lives there is.
4 These folks in the marijuana industry have created the
5 demand, primarily by lying to people about the
6 addictive qualities and the dangers of marijuana.
7 We've probably all gotten things on the Internet about
8 CBD, that it's the wondrous plant.

9 And by the way, this meeting has been very
10 helpful to me on a personal level. I am an anxious,
11 combative individual and I have come -- and I have
12 come to realize that my problem is I have a
13 cannabinoid deficiency. And I'm going to -- my wife
14 is driving me home. That's the first thing I'm going
15 to tell her, is sweetheart, I've figure out what's
16 wrong with me finally. I don't have enough of this
17 stuff.

18 Now, who agrees with me? All of these
19 organizations have put in damage reports about
20 marijuana. The science is clear. It's not debatable.
21 There is no regulatory ambiguity. You guys have said
22 don't sell this stuff. It's illegal.

1 Now I'm just going to ask you a question.
2 These people have been operating for years, okay? And
3 they have ignored you. What makes you think if you
4 come out with something now that the situation is
5 going to be any different? The only way it's going to
6 be different is if you enforce it. And you have not
7 been doing that.

8 And in all my years in government -- I used
9 to work for the New Jersey Department of Health --
10 this is the most negligent, damaging thing I've ever
11 seen a government agency do, the FDA's negligence in
12 not dealing with marijuana and cannabinoids.

13 You've seen very good science here and I urge
14 you clean it up. Redeem yourselves and go after this
15 criminal industry that's damaging our children.

16 This is not a states' rights issue. The U.S.
17 Supreme Court has determined that regulation of
18 medical marijuana is a medical issue. I've got a
19 minute left and I've got other points. But I want to
20 just spend a few minutes looking at some people's
21 children. Every one of these people is dead, except
22 for one. And their parents all say that their deaths

1 were caused by marijuana. This is the only one of
2 these folks that's alive. They committed suicide,
3 they overdosed or they died as a result of their
4 marijuana use.

5 So you have a tremendous responsibility.
6 You're going to meet with a lot of smooth talking
7 lobbyists here, okay, who are going to spin a lot of
8 bullshit to you about their products. Keep these
9 people in mind. Their photographs are on my office.
10 I look at them every day. Thank you.

11 (Applause.)

12 MS. CRISTINZIO: Thank you. Next, we have
13 Lisa Gill.

14 MS. GILL: Hello. I'm Lisa Gill. I am a
15 health and medicine investigative reporter for
16 Consumer Reports. I have been as a journalist
17 covering prescription and over-the-counter drugs now
18 for the better part of 20 years. And I've spent about
19 11 of those at Consumer Reports. Hang on here. Let's
20 figure out -- okay.

21 CBD for me personally represented a compound
22 that I had never really come across before, both in

1 terms of how people used it, why people used it, how
2 they purchased it, how it's regulated or not.
3 Consumer Reports had very similar feelings about it
4 and started to take a great interest in this product
5 about a year-and-a-half ago when we started seeing the
6 market flooded with products, the retail market and
7 online.

8 At the same time, we became quite concerned
9 by some of the safety problems uncovered by the FDA as
10 well as good researchers like Michelle Peace and Ryan
11 Vandrey and others.

12 At the same time, we also started to hear
13 stories of individual consumers telling us though that
14 CBD was actually very helpful to them. And so, we
15 took a deeper dive into this topic and the
16 organization made substantial investments in trying to
17 understand what was happening in the marketplace and
18 what was happening with consumers.

19 Now, you may know Consumer Reports as an
20 organization that -- nonprofit, that tests things like
21 cars and washing machines and washers and dryers and
22 even lawnmowers. But we have a long, 83-year history

1 in the area of consumer health and safety.

2 And I have to say I have no conflicts of
3 interest to report. Part of that is because Consumer
4 Reports does not accept any kind of advertising or
5 sponsorship or partnerships of any kind. We are
6 supported entirely by consumer members, millions of
7 them, and consumer donors.

8 We actually buy every product that we test
9 and we sell it back to people like me, employees, who
10 purchase those products. I've personally purchased a
11 number of coffeemakers on my own.

12 So part of the substantial investment that
13 Consumer Reports made in this space was a national
14 representative survey just this past January of 4,355
15 adults, adult Americans, a telephone survey asking
16 people all kinds of questions. Do you take CBD?
17 Where'd you get it from? Why did you buy it? Did it
18 work? And there were three really important takeaways
19 that I'm very delighted to show you today.

20 First off, number one, many adults use CBD.
21 The second, a majority of people told us that they
22 found it effective though for the thing that they were

1 trying to treat. And the third is that consumers may
2 assume that CBD is safe.

3 All right. So the first thing here, many
4 adult consumers, basically one out of every four adult
5 Americans told us that they had tried CBD at least
6 once in the last 24 months. About 70 percent of those
7 told us that they had taken the product more than
8 once.

9 One out of seven said that they take it on a
10 regular basis. If you're wondering, 26 percent of
11 adult Americans represents about 64 million people,
12 which is a lot. We also broke it down by age. You
13 can see it's concentrated mostly in the people under
14 the age of 44. But all generations are represented.

15 Okay. We also asked, hey, why do you use
16 this stuff? Number one reason, to reduce stress and
17 anxiety. Also joint pain. Eleven percent told us
18 they use it for fun or recreation. And I think that's
19 where we get into a whole other category. Ten percent
20 said they did it to help with their sleep. Not
21 surprisingly, millennials said they use it to treat
22 anxiety. Baby-boomers said that they use it to help

1 with their joint pain.

2 Also we asked, you know, what form do you use
3 it in. the top three that I think are really
4 important, particularly for this meeting, they told us
5 the top way they got it, they drink CBD or they eat it
6 or, second way, they use drops or oil sprays or they
7 vape it. I think that's important considering a lot
8 of the vaping research that's been done. There's
9 other ways as well.

10 Then we asked, you know, where do you guys
11 buy this stuff, just out of curiosity. So I was very
12 surprised to see that 40 percent get it from a
13 dispensary. That beat out 34 percent that said they
14 were getting it at a retail store. And please take
15 note here. One out of every four said they were
16 buying it online.

17 All right. Then we asked, well, is it
18 helpful for the thing you're trying to treat. A
19 majority here, for the people who said they were
20 treating it for stress or anxiety, I'd like you to
21 look at this column here. Sixty-three percent that it
22 was extremely or very effective.

1 The column on the right shows when people
2 said that it was slightly or not effective at all.
3 That was 16 percent. You can see that it helped 38
4 percent with joint pain.

5 Twenty-four percent were satisfied with how
6 they felt after using it for fun or recreation. And
7 half of them said that it helped with their sleep.
8 But taken in total, about half said that CBD was very
9 or extremely effective for them.

10 And this is the slide I'd like you to --
11 everybody should put down the phones and close the
12 computers because there are three stats on here that
13 are extremely important.

14 And the first one is that when we asked
15 people, hey, did you use your CBD to replace it with
16 any medication that you were taking, one out of every
17 five told us that they stopped taking a medication as
18 a result. And of that, a third said that they stopped
19 using their opioid prescriptions, and that includes
20 things like Percocet and OxyContin, Vicodin --

21 (Applause.)

22 MS. GILL: The other number that was

1 important and much higher than I expected, 30 percent
2 said that they were taking their CBD along with
3 medication, which is important. We did not ask them
4 if they did this with their doctor's advice or not.
5 That would hopefully be a follow-up survey.

6 All right. We also asked about side effects.
7 The majority told us no. But the 26 percent who did
8 said that they experienced a change in appetite or
9 fatigue. And don't forget, fatigue might be something
10 that they actually are looking for.

11 And in terms of the area of safety, most
12 important, half of the people told us that they were
13 extremely or very confident that there was a
14 regulation in place that required their CBD to be
15 tested for safety and accuracy by outside labs. But
16 we know if you get it at a retail store in most states
17 or online, that is absolutely not true.

18 It was also asking about safety, when we said
19 what are your top concerns, that the product wasn't
20 safe, only 13 percent told us that. They were
21 actually much more concerned that CBD would be too
22 expensive.

1 If you have any comments or questions, I
2 would love to hear it. If you think we're wrong about
3 anything or you'd like us to take a look at something,
4 let me know. I'm at Lisa, or lgill@consumer.org.
5 Thank you.

6 (Applause.)

7 PANEL MEMBER: Did you ask if they had given
8 it to pets?

9 MS. GILL: You know, we did not. But we have
10 done a couple -- or at least one story on pets. And
11 we do know that it is a growing area and that a lot of
12 people are very interested in how CBD might be able to
13 help their household pets. Thank you.

14 MS. CRISTINZIO: Thank you. Next, we have
15 speaker number 70, Yael Ossowski. Sorry.

16 MR. OSSOWSKI: Hey, you got it the second
17 time. Thank you. Good afternoon, FDA. Pleasure to
18 speak with you all. So I'm here on behalf of the
19 Consumer Choice Center. We are a consumer advocacy
20 group, ab it different than the previous speaker.
21 We're the group that is actually supporting lifestyle
22 freedom, innovation, privacy, science and consumer

1 choice. We are active around the world, though our
2 base is here in Washington, DC.

3 And the main policy areas that we focus on
4 are digital, mobility, we look a lot at lifestyle and
5 consumer goods and health and science. And it's in
6 that last category that we focus on cannabis and
7 specifically CBD.

8 We've worked on this issue internationally.
9 We've done a lot, particularly in Canada where
10 cannabis is now legal recreationally, and also in many
11 local jurisdictions throughout the United States and
12 also now in Luxembourg, which is to be the next
13 European country that will legalize recreationally.

14 So our goal is to promote smart cannabis
15 policy. The idea that you're going to promote
16 competition, that you're going to promote safety and
17 you're going to eradicate black markets.

18 I believe the previous speaker mentioned a
19 lot of issues before. I think that really comes
20 because of the black markets because there is no
21 regulation and it's left only where there is no
22 regulation, there are no rules and there's no way for

1 consumers especially to have good products or to know
2 what the products are.

3 So I'm going to go through some of our points
4 here, things that are very important for us, looking
5 at smart regulation. Number one is going to be clear
6 labeling standards. I think that's probably one of
7 the most important things.

8 It sounds as if there are many consumers in
9 the house who've been to some CBD shops or stores.
10 They've been able to see what some of the products are
11 there. But we don't necessarily know the exact
12 percentage.

13 And as a consumer, how are you supposed to
14 know exactly what to take, how much to take, at what
15 cost? This is the thing that's very important to
16 know, is that as old as the cannabis industry or
17 cannabis use has been, everyone is new to the new
18 legal CBD market. Therefore we need to have great
19 clarity and great labeling as to how much CBD is in
20 this, how much THC is in this. That's very important
21 for consumers. Otherwise they have no idea exactly
22 what they're taking and the effect that will be on

1 them.

2 The second point is to allow branding and
3 advertising of CBD goods. I know this is already
4 happening. So we're just kind of regulating after the
5 fact. But we have to allow companies and brands to
6 exist because that's the only way the consumers are
7 going to be able to differentiate between good
8 products and bad products. We allow that with every
9 other product.

10 Unfortunately in Canada, there they've plain-
11 packaged a lot of their cannabis products. So there
12 is no branding necessarily. You can't really tell the
13 differences between brands. And because consumers
14 don't have that option, they're not really able to
15 establish loyalty. They can't figure out exactly
16 which product is meant for them and they can't figure
17 out if it's a bad company and a product that they
18 don't want to use.

19 Next is age restriction. I know that this is
20 important for a lot of people here. I know that there
21 are probably going to be a lot of people advocating
22 for 21. When it comes to the smokable products,

1 obviously an 18 age restriction we think is very
2 appropriate.

3 But because of the oils and the edibles and
4 this entire new industry that's coming about, that's
5 something to where the age restrictions might not be
6 as necessary and assuming that we have clear laws and
7 standards, should be addressed in the right way.

8 But to have a total 18-plus or 21-plus even
9 age restriction on all CBD products, we don't really
10 think that's going to be helpful, particularly to the
11 medical consumers who are going to need that.

12 Next is the benefits and the side effects.
13 Obviously as many researchers have pointed out, there
14 is a need for more research, for more information.
15 But we don't need to allow the companies that are
16 marketing. As consumers, we need to be able to know
17 what are the health claims. Can they prove them? And
18 they should be allowed to testify that and to include
19 that in their promoting and in their branding.

20 As a consumer, it's very important to know
21 that what the side effects are going to be, what the
22 benefits are going to be. We think that's very

1 important and something that should be upheld.

2 And lastly, harm reduction. So the idea is -
3 - and the mistakes that were made in Canada when it
4 came to cannabis legislation is they actually
5 legalized the flower and the oils first.

6 So if you wanted to consume cannabis, you
7 could only smoke it. You couldn't have any brownies
8 or chocolates or food or drink. And that's been very
9 bad for many people who would like to take these
10 products and not have that additional harm.

11 So we need to allow CBD to be infused in many
12 of these products and allow consumers to ingest them
13 in the least harmful way possible. And I have some
14 testimonials of people who do use CBD that is
15 available and you can follow us, Consumer Choice
16 center. Thank you very much.

17 (Applause.)

18 PANEL MEMBER: I have a question.

19 MR. OSSOWSKI: Yes, ma'am.

20 PANEL MEMBER: I have a question for you.
21 What evidence do you have about the different routes
22 of administration that causes you to have a

1 distinction of age restrictions between different
2 types of infused products?

3 MR. OSSOWSKI: That's been done in some
4 states, in some markets. Again, this is --

5 PANEL MEMBER: But in terms of its effect on
6 the body, why would it -- do you have evidence that
7 shows that some routes are different than others that
8 would justify having different age limits for
9 different routes of administration?

10 MR. OSSOWSKI: In that case, we're mostly
11 talking about medical uses and because if you have the
12 blanket ban, then you have exceptions, then we're just
13 carving out laws that's carving out laws. It has to
14 be as general as possible so it can be applied.

15 Ideally if there's going to be any age
16 restriction, we talk about 18. Ideally there wouldn't
17 be perhaps. That's to be determined by obviously your
18 agency. So thank you very much. Any other questions?
19 Okay. Thank you.

20 MS. CRISTINZIO: Thank you. Now we are
21 moving onto the health professionals category.
22 Speaker number 71, Ann Allworth?

1 HEALTH PROFESSIONALS

2 DR. ALLWORTH: I've got to get this down.
3 There we go. Hello, everyone. I'm Dr. Ann Allworth
4 and I'm very grateful to have this incredible
5 opportunity to share the reasons why I, like thousands
6 of other scientists and doctors, believe that the
7 endocannabinoid system is scientific proof that
8 cannabis is medicine.

9 I'm a cell biologist who studied, researched
10 and taught various aspects of the human body for over
11 35 years. Cells, medical school gross anatomy, breast
12 and ovarian cancer, innate intelligence, the critical
13 role diet has to human wellbeing. And over these
14 years, I've acquired much wisdom about human health,
15 which has led me here today.

16 We need to know -- we know the needed
17 cannabis research cannot be done. So please give
18 strong consideration to the fundamental empirical
19 evidence that I'm going to share with you today
20 relative to the need for de-scheduling cannabis.

21 What do we know about cannabis as medicine?
22 Conservatively, it's estimated that more than 60,000

1 doctors are practicing cannabis medicine and there are
2 more than 3 million registered medical marijuana
3 patients. The stories these docs tell are variations
4 of miraculous cures in patients who found no relief
5 from conventional medicine.

6 Some examples. A young teen whose 70 chest
7 tumors disappeared. A two-year-old with brain cancer
8 not expected to live three months is now six-and-a-
9 half. Dramatic decreases in opioid use, helping to
10 resolve this heinous health crisis. Veterans who
11 experienced horrible PTSD experiencing powerful
12 relief.

13 These stories are not miracles. They're
14 empirical evidence that cannabis is potent medicine.
15 It works when approved medicines do not. And it works
16 for a wider range of conditions than any medicine
17 known.

18 Here is a composite of the -- of all the
19 qualifying conditions that are in the legal states.
20 There are more than 75 of them. And these conditions
21 are as disconnected as autism is to pancreatitis as
22 cancer is to multiple sclerosis.

1 There's no time to read all of these. These
2 slides are here to emphasize their number and range of
3 beneficial effects this medicine provides for
4 conditions in every single system of the body.

5 Some of you might ask, well, just how
6 effective is this medicine. Let's look at three of
7 the commonly treated ailments: migraines, epilepsy and
8 chronic pain. Dr. Patricia Frye, of Takoma Park
9 Alternative Care in Maryland, saw a 60 to 75 percent
10 decrease in opioid use in 80 percent of her patients
11 with chronic pain. And in patients with migraines and
12 chronic headaches, 66 percent showed definite
13 improvement.

14 Dr. Dustin Sulak in Maine, Russell Saneto in
15 Washington and Bonni Goldstein in California published
16 a very important paper in Epilepsy Behavior using
17 pooled data on epilepsy patients treated with
18 artisanal whole-plant cannabis. In 272 patients with
19 medically refractory epilepsy, 86 percent had some
20 decrease in the number of their seizures.

21 Clearly cannabis is effective medicine. But
22 how is it that cannabis can fix 75 very diverse

1 ailments? The answer is the endocannabinoid system, a
2 critically important body system, a system that
3 regulates every system in our body, and when it's
4 disrupted, can manifest as the very conditions we just
5 saw.

6 So let's take a quick look at the components
7 of the system, the ECS. Receptors include CB1, CB2,
8 CB3. We have endocannabinoids AEA and 2-AG which we
9 make in our body that our body uses to maintain
10 balance. We have the enzymes that synthesize them,
11 the enzymes that degrade them.

12 So what does the ECS have to do with cannabis
13 as medicine? The simple answer is everything. And
14 though empirical, it is important fundamental
15 knowledge that needs to be recognized. Just look at
16 the relationship of the endocannabinoid system to
17 other body systems.

18 Our systems include the reproductive, the
19 urinary, the digestive, the respiratory, the
20 endocrine, the circulatory, the nervous, lymphatic
21 immune, skeletal, muscular.

22 So where does the ECS fit into this picture?

1 It literally coexists with cells in all systems of the
2 body. It is everywhere. It maintains balance in
3 every system and between systems. Research, primarily
4 animal studies, shows that disruptions of ECS
5 components are seen in many conditions.

6 Conventional medicine is never effective
7 because it's not treating the real issue. Cannabis
8 resolves a broad spectrum of issues because it fixes
9 the disrupted endocannabinoid system. And it is the
10 only medicine that can do this. All of this is
11 fundamental evidence demonstrating that cannabis is in
12 fact actual medicine which should be de-scheduled.

13 Thank you.

14 (Applause.)

15 DR. ALLWORTH: Any questions?

16 MS. CRISTINZIO: Thank you. Now we're moving
17 onto speaker number 72, Jerry Bryant.

18 MR. BRYANT: Thank you. My name is Jerry
19 Bryant. I'm president of -- and managing member of
20 Vyripharm Biopharmaceutical. We're located in
21 Houston, Texas in the medical center and we -- we're
22 located in the Texas Medical Center and we work with

1 several institutions within the medical center.

2 Vyripharm is focused on diagnostic and
3 therapeutic application in the area -- in the areas of
4 neurological disorders and cancer. The focus was to
5 present the company where we can integrate medicinal
6 cannabis with traditional medicine. So medical
7 cannabis integrated with traditional medicine was sort
8 of the platform.

9 We had to ask several questions. The
10 question that we had to ask is, is medical cannabis a
11 medicine. Did it have uniformity in the sector?
12 Diagnostic application, meaning the dosing issues as
13 well as the biodistribution. Also the treatment
14 outcome, how can be quantitate? Do we have -- can it
15 fall into the category of personalized medicine and
16 IP, intellectual property?

17 We were able to develop a collaboration with
18 the University of Texas MD Anderson Cancer Center.
19 And lo and behold, we studied some of the malignant
20 lymphoid cell lines. We were able to use medical
21 cannabis to treat and look at the efficacy of the --
22 and cytotoxicity of those cells. And we determined

1 that medical cannabis is a drug.

2 The work that's been done by companies such
3 as Vyripharm can only deliver its true benefit to the
4 public if the federal government takes the lead in
5 developing a uniform and comprehensive approach
6 towards cannabis products. Uniformity means the
7 federal government must resolve inconsistencies in
8 state and local approaches. Comprehensive means
9 guidelines, effective testing, QC/QA and clear and
10 consistent product labeling.

11 Let me move to the next slide here. There we
12 go. As you can see from this slide, we have pure
13 chaos. In the absence of federal regulation, dozens
14 of states have legalized medical and recreational
15 cannabis products that have been left to their own
16 devices.

17 According to the study performed by the
18 Center for Public Health Law Research at Temple
19 University in the area of health policy, states are
20 serving as laboratory democracies.

21 But the exercise is only productive if
22 research, which we have done, and partnered in Texas

1 Medical Center, step up to rigidly evaluate the impact
2 on state innovation.

3 We largely have no idea about how well these
4 laws protect patients and the public. The FDA really
5 need to integrate and help this industry with
6 guidelines on standardization. Uniformity is a
7 necessity when it comes to the development of safe and
8 effective medicine. It is only through uniform
9 standards that regulators, sellers and customers can
10 learn about what actually makes one product different
11 from the other.

12 And so, you get some normalcy and
13 differentiation in this whole process. And that's one
14 thing that Vyripharm has really designed platform to
15 maybe assist the FDA in establishing.

16 Accessibility is critical. In addition of
17 uniform standards, information collected must be under
18 a universal, recognizable, usable platform and the
19 status quo, which we have now, different states use
20 different testing protocols.

21 Tests have different components, track
22 products differently and do not share information with

1 each other. However, the entire supply chain needs to
2 have access to the best and most consistent
3 information.

4 What we have learned at Vyripharm means
5 embracing what new technology has to offer. For
6 example, we have developed an interface and database
7 using block chain technology that allows access to
8 extensive product information down to the strain
9 source, genotype, phenotype and particular plant that
10 you can correlate with a patient.

11 If we actually think that medical cannabis is
12 a medicine, well, let's treat it as medicine. We do
13 hold tremendous medical potential. Then we must treat
14 this medicine as medicine. Consumers of medicine in
15 our country know and they can rely on the information
16 of medical labeling because we have to build a uniform
17 and comprehensive platform.

18 Companies like Vyripharm are leading this
19 cause right now. But every day the federal government
20 delays in taking the need puts more consumers at risk
21 and puts the true benefits of these medical products
22 out of the grasp. We look forward to partnering with

1 FDA and other regulatory officials in this important
2 issue. Thank you for the opportunity to speak.

3 MS. CRISTINZIO: Thank you.

4 MR. BRYANT: Thank you.

5 MS. CRISTINZIO: We have two more speakers
6 before we break for lunch. Next up is Najla Guthrie,
7 speaker number 73.

8 MS. GUTHRIE: Thank you. Good afternoon.
9 I'm Najla Guthrie, CEO and president of KGK Science, a
10 global health and wellness contract research
11 organization.

12 KGK Science has been designing and conducting
13 clinical trials for over 22 years to support clients
14 with product development claims, claim substantiation
15 and new dietary ingredient notifications. KGK Science
16 is a subsidiary of Oxley Cannabis Group, operating in
17 Canada and abroad.

18 The volume -- sorry. The volume of
19 unsubstantiated claims being made on CBD products is a
20 clear abuse of the rules set forth by FDA and FTC.
21 CBD foods are not permitted to make disease or
22 therapeutic drug claims.

1 CBD has been marketed for multiple broad
2 areas besides rare epilepsy in children. It has been
3 marketed for its neuroprotective, anxiolytic,
4 antipsychotic, analgesic, anti-inflammatory and anti-
5 asthmatic properties, as well as combatting hypoxic
6 ischemia.

7 FDA has asked what systems are in place to
8 ensure adverse events are collected to mine toxicology
9 signals and about margins of exposure. Dietary
10 supplements are the only food commodity which there is
11 a mandatory reporting requirement for serious adverse
12 events.

13 CBD is a new dietary ingredient. NDI
14 notifications must provide the basis for reasonable
15 expectations of safety, which should include the NOEL.
16 FDA asks about margin of exposure. Knowing the margin
17 of exposure is a critical component of the NDI
18 evaluated by the NDI review team at FDA CFSAN.

19 There are clear gaps in safety. But FDA has
20 an established NDI process to receive and evaluate
21 those concerns. There are two main intercellular
22 targets for CBD, namely CB1 and CB2 receptors. They

1 are located in the central nervous system and some
2 expression in peripheral tissues on cells with immune
3 function and in the GI tract.

4 However, a pharmacologist might ask -- or
5 might say that CBD is a dirty rather than a clean
6 compound, not because of where it acts or any bad
7 connotation. It acts on a wide array of intercellular
8 targets. Therefore it is not surprising that there is
9 a diverse array of purported uses.

10 CBD is considered to have low toxicity. In
11 clinical trials and research studies, CBD is
12 administered orally as either a capsule or dissolved
13 in an oil solution. It can also be administered
14 through sublingual or intranasal routes.

15 A wide range of oral doses have been reported
16 in the literature, from 100 up to 800 mg per day. It
17 is used in Epidiolex at up to 20 mg/kg daily with some
18 concern in patients with hepatic impairment. This is
19 not surprising, given its liver metabolism.

20 Studies on CBD show no effect on embryonic
21 development. CBD has no effect on a wide range of
22 physiological and biochemical parameters unless

1 administered at extremely high doses.

2 CBD has no mutagenic potential, based upon
3 Ames, comet and micronucleus assays. In rats, CBD at
4 low doses does not change the threshold for
5 intracranial cell stimulation. At higher doses, CBD
6 actually raises the threshold, meaning that it
7 interferes in reward behavior. This is the exact
8 opposite of what drugs of abuse do, like cocaine and
9 opioids. Drugs of abuse lower the threshold.

10 In human clinical research, CBD was not
11 associated with abuse potential or addiction. Unlike
12 THC, CBD showed no physiological changes on heartrate,
13 psychotic symptoms or anxiety.

14 In terms of food, nutraceutical and drug
15 interaction, there is only potential for CBD to be
16 associated with drug interactions through inhibition
17 of some cytochrome P450 enzymes. However it is not
18 yet clear whether these effects occur at physiological
19 concentrations.

20 In terms of unique populations such as
21 pregnant women and elderly, one should consider
22 undertaking safety studies for NDI notification or

1 other safety dossier. There is a clear knowledge gap
2 in our understanding of CBD which should be addressed
3 in the future if products are to be intended for these
4 sensitive populations.

5 The Epidiolex dosing guidelines indicate that
6 with severe hepatic impairment, dosing should vary
7 between 1 and 4 mg/kg/day. A significant difference
8 however is that Epidiolex is exclusively directed to
9 pediatric patients, which are not considered smaller
10 versions of adults.

11 CBD in foods is typically marketed to healthy
12 adults and should never be marketed to those with
13 hepatic impairment. In addition, there should
14 probably be a voluntary black box warning on all CBD
15 food products, conventional food or dietary supplement
16 that they should not be used in the setting of liver
17 disease.

18 And to conclude, the recommendations for
19 labeling and claims for dietary supplements containing
20 hemp-derived CBD extracts is to remove the inclusion
21 clause in 201(ff) for CBD products to permit
22 eligibility as dietary ingredients. Issue a

1 regulation approving as a food substance under section
2 301(11).

3 Enforce the regulations from the Dietary
4 Supplement, Health and Education Act of 1994 and the
5 1990 Nutritional Labeling and Education Act. This
6 would require an NDI notification within 75 days of
7 marketing, would require GRAS affirmation and NDI
8 status will allow lawful companies to make
9 scientifically validated health claims regarding
10 nutrient content, structure function and qualified
11 claims.

12 And amend the labeling regulations to include
13 separate identity statement and standardized hemp-
14 derived CBD symbol. And thank you for allowing me the
15 opportunity to speak today.

16 (Applause.)

17 PANEL MEMBER: Quick question. As a CRO in
18 this space, how many CBD-related studies do you
19 currently have ongoing?

20 MS. GUTHRIE: We've got I believe around nine
21 of 10 studies now going on and a number of them are
22 looking at the pharmacokinetic properties of CBD and

1 THC being located in Canada where we're able to look
2 at both of those, as well as other indications.

3 So we're looking at indications such as
4 sleep, anxiety, pain are some of the indications we're
5 looking at.

6 PANEL MEMBER: Thank you.

7 MS. GUTHRIE: And we plan to submit written
8 comments as well.

9 MS. CRISTINZIO: Great. Thank you. We have
10 one last speaker before we break for lunch, Lucille
11 Vega.

12 DR. VEGA: Hello, and thank you for allowing
13 me to speak today. My name is Dr. Lucille Vega. I
14 have a degree in biology at University of Irvine --
15 University of California, Irvine. I went to medical
16 school at Dartmouth Medical School, Brown University
17 for residency and also I have been on concierge
18 private practice, private practice for the last 19-
19 and-a-half years.

20 When I first heard about CBD, I did not
21 believe it worked. I thought it was snake oil. Oh,
22 come on. This is from the medieval times. Are you

1 kidding me? I would have learned this in medical
2 school, right?

3 Well, since then, I have done a trial with
4 EcoDrop oil. Since it's full spectrum, it has the
5 CBD, CBG, CBC and that trace amount of THC, less than
6 0.3 percent. In my trial, the first question -- let's
7 do this here. In my trial, the first question is
8 pain: 65.5 percent dropped their pain scale by two
9 points. Pretty significant in my book.

10 Number two, sleep question. Let's get back
11 to that sleep question: 43.1 percent gained more than
12 two hours of sleep. Here's the abdominal question.
13 To save time, here's a quick review of the results.
14 Also for my headaches and migraine question as well.

15 Moving along, buckle up, folks. We have a
16 lot more to go. Anxiety, 75.3 percent had a reduction
17 of their anxiety symptoms or the intensity of it. And
18 then, my last question, would other people represent
19 the CBD drip, or the EcoDrop now, 88.7 percent would
20 recommend the EcoDrop to their fellow friends or
21 family members.

22 Other witnessed benefits that I have seen,

1 there's a list here. You've seen more today I'm sure.
2 But PTSD, that one really surprised me. I was very
3 excited to see that. As far as concussions and
4 diabetic neuropathy, wow, I'm impressed. PMS, sure.
5 And then, high blood pressure, wow, I'm lowering blood
6 pressures right inside the office. That's fantastic.

7 Other benefits of the EcoDrop oil I saw,
8 arthritis in canines and separation anxiety. There's
9 a full list. Not enough room on this slide. Other
10 CBD products I use is PainQuench cream and also
11 FreshLeaf edibles.

12 Again, I did not believe this stuff would
13 work. PainQuench cream, I was surprised that folks
14 were coming to me and saying, hey, it works for my
15 psoriasis patches. Plantar fasciitis, diabetic
16 neuropathy. What? I did not understand. Wow.

17 Second degree burns, you kidding me? Wow.
18 Acne. And then, as far as the edibles, a lot of
19 people came to me and said the anxiety and the sleep,
20 it really helped with that. Again, I'm always about
21 minimal effective dosing. I remember in medical
22 school, first do no harm.

1 Here we have PTSD trigger prophylaxis.
2 People are using it at 7.5 mg per dose, two to three
3 times a day. You may see these as low numbers. But
4 with the full spectrum oil, it doesn't require as --
5 I'm noticing it doesn't require as much CBD isolate.

6 Okay. Post-concussion, people are using it
7 10 mg. We usually do it three times a day for a week
8 and then twice a day. Autism, seeing a lot of good
9 results in adults with 37.5 mg, all using this EcoDrop
10 oil because it's full spectrum.

11 Most common side effects, it's too relaxing.
12 Perhaps that's dose-dependent, which I believe it is.
13 Next, my thoughts about safety, I prefer sublingual
14 dosing.

15 Why? One, I didn't get many complaints in
16 the medications interactions because they're my
17 primary care patients. I know what they're writing.
18 And do I write for pain medication? Absolutely. And
19 I'm here to testify, to say, look, I want to be part
20 of the solution.

21 Okay. We had Coumadin and dialysis patients.
22 Again, no major interactions. In fact, there were no

1 interaction complaints in that trial. Also I didn't
2 have to worry about that first pass effect with the
3 sublingual dosing. That's why as a physician I prefer
4 sublingual dosing.

5 Oral consumption, the minimal dose necessary,
6 I have no complaints at the -- I had no complaints at
7 the 50 mg or less at one to two times a day. Topical
8 application, of course not for open wounds. On dry
9 skin.

10 Last thing, my thoughts about public safety
11 issues. Definitely lab results need to be found
12 online or easy in the packaging for consumer. I would
13 prefer as a physician also product testing, which
14 we've heard before today, heavy metals,
15 organophosphates, pesticides, to name a few.

16 We need more research. We need more
17 research. We need more education for physicians.
18 Why? Because people are coming to me, coming to the
19 ER asking us physicians what do I do. I need to know
20 what's online. Or if you're putting out a product,
21 what do you have in there. What am I concerned about,
22 so I can start to assess this patient.

1 Labeling. My biggest pet peeve as a
2 physician, seeing these CBD companies put out 1,000 mg
3 in a bottle. I want to know what's the milligram per
4 smallest dose unit, per drop, per edible, et cetera.
5 Also, definition, broad spectrum, full spectrum, we
6 should probably get a consensus on it, possibly a new
7 language considering how many cannabinoids are in this
8 particular product. There are one, two, three, four
9 cannabinoids.

10 It looks like the FDA may have to bring me
11 back for some more information on my study. And thank
12 you all for listening and being here today and
13 testifying. Thank you.

14 PANEL MEMBER: I have a quick question. I
15 saw on your slides you said something about a
16 FreshLeaf edible. And I wasn't -- is that a brand
17 name of a product --

18 DR. VEGA: It is.

19 PANEL MEMBER: -- or are you talking about
20 actually consuming a fresh leaf?

21 DR. VEGA: it is a brand name of a product,
22 correct.

1 PANEL MEMBER: Okay. Thank you.

2 DR. VEGA: Sorry about that.

3 PANEL MEMBER: So it's a processed product.

4 DR. VEGA: Mm-hmm. (Affirmative.)

5 PANEL MEMBER: Not a fresh -- okay.

6 DR. VEGA: A processed product, edible.

7 PANEL MEMBER: Thank you.

8 PANEL MEMBER: And when you're recommending a
9 specific -- when you're recommending a patient use CBD
10 for a specific use, you had several on your slide, how
11 have you determined what dose to recommend for each
12 use?

13 DR. VEGA: So I always start with sublingual
14 because, to me, I don't have to worry as much about
15 the medications that they're taking.

16 I figure most people over 55 are probably one
17 some type of anti-hypertensive, cholesterol medication
18 and such. So I always start with 1 mg and let's see
19 how you do, the lowest dose possible.

20 PANEL MEMBER: Are there any conditions for
21 which you are screening patients before recommending
22 use of CBD? So liver issues or things like that?

1 DR. VEGA: I actually take that into
2 consideration with the liver. That's why I start with
3 the very lowest dose, possibly maybe half a milligram
4 and see how we do.

5 But on the other end, I know what I'm
6 prescribing them for their blood pressure, their
7 cholesterol and such. And so, that's constantly in
8 the back of my mind.

9 Every person I see, I always want to know
10 what's your kidney function, what's your liver
11 function and what's your blood pressure. Absolutely.
12 Thank you very much.

13 MS. CRISTINZIO: Thank you.

14 (Applause.)

15 MS. CRISTINZIO: We are now going to take a
16 break. Unfortunately we went a little over and we're
17 going to have to take some of that time out of the
18 lunch. We will reconvene at 1:30. Thank you.

19 (Whereupon, the foregoing went off the
20 record.)

21 MS. CRISTINZIO: Sue, on the line, give us
22 one more minute.

1 DR. SISLEY: Sure.

2 MS. CRISTINZIO: Okay. We are ready to begin
3 our afternoon program. The good news is we're about
4 halfway through our speakers. We have joining us on
5 the phone, continuing our health professionals
6 segment, Sue Sisley from Scottsdale Research
7 Institute. And she's going to tell us verbally when
8 to move the slides forward. Thank you. Go ahead,
9 sue.

10 DR. SISLEY: Okay. Wonderful. I'm Sue
11 Sisley. I'm an internal medicine physician from
12 Arizona and I'm the head of Scottsdale Research
13 Institute. You can see on the next slide our mission
14 is to strive to evaluate the safety and efficacy of
15 smoked and vaporized cannabis flower. So we're
16 striving to put flower through the entire FDA drug
17 development process.

18 On the next slide you'll see we just
19 completed an FDA Phase II trial looking at four
20 different varieties of cannabis for military veterans
21 with PTSD. And on the next slide, you'll see why this
22 study took us 10 years to get through, you know, to

1 navigate all of the regulatory hurdles.

2 And this schematic really demonstrates the
3 excessive layers of government red tape involved in
4 trying to study efficacy of cannabis through the --
5 you know, the regular drug development process.

6 The next slide, you'll see these are some
7 examples of pictures from investigators who used NIDA
8 study drug in the past. The top ones were from a few
9 years ago. The bottom picture is our most recent
10 shipment from NIDA and on the next slide you'll see we
11 were one of the first scientists to ever do secondary
12 independent testing on the cannabis from NIDA.

13 And we sent this to Schedule 1 licensed
14 laboratories in the U.S. to do proper testing. And we
15 did three rounds of testing that all showed
16 excessively high levels of mold in all the batches
17 that would not have passed state testing in any of
18 these regulated markets that mandates testing.

19 Next slide you'll see, you know, we were
20 somewhat optimistic to see that the DEA announced on
21 the Federal register back in 2016 that they would
22 finally license other growers for research.

1 And on the next slide, you'll see that even
2 though the DEA received almost 30 applications from
3 potential growers that wanted to provide cannabis for
4 clinical trials, the DEA has not processed any of
5 these applications. And despite members of Congress
6 repeatedly urging the DEA to either process the apps
7 or explain the delay, we've gotten no response to
8 these letters.

9 And the next slide shows you a good example
10 of one of the -- of one of over a dozen bipartisan
11 letters that was sent to DEA asking for an
12 explanation, and nothing.

13 So you'll see, next slide, shows you that the
14 real issue for us is the fact that we don't have
15 flower to use for FDA Phase III trials. So right now,
16 you know, the FDA of course requires that whatever
17 drug you use in Phase III, it's a drug that you would,
18 you know, go to market with later.

19 And NIDA cannabis is not authorized, you
20 know, to be available for sale as a prescription FDA-
21 approved medicine. So there's currently no way to put
22 flower through the entire FDA process unless we use

1 flower from a foreign manufacturer.

2 So next slide, you'll see here are just our
3 final points for the FDA, things that we hope you can
4 address. We'd like to see the paradigms with
5 botanical medicine become different than the paradigms
6 we use for standard pharmaceutical prescriptions.
7 Like we hope that eventually you'll allow, embrace the
8 idea of patient self-titration.

9 We're using that in the recent study we just
10 completed. Patient self-titration was an optimal way
11 of administering smoked cannabis flower because it
12 allows for small variations in the potency of the
13 flower and it enables patients to discover a much
14 lower therapeutic dose and avoid a lot of the adverse
15 events that we see when patients overuse flower.

16 So next slide, you'll see that we also hope
17 that the way you define GMP will evolve to ensure that
18 we're only getting the flowering tops of the plants,
19 not the extraneous plant material, stems, sticks,
20 leaves, that all, you know, confound the efficacy of
21 the study drug.

22 The idea is just flower only and other things

1 that we agree on that should be GMP, like free from
2 pesticides, free from microbial and mycotoxins. But
3 the idea is not so over-processed that it no longer
4 resembles real world flower. We feel that in this
5 excessive exuberance to make sure that the cannabis
6 flower is so standardized, that we lose a lot of the
7 efficacy of the natural flower.

8 So finally, the next slide shows you that our
9 big push here today is to urge you to help us, you
10 know, work with the DEA to urge them to make good on
11 their pledge to the public and license other growers
12 for research so that we can finally put flower through
13 the Phase III trials because currently there is no
14 federally legal drug supply for drug that can be used
15 in Phase III and then sold later as a prescription
16 medicine.

17 And the next slide shows you, this is my
18 final point, that the next clinical trial at our
19 laboratory will be looking at smoked cannabis flower
20 compared to fentanyl for late-stage cancer patients
21 with breakthrough pain.

22 But lastly because of the -- you know, of

1 this limitation with the current drug supply, we are
2 forced to import study drug from a Canadian
3 manufacturer. And that's disappointing to us. We'd
4 like to see our own domestic -- you know, a variety of
5 domestic manufacturers. The point is that researchers
6 need access to options. Scientists need options to
7 embolden scientific freedom. And my last slide just
8 gives you my contact information. Thank you very
9 much.

10 MS. CRISTINZIO: Thank you, Sue. All right.
11 I think we're about to move onto our next category of
12 speakers. We have next manufacturers up. And the
13 first one is number 76.

14 MR. BLEHAR: Is that me?

15 MS. CRISTINZIO: Number 76, Justin Blehar.

16 MANUFACTURERS

17 MR. BLEHAR: Hi, guys. How are you? I'm
18 Justin Blehar, with Genco Pura Oil Company. And I
19 think we'll be bringing up our slide in a minute.
20 I'll just go ahead and introduce myself to start. I
21 started -- I'm not a billionaire. I'm not a lobbyist.
22 I am an owner of a company that I started. I am a 15-

1 year veteran, served overseas a couple different
2 deployments, honorably discharged. And my partners
3 and I had no idea what CBD was a few years ago.

4 We started looking at what could help, what
5 would make a positive difference. This is what we got
6 into looking at vets and trying to have a positive
7 impact. Since that time, we've become a single point
8 manufacturer with a large network. We work at all
9 different levels.

10 And we'll start with the farms. A lot of the
11 other stuff has been touched on. But I want to hit a
12 couple of these points. So one of the things that we
13 do is working with the farms and the farming co-ops is
14 these farmers, you have micro farmers, one acre, five
15 acre plots and then you have these large farmers.

16 One of the things that wasn't addressed that
17 is going to be important, there's going to be a
18 surplus of biomass and there's going to be a limited
19 amount of certified extraction places to make CBD. We
20 also work with the networks of these labs. These labs
21 could be anywhere of something like a small corner
22 area over there that God knows what they're putting in

1 there in the back of their room, sending out isolate,
2 broad spec.

3 Then you have larger facilities that are
4 doing it properly and there's different types of
5 processing. These facilities are not -- there's not
6 enough of them in the U.S. to handle the production
7 that's going to be coming out. A hundred thousand
8 acres to 200,000 acres is projected for this year,
9 2,000 to 3,000 pounds per acre. It's not going to
10 work.

11 So you're going to have a surplus. Then
12 you're going to have farmers that are going to have to
13 make decisions on whether to burn their crops or not.
14 And then making those decisions on \$20,000 or \$30,000
15 of annual income is a big deal.

16 So just something that I want to bring up.
17 And having a certification process for the labs or
18 some type of QA or QM process is something we've been
19 working on and other companies are as well.

20 Cold packaging facilities, we work with pet
21 food manufacturers, cosmetic manufacturers, nutrition
22 and food and beverage. All of them are a little bit

1 sketch and concerned about what's going on in the FDA
2 and how to work with that and how to get people to
3 process stuff in a quality manner and not be dealing
4 in the gray area or the conmen and the Wild West.

5 You also have several small businesses trying
6 to get started right now. They're buying \$500 to
7 \$1,500 at a time every month. They're trying to do
8 the right thing. They want to implement testing.
9 They want to have stuff on the base oil. And they
10 want to be able to move everything through and grow
11 their businesses and have a positive impact.

12 A lot of what I'm hearing is not stuff that
13 allows them to do that. They can't do through any of
14 these new drugs' certifications. You've got the
15 patchwork of states. In Utah, for example, people are
16 already having to register as manufacturers. Per SKU
17 can start costing so many hundreds of dollars.

18 So I think overregulation would be a big
19 problem. We're five years into a multibillion dollar
20 industry right now and we're just talking about it
21 with you guys and you guys weren't aware of some of
22 the issues for the researchers to be testing stuff.

1 So it's not a ding on you. I love we're
2 having this convo. But I think the industry should
3 take the lead, utilizing networks, using ISO 9001 2015
4 standards and establishing those processes that the
5 consumers and businesses are already demanding.

6 All right. So sticking with the gray areas,
7 it shouldn't be a fear of the FDA. This should be a
8 conversation that we should be able to have.
9 Companies shouldn't be scared that they're going to
10 get warning letters to come up here and tell you guys
11 some of the issues they're dealing with and other
12 stuff going on.

13 But they're scared because, God forbid, you
14 know, I tell you I'm making a drink line in a few
15 months and it's not ready and it's going to mess up
16 our dollars. We need to move forward in a way that
17 everyone is being safe and can do this, you know, in a
18 constructive manner.

19 So the legalities especially, and going back
20 to the farms, you guys brought it up, delta-9 versus
21 THCA. There is a difference and there's a gray area
22 in regulation. If I want to go from a farm in Oregon

1 and drive, you know, 10 truckloads down to California,
2 is my delta-9 at 0.4? Am I now a federal drug
3 trafficker?

4 All right. And then, is everyone done and
5 what happens from that point in our logistics systems?
6 So if I'm a manufacturer and we're licensed, there
7 should be some variance in that and clarification on
8 THCA versus delta-9 so we don't have to work in that
9 area and worry about it.

10 It was already brought up the differences in
11 CBD. Along with academics and research, isolated CBD
12 is different from utilizing full spec CBD at scale
13 with manufacturing processes. This can become an
14 issue. So that's when you get into broad spectrum and
15 distillate, something we can submit later on to you
16 guys as well.

17 Next piece, ability for real research we
18 discussed. Consensus and the benefit to CBD, everyone
19 sees that overall and acknowledgement, you know, that
20 hey, we do have a patent on this and we've been
21 studying this stuff for over 50, 60 years at least
22 right now. There is a dearth of research. There's

1 meta-analysis, including stuff on dosing. We have
2 enough to move forward overall.

3 All right. Lastly, as we're running short on
4 time, one of the things is I just, you know, always
5 like to stick this out there as far as the benefits of
6 CBD. We can't ignore that. We see it across the
7 world internationally along with in the UK and Israel.
8 We're doing commercial trial arrangements with
9 different people and working logistics. All of them a
10 nightmare.

11 So I'm hoping we can go ahead and move that
12 forward. But that small difference, what CBD can do
13 can make a life-changing impact in people. I'm out of
14 time. Any questions? All right. Thanks so much.

15 MS. CRISTINZIO: Thank you. Next we have
16 speaker number 77, Richard Brumfield.

17 MR. BRUMFIELD: Good afternoon, ladies and
18 gentlemen and panelists. My name is Richard
19 Brumfield. I'm the CEO and founder of Full Spectrum
20 Omega, Incorporated. We are a phytocannabinoid life
21 science company out of California since 2010. We have
22 developed a non-euphoric THC product which has shown

1 benefits in the California medical marijuana group of
2 patients that we are serving in California.

3 Full Spectrum currently has two signed
4 agreement with the United States government to do
5 research in their lab for multiple applications
6 supporting national security and specifically military
7 need.

8 Now, I want to concentrate a little bit on
9 why we're here today. We're here today because we are
10 trying to get our products from California to the
11 federal lab in Maryland and San Antonio, Texas. And
12 our problem is there is no bridge between research and
13 drug development to have our product tested because
14 the product in the industry is my own invention.

15 We discovered the plant that we need. And we
16 are in control of those plants. And we work in a
17 state-sponsored program which is able to allow us to
18 use these products to help patients in different
19 needs.

20 Now, my next slide, going through some
21 discussion points, discussion point one is FDA
22 recommends data and the data is captured by the

1 National Institute of Drug Abuse and locked away where
2 researchers like myself who are in independent states
3 with cannabis programs, we cannot take our product
4 that we didn't develop into research because there's
5 no bridge between a state-sponsored development
6 program to where it could go to the FDA and say, look,
7 we discovered a new benefit.

8 So we need to be able to find a way to bridge
9 that gap where innovators like myself are not
10 handicapped to use a subpar or substandard product to
11 try to prove a point.

12 The next slide is the challenges moving
13 forward. Wait a minute. Hold on. Okay. I hit the
14 wrong button. Discussion point we want to talk about
15 is safety and effectiveness. I just went over that.
16 I'm sorry.

17 Discussion point number two. There are now
18 three definitions for hemp. The Farm Bill has 3
19 percent -- 0.3 percent. The World Health Organization
20 has got 0.2 percent. FDA has done 0.1 percent. Where
21 is the standard between dietary supplements and a
22 drug? There's no standard. You have no separation.

1 Everything that falls under 0.3 percent and it says
2 under the Controlled Substances Act that it's legal to
3 ship across state lines.

4 But if your source material is cannabis,
5 Schedule 1, how do you cross over once you develop a
6 product that's 0.3 percent? Can that product now
7 cross state lines if it starts with a Schedule 1
8 product?

9 As far as we understand, it cannot. I've
10 been working two years with the FDA, NIH and DoD
11 trying to find that bridge to cross over. And what we
12 have found is that if the FDA and the DEA don't come
13 together and work with these state programs to capture
14 the data that we have, then we aren't even going to
15 get the true information that we need.

16 Let's see here. Next slide. Any drug
17 developer has to control his raw material. I cannot
18 trust my raw material in the hands of someone else to
19 produce a quality product every time I need it. If we
20 don't have control of our raw material, how can we not
21 have a drug shortage later on? So it's imperative
22 that the industry controls its raw materials. And the

1 bulk manufacturer license that's currently being
2 applied don't apply to industry standards. So we need
3 the FDA to help educate Congress on what is a
4 botanical drug development program and what is
5 research.

6 I'm trying to hurry up. Number four, the FDA
7 don't want us to go around using other people's
8 products without it first being tested. But if
9 there's no bridge to go there, how can we get there?

10 Let me hit number five. Number five is the
11 most critical one to me. FDA and DEA allow foreigners
12 to import cannabis products to the United States for
13 research and development. But there are no pathways
14 for American industry to go. That is not right.

15 As Sue Sisley just said, she's fixing to
16 import from Canada. I'm located in California. We
17 are growing. We are processing and we're treating.
18 Now we need the FDA to come in and help us regulate
19 that because we believe the FDA should be the
20 regulatory agent over this process. That's it.

21 This slide will be put up in 72 hours. So if
22 anyone wants to capture the information, it'll be up

1 in 72 hours. And we just want to thank you for
2 allowing us to stand up here and talk to you for these
3 few minutes. Thank you.

4 MS. CRISTINZIO: Thank you.

5 MR. BRUMFIELD: Oh, okay. No questions.

6 MS. CRISTINZIO: Our next speaker is Guy
7 Chamberland, speaker number 78.

8 MS. MAZLOUM: Hi. I'm Rola Mazloun. I think
9 that's okay. Is that okay?

10 PANEL MEMBER: No. We still can't hear you.

11 MS. MAZLOUM: Hi. I'm Rola Mazloun,
12 regulatory affairs director at Tetra Bio-Pharma.

13 MS. CRISTINZIO: You need to move a little
14 closer to the mic so we can hear you.

15 MS. MAZLOUM: Okay. I'm Rola Mazloun, a
16 regulatory affairs director at Tetra Bio-Pharma. I am
17 here to present you the corporate slides on behalf of
18 Dr. Guy Chamberlain. Next. Okay. To date, Tetra
19 Bio-Pharma has conducted four clinical trials, three
20 of which were Phase I trials and one Phase II trial.
21 Phase I clinical studies assessed safety, tolerability
22 and PK of single and multiple daily doses of cannabis

1 administered by smoke inhalation, vapor inhalation or
2 orally as cannabis oil capsules.

3 Phase II trial was a randomized, double
4 blind, placebo-controlled pilot study followed by an
5 open label extension phase that assessed safety and
6 efficacy of oral cannabis oil in patients with chronic
7 pain.

8 When we look at the PK parameters obtained
9 from Phase I trials, there's no -- there are no
10 significant differences between smoke and vapor. We
11 see that Cmax for both smoke and vapor is reached
12 between 0.5 and 0.17 hours and this was also achieved
13 for both THC and CBD. Obviously we see that PK
14 parameters for oil are much more different.

15 When we compare the THC Cmax obtained from
16 smoke, it is six to 20 times higher than the THC Cmax
17 reported in Sativex. When we look at the THC Cmax
18 obtained from vapor, it is around 12 times higher the
19 THC Cmax reported for Sativex.

20 When we look at the adverse events reported
21 with inhaled cannabis, with smoked cannabis, hundred
22 percent of patients experienced adverse events. There

1 was a dose-related trend that was observed.

2 The most common types of adverse events in
3 single dose were nervous system disorders and multiple
4 dose were euphoria and general disorders. Majority of
5 AEs were mild and considered drug-related. There were
6 some severe adverse events and most common adverse
7 events are listed here.

8 With vaporized cannabis, again, hundred
9 percent of patients experienced adverse events. Most
10 common was euphoric mood, which is the cannabis
11 expected pharmacological effect. Majority of AEs were
12 drug-related and were mild to moderate in severity.

13 In Phase I trial with smoked cannabis, we
14 have also assessed cardiac function following the
15 multiple dose phase. There was a substantial heart
16 rate effect that was observed at five minute time
17 point. That difference ranged between 15.4 and 24.2
18 bpm and it remained elevated 60 minutes post dosing.

19 Neurologic adverse events that were reported,
20 we're talking about dizziness, fainting, headaches,
21 fatigue, somnolence, feeling abnormal. Cardiac
22 adverse events and neurologic adverse events were

1 related to Cmax.

2 And now, if we look at the adverse events
3 with oral cannabis oil, after seven day repeated dose,
4 two out of seven patients experienced at least one AE.
5 All AEs were mild. They occurred and resolved on day
6 one and did not reoccur even with higher CBD
7 concentration throughout the study duration, which
8 suggests a mechanism of tolerance.

9 Now if we look at adverse events and safety
10 data obtained from oral cannabis oil from our Phase II
11 study, here the THC/CBD ratio of interest is 120, with
12 5 mg CBD. There are no observed adverse effect levels
13 while at 5 mg CBD, following a daily consecutive
14 intake for six days. The first time an adverse effect
15 was observed was at day seven with 5 mg CBD.

16 Now again with our Phase I trial with smoked
17 cannabis, for the multiple dosing phase, we have
18 applied a program titration where after multiple
19 dosing for seven days, no adverse events classified as
20 nervous system disorders were reported, where also the
21 negative impact on cognition was not evident after
22 seven days of repeated dose, which also suggests the

1 mechanism of tolerance.

2 So to summarize, with inhalation, we have
3 much more neurologic and cardiac adverse events. With
4 single dose, we have much more neurologic adverse
5 events. And with multiple doses, cardiac adverse
6 events are much more important.

7 Another safety issue that we have to address
8 here with cannabis product and cannabis-derived
9 products is the mycotoxin contamination. Tetra Bio-
10 Pharma detected and quantified mycotoxins in three
11 lots of dried cannabis and one lot of cannabis oil.
12 Levels averaged between 1 and 10 mcg/g.

13 Several screening tools were developed and
14 validated to map out the organism growing on a crop
15 and bulk plant supplies. Tetra has developed also and
16 validated assays to quantify multiple known
17 mycotoxins. We also performed assays on all raw
18 materials as well as finished product and all our
19 supplies of bulk plant material are subject to our
20 monitoring program.

21 Thank you for your attention. I just want to
22 add that complete data will be submitted to the FDA

1 through the confidential path.

2 MS. CRISTINZIO: Thank you. Next we have
3 speaker number 79, Josh Epstein.

4 MR. EPSTEIN: Hello, and thank you. I'm Josh
5 Epstein, from Socati. On screen is a short profile of
6 our company. We're focused on manufacturing broad
7 spectrum hemp extract as an ingredient by investing
8 heavily in science and technology to assure quality
9 and consistency.

10 Consumers rightfully expect CBD-infused
11 products to be made like others they routinely
12 consume, using certified good manufacturing practices
13 and quality standards with validated analytical
14 testing and with enforceable oversight.

15 They rightfully expect labeling that is
16 standardized, accurate, relevant and clear. And they
17 expect important terms such as THC, broad spectrum,
18 full spectrum, isolate to be well defined and
19 universally understood.

20 Consumers, and in fact producers, will also
21 expect FDA to be engaged. Some will want FDA to allow
22 only a pharmaceutical pathway for the regulation of

1 hemp extracts. In our view, this will frustrate
2 consumers and bog down the agency without adding
3 appreciably to product safety. Others may call for
4 the barest minimum of an FDA regulation. A lack of
5 regulation has already begun to trigger a race to the
6 bottom in our view, eroding people's trust and
7 consumer safety.

8 We don't want a race to the bottom. We want
9 a race to the top. The starting line is a regulatory
10 framework that sets a high bar for manufacturing,
11 analytical testing and labeling, encouraging
12 investment in quality, choice and innovation.

13 When it comes to CBD, we recommend that the
14 FDA capitalize on its long experience in regulating
15 foods, beverages and supplements, specifically with
16 respect to these three items, the manufacturing,
17 testing and labeling.

18 The model, in our view, represents the
19 goldilocks zone of regulation that's strong enough to
20 ensure consumer safety, clear enough to empower choice
21 and confidence and flexible enough to promote
22 investment and growth.

1 Sorry about that. Allow me to offer some
2 specifics. First, the FDA should narrow the wide
3 variances in the standards for how CBD companies are
4 now making products, certify their processes through
5 third party validation and protect and ensure the
6 transparency of their supply chains.

7 A good start would be requiring CBD producers
8 to demonstrate quality manufacturing through global
9 food safety initiative recognized certifications.
10 This would assure that every stage of production is
11 both validated and auditable.

12 Certainly the use of CBD extract begs the
13 question how do we validate a product as THC-free,
14 which a lot of other people have touched on today, or
15 full spectrum or isolate or broad spectrum. And there
16 is no standard definition of that right at this point
17 in time and no agreed upon approach to measuring it.

18 The FDA should for example establish this
19 threshold for THC-free and a standard analytical
20 laboratory approach to validate it.

21 In short, consumers should be armed with the
22 information they need, including FDA recommendation as

1 to how much CBD can safely be ingested in a 24-hour
2 period and they need answers on whether and how much
3 consumption may trigger a positive drug test.

4 The first important step is being able to
5 accurately identify the content of products.

6 Accordingly, the FDA should also require appropriate
7 analytical testing and exposure of both the desired
8 and undesired components found in CBD products.

9 For the undesired components such as heavy
10 metals, the regulations governing food ingredients may
11 apply. For desired ingredients, consumers and product
12 manufacturers will want to evaluate the synergies and
13 various compounds found in CBD products, whether it's
14 full spectrum or broad spectrum, the synergistic
15 effects commonly known as the entourage effect. But
16 to do so, again, we must know what's in the products.

17 Overall, we believe the FDA can consider a
18 range of analogs from food, beverage and supplement
19 industries to build a regulatory framework and do so
20 with comparative speed. With that, consumers will be
21 well protected and have their expectations well met.

22 In closing, a legal CBD market is projected

1 to grow exponentially in the coming years. Behind
2 wise and timely regulation, the FDA can both protect
3 and empower consumers while galvanizing and
4 appropriately guiding the inevitable growth of a
5 dynamic new industry. Thank you.

6 PANEL MEMBER: I have a question.

7 MR. EPSTEIN: Yes?

8 PANEL MEMBER: Well, actually a couple of
9 questions.

10 MR. EPSTEIN: Okay.

11 PANEL MEMBER: so the first one, you
12 mentioned a couple of different terms, broad spectrum
13 and full spectrum.

14 Are those -- and I know you said they're not,
15 you know, necessarily defined in the industry. But
16 are you using those terms interchangeable or are they
17 the same or different?

18 MR. EPSTEIN: No. They are different. So
19 broad spectrum -- start with isolate, and I'm sure
20 there are multiple definitions within this room, quite
21 frankly. But isolate is CBD without any other
22 component that came from the hemp plant.

1 Full spectrum is pulling through all of the
2 synergistic compounds, other cannabinoids that other
3 people have mentioned today, terpenes, et cetera, into
4 an extract. That's full spectrum. Broad spectrum
5 would be that, but with THC removed.

6 PANEL MEMBER: Okay. So full spectrum would
7 include THC?

8 MR. EPSTEIN: The residual amounts, correct.

9 PANEL MEMBER: Got it. And is there any -- I
10 mean, is anything removed or is this, you know,
11 literally just extracted from the plant and you don't
12 do anything else with it or do you do some kind of
13 processing, concentrate some things, remove other
14 things?

15 MR. EPSTEIN: Well then it depends on what
16 the manufacturer is producing. So it could be in a
17 tincture where it's diluted with a carrier oil. It
18 could go into all of the other products that you guys
19 have seen people present on today.

20 PANEL MEMBER: So the broad spectrum --
21 because you manufacturer a broad spectrum product,
22 right?

1 MR. EPSTEIN: That's what we're primarily
2 focused on, yes.

3 PANEL MEMBER: So what types of levels of CBD
4 do you see in that?

5 MR. EPSTEIN: In the extract, it's a range.
6 It depends on the starting materials in large part.
7 But ultimately, anywhere -- once you do -- once you go
8 through the entire manufacturing process, the CBD
9 content in the oil will be anywhere from 70 to 90
10 percent.

11 PANEL MEMBER: Just a follow-up question to
12 both of those. You can understand the challenge in
13 creating a standard around something that varies like
14 that.

15 MR. EPSTEIN: Absolutely.

16 PANEL MEMBER: If you have ideas for --

17 MR. EPSTEIN: That's part of what we'll be
18 submitting in our comments, yes.

19 PANEL MEMBER: -- it'd be really useful to
20 have you submit those to the docket just so we -- and
21 then, the other thing was just you had mentioned a few
22 other things, THC-free and other people have talked

1 about full spectrum phytocannabinoids or something
2 like that.

3 If there's a list of these sorts of terms
4 that you feel would benefit from some kind of a
5 standardization, it'd be just useful if we had a full
6 list of the different terms that people are using
7 today.

8 MR. EPSTEIN: Yeah, absolutely.

9 PANEL MEMBER: Thanks.

10 MR. EPSTEIN: Thank you.

11 PANEL MEMBER: Just one last question.

12 MR. EPSTEIN: Yeah.

13 PANEL MEMBER: You also used -- you talked
14 about cGMPs as well. Are you seeing that most
15 manufacturers are actually following the cGMPs in this
16 space?

17 MR. EPSTEIN: No. Thank you.

18 MS. CRISTINZIO: All right. Moving onto our
19 next manufacturer, number 80, Bill Grubb.

20 MR. GRUBB: Good afternoon. I'm here this
21 afternoon representing Noramco. We are a cGMP active
22 pharmaceutical ingredient manufacturer. We're

1 registered with the FDA and DEA at our facilities in
2 Wilmington, Delaware and Athens, Georgia.

3 We supply around -- materials registered
4 under around 24 U.S. DMFs and then other registrations
5 around the world. We supply our products into 40
6 countries. And again, that's active pharmaceutical
7 ingredient, not drug product.

8 For 12 of the -- oh, sorry. For 12 of the 40
9 years that we have been in existence, we've been
10 manufacturing cannabinoids, again under a U.S. DMF.
11 And that's up on my slide, the DMF number. Sorry.
12 Didn't realize it hadn't advanced.

13 If you look at Noramco today, we actually
14 produce 30 -- over 30, around 35 individual
15 cannabinoids that are used in pharmaceutical, clinical
16 or analytical testing applications. And again, those
17 are produced using validated analytical methods and
18 procedures described in our SOPs.

19 More specifically to CBD, as described in our
20 drug master file that's listed up on the screen there,
21 33223, we manufacture CBD synthetically using well-
22 characterized regulatory starting materials. We also

1 test our material with validated analytical methods as
2 described in our DMF on file with the FDA.

3 So while our approach does implicitly mean
4 that we're not looking out for pesticides or heavy
5 metals from the soil or plant impurities, I still
6 think that we have a lot of common ground with people
7 that are talking here today related to the principles
8 that should apply to extractors or people who are
9 producing CBD synthetically.

10 Some of this has been covered today and so I
11 won't go back through it in quite as much detail as I
12 was planning. But unfortunately there's a lot of
13 mislabeled or misrepresented CBD in the marketplace.

14 And so, I selected specifically a reference
15 from 2017, 2018 and 2019, all from peer-reviewed
16 journals or respected government agencies like the CDC
17 to say, you know, that there is a need for specific
18 federal oversight to guarantee consumer safety and to
19 make sure that frankly people know what they're
20 taking.

21 To me, the simplest way to get there -- and
22 this has bene covered in some instances today -- is to

1 follow codified cGMPs that exist for foods,
2 supplements and for drugs.

3 And Noramco's position and what we're
4 entering in is a comment and we'll upload our
5 information in more detail to the portal is that
6 whether the CBD is extracted or synthesized, whether
7 it's intended as a drug, a food or a supplement and
8 whether -- you know, we're agnostic to the delivery
9 mechanism because that's not our role.

10 But if it's oral, topical or inhaled, we
11 believe that CBD -- I mean, cGMP regardless of which
12 one of those is very, very important for public
13 safety.

14 Our next comment is that while the
15 Agricultural Improvement Act, or the Farm Bill, says
16 0.3 percent might be okay for agricultural products,
17 we don't believe that to be true.

18 We think that 0.1 percent, as noted in the
19 references that are on the screen, the FDA's own
20 assessment, the World Health organization's expert
21 committee on drug dependence is certainly less than
22 the 0.3.

1 And if you just follow ICH guidelines for
2 control of related substances and impurities, 0.1
3 percent makes sense. And so, that, you know, is
4 something that we really do believe in. And we're
5 able to produce that as are others that have reported
6 today. And so, we feel that it should be adopted as a
7 standard.

8 In practice, as it says on the slide, you
9 know, we're around 10 parts per million, or 0.001
10 percent. And we've submit in our DMF a limit of 0.10.

11 Tightly controlling related substances is
12 very important and I think that whether you're
13 extracting or synthetic, following ICH guidelines for
14 the control of related substances is very important
15 and assures public safety.

16 We ourselves down to a limit of quantitation
17 of 0.02 percent, have five batches that we
18 manufactured this year shown at commercial scale that
19 have no detection of total impurities.

20 End product label accuracy, consumer or
21 drugs, depends on a pharmaceutical ingredient that has
22 undergone rigorous stability testing. And again, we

1 test our research and commercial batches under an ICH
2 stability guideline and we report those results in our
3 DMF. I'm showing some publicly here today just to
4 demonstrate the point that very close to the actual
5 melting point of CBD, crystalline solid, 40 degrees
6 Celsius at 75 percent relative humidity, you can have
7 a stable product.

8 Finally and in closing, I've summarized our
9 points here, as well as one I didn't make regarding
10 working with the USP. But we do believe that
11 regardless of the method of production, the intended
12 use for drug, foods or supplements that patients and
13 consumer deserve a CBD that's produced according to
14 GMP and that's tested for identity, purity, quality
15 and strength. Thank you.

16 PANEL MEMBER: You mentioned on slide three
17 several advantages to synthetic CBD compared to
18 botanically derived, less variability, fewer
19 contaminants. Are you aware of any risks in
20 synthesizing CBD relative to botanicals?

21 MR. GRUBB: No, I'm not. And I'm not because
22 these are -- you know, it's well characterize CBD.

1 It's described in a DMF. It's included in clinical
2 trials. And we're going through validated test
3 methods and procedures to assure that it really is
4 CBD.

5 PANEL MEMBER: What challenges do you
6 encounter in synthesizing it that might be either a
7 barrier to entry or might be a reason why others might
8 not be able to follow suit commercially?

9 MR. GRUBB: Frankly our biggest challenge
10 right now is that if you grow and extract hemp in an
11 unregulated manner, you're not subject to DEA
12 controls, and we are.

13 That is our single biggest challenge is that
14 we're making a very pure product that's under the
15 purview of the FDA and registered facilities and even
16 DEA-registered facilities because both of ours are.
17 But it's not a very level playing field since last
18 December. Thank you.

19 MS. CRISTINZIO: Thank you. Our next
20 speaker, speaker number 81, is Deb Kimless.

21 DR. KIMLESS: So how do we do the slides?

22 MS. CRISTINZIO: Just one second. We're

1 almost there.

2 DR. KIMLESS: There we go. Hello, and thank
3 you for this opportunity to present to you today. My
4 name is Dr. Deborah Kimless, and I'm a 25-year, board-
5 certified anesthesiologist and pain medicine
6 specialist. I'm here on behalf of Pure Green, a
7 licensed medical cannabis processing company in
8 Michigan.

9 I was confident to try sublingual CBD with
10 patients because of Pure Green's processes and
11 procedures. And what I learned is that Pure Green
12 sublingual CBD was safe and effective treatment option
13 for my patients. And while I've presented our
14 clinical data in many scientific forms, never in this
15 short amount of time.

16 So I do regret that I can only present a high
17 level summary to demonstrate that data does exist to
18 help the FDA gain insight into safety and efficacy of
19 sublingual CBD products manufactured under a state-
20 regulated program. And I'll describe how an
21 integrated approach achieves this goal.

22 So the clinical data. Six pilot clinical

1 trials were run in diverse populations with symptoms
2 including PTSD, opioid dependency, insomnia, anxiety
3 and pain and all with positive results. I will report
4 here on one of those trials, the pain trial.

5 So we had a 16-patient trial with mild to
6 moderate chronic pain that was being treated with
7 NSAIDs. The average starting pain scale score was 5.2
8 on a scale of zero to 10.

9 The data demonstrates clinically and
10 statistically significant pain reduction most
11 beginning within eight minutes of taking the
12 sublingual tablet where the average pain scale score
13 dropped by more than 50 percent.

14 Pain relief routinely lasted four to six
15 hours, sometimes over a 24-hour period, without
16 adverse effects. In fact, the one side effect that
17 was reported by the majority of patients was an
18 overwhelming sense of wellbeing. We're currently
19 running a follow-up multicenter clinical trial with an
20 n greater than 16 and we're also doing PK tests.

21 The tablet. Patients were given a 5 mg CBD
22 sublingual table that also contains terpenes. The

1 patent-pending formulation renders the tablet water
2 soluble to enhance bioavailability. A 20 mg
3 sublingual CBD iteration of this tablet has been on
4 sale in Michigan because the company Pure Green was
5 granted the first state medical cannabis processor
6 license.

7 The tablet is manufactured under a validated
8 GMP production conditions and each batch is tested by
9 an independent testing lab guaranteeing every batch to
10 have accurate and reliable dosing.

11 The entire tablet processing method and API
12 processes method is fully regulated, meets good
13 manufacturing practices and is tested throughout the
14 production life cycle for potency, residual solvents,
15 heavy metals, microbials and pesticides by the state
16 licensed independent testing laboratories.

17 The vertical integration of the business
18 lines ensures complete beginning to end product
19 quality control. Pure Green was one of the first
20 Michigan medical cannabis state licenses and because
21 of this they've obtained pharmacovigilance data in
22 nearly 500,000 dosages in just 10 months.

1 And it can be concluded that this sublingual
2 form of CBD was well tolerated, safe and effective.
3 And in fact, the only two side effects that were
4 reported, one in less than 1 percent of the
5 population, was transient drowsiness and then, from
6 the pain trial, where patients claimed an overwhelming
7 sense of wellbeing. And we're prepared to submit
8 additional proprietary data to aid the agency in
9 deliberations.

10 And here's a picture of a labeled box that
11 contains a similar narrative to what you would see
12 with a traditional over-the-counter pain reliever. We
13 believe that with CBD safety and efficacy, a parallel
14 pat can coexist, the traditional FDA drug path along
15 with the current regulated state programs.

16 We appreciate the FDA considering this CBD
17 presentation and thank you again for your time and
18 consideration.

19 PANEL MEMBER: Thank you, and look forward to
20 seeing your data. Out of curiosity, what's
21 overwhelming sense of wellbeing and how is it
22 measured?

1 DR. KIMLESS: It was a statement in the notes
2 section in their -- when they were submitting them on
3 the app. We have a smartphone app that patients who
4 are identified get to enter it in. And in the notes
5 section, many say they had a feeling of wellbeing or
6 overwhelming feeling of wellbeing or incredible sense
7 of wellbeing. Thank you.

8 MS. CRISTINZIO: Thank you. Next up, we have
9 Douglas MacKay.

10 DR. MACKAY: Hi. My name is Douglas MacKay.
11 I'm scenarios vice president, scientific and
12 regulatory affairs, for CV Sciences. I think there's
13 one thing that we can all agree is very clear. You
14 guys have a really tough job ahead of you. It's going
15 to be really hard to manage this diverse set of
16 viewpoints and good luck with that.

17 CV Sciences operates two distinct divisions.
18 The consumer division delivers hemp products through
19 its Plus CBD oil brand and we also have a
20 pharmaceutical division that's pursuing an FDA-
21 approved drug. Responsible industry fully embraces
22 robust FDA regulation.

1 An appropriate and predictable regulatory
2 framework protects consumers while allowing a pathway
3 for companies to lawfully market various types of
4 cannabis-derived products. Industry applauds FDA for
5 the significant work done so far to respond to this
6 rapidly changing environment.

7 USDA and FDA have been tasked with developing
8 regulations that separate an agricultural commodity
9 from a controlled substance. Let me repeat that. You
10 have to separate an agricultural commodity from a
11 controlled substance.

12 Responsible industry strongly encourages that
13 FDA and USDA closely collaborate to ensure that the
14 corresponding regulations are synchronized to
15 efficiently differentiate the hemp and marijuana
16 supply chains.

17 International hemp regulatory models apply a
18 seed licensing and registration scheme that assures
19 that only appropriate food, fiber hemp cultivars are
20 used as a raw material source for the hemp-based
21 industries.

22 A verified food fiber hemp supply chain

1 provides a safe, non-intoxicating botanical starting
2 material. Hemp can be safely regulated by FDA like
3 other natural ingredients. Current FDA regulations
4 allow naturally derived ingredients to coexist as
5 conventional foods, dietary supplements and drugs.
6 This slide provides examples of different ingredients
7 derived from the same natural resource being
8 appropriately marketed in different lanes.

9 CV Sciences suggests that FDA rulemaking is
10 not required if FDA provides clear industry guidance
11 to the type and scope of hemp ingredients allowed in
12 each FDA-regulated category.

13 For conventional foods, FDA has completed
14 three GRAS notices for hemp seed derived ingredients.
15 The food pathway is clear for companies that want to
16 use nutrient-rich components of hemp in food or to
17 develop new ingredients.

18 The drug regulatory pathway is also clear for
19 companies that want to develop new drugs or new
20 botanical drugs to treat different diseases. For
21 supplements, FDA has been clear that highly purified
22 and isolated CBD can't be added to food or dietary

1 supplements.

2 However, scientific and legal experts agree
3 that a hemp extract containing a full array of
4 cannabinoids and other plant constituents is a
5 significantly different article than a highly purified
6 CBD.

7 Each has a unique identity and a unique
8 biological activity. CV Sciences suggests an FDA
9 guidance that differentiates a hemp extract from a
10 prescription CBD will allow companies to
11 confidentially file the requisite NDI notifications.

12 Today, FDA has made a broad request for data
13 on cannabis safety. To satisfy this request, one must
14 first qualify the specific composition of the
15 cannabis-derived ingredient and, second, the intended
16 use of the ingredient. Cannabis or hemp product
17 safety is based on the chemistry of the ingredient and
18 the intended use.

19 FDA regulations, when evaluated holistically,
20 provide an appropriate framework to regulate cannabis
21 for different intended uses. A product intended to
22 treat children with epilepsy is a drug and it should

1 come with the pre- and post-market rigor of FDA-
2 approved drugs. However, a food product that provides
3 nutrition or a supplement that supports a healthy
4 lifestyle have regulatory paradigms that appropriately
5 correspond with those uses.

6 CV Sciences looks forward to submitting
7 detailed written comments to share our experience
8 working with hemp. Time constraints will only allow
9 me to share a few ways that we ensure we provide
10 consumers with safe and high quality hemp products.

11 We start with a food fiber hemp cultivar from
12 a licensed and registered hemp seed. We establish the
13 identity of our ingredients through technical
14 analysis. We have published in the peer-reviewed
15 literature the appropriate toxicology studies on our
16 ingredient. Those are available on PubMed and I will
17 submit them to the docket.

18 We also manufacture in a third party GMP-
19 verified facility and we are compliant with labeling
20 and marketing regulations, as well as adverse event
21 reporting and recordkeeping requirements.

22 In closing, I want to emphasize that

1 responsible hemp companies and FDA have a shared goal
2 of protecting consumers while providing access to
3 appropriate hemp products. Thank you for this
4 opportunity to share our experience and we look
5 forward to providing more substantive written
6 comments, and I'm open to questions.

7 (Applause.)

8 PANEL MEMBER: It's interesting that you sort
9 of outlined three different pathways, which obviously
10 we're familiar with. But -- and the fact that you
11 believe -- seem to believe strongly that they coexist.

12 And I guess one of my questions is do you see
13 any of them disincentivizing sort of the other, in
14 other words, allowing a broader use disincentivizing
15 the ability to complete clinical trials. We've heard
16 a little bit about that today.

17 MR. MACKAY: Yeah. I mean -- yeah. So if --
18 with all due respect, the pharmaceutical companies
19 have gone through the investment and gotten the drug
20 improved. The provision that is in place that says we
21 can't introduce that to the food supply.

22 So isolated CBD in my humble opinion,

1 isolated CBD and THC are off limits. But we have hemp
2 extracts. And defining a hemp extract, establishing
3 the safety of the hemp extract, understanding the
4 level of cannabinoids and other constituents in that
5 product is what we do in botanical medicine under the
6 current regulatory paradigm -- excuse me, botanical
7 dietary supplements. That was a slip. I didn't mean
8 to say medicine.

9 You know, it's all there is what I'm trying
10 to say. But yes, I think if we allow isolated
11 crystalline CBD to be free-flowing in the food space,
12 it disincentivizes additional research.

13 PANEL MEMBER: And so how are you defining
14 hemp extract and what levels of CBD and THC are you
15 seeing in that?

16 MR. MACKAY: Well, the levels of CBD are
17 depending on not only extraction method, the plant
18 starting material, but also the data we have on
19 safety. Those are all guiding principles.

20 I know you're dying for a number. Our
21 product has about 15 mg per soft gel in it and that's
22 what was supported by our safety studies.

1 PANEL MEMBER: In any of your comments, do
2 you explain the taste, aroma, nutritive value or
3 technical effect that these extracts would have in a
4 conventional food?

5 MR. MACKAY: So I have similar questions
6 about the appropriateness in conventional food because
7 of the lack of those properties. There's some
8 indications that CBD does have a bitter taste similar
9 to caffeine.

10 So we might have a taste and there may be
11 some technical effects that might be reasons to add it
12 to food. But I haven't seen frank, clear arguments
13 about how it could be or why it could be a food
14 product. And my company hasn't gone down that pathway
15 for those reasons.

16 MS. CRISTINZIO: Thank you. Our next speaker
17 is number 83, Ray Mannion.

18 MR. MANNION: Good afternoon. My name is Ray
19 Mannion, vice president of manufacturing with Zynerba
20 Pharmaceuticals, located in Devon, Pennsylvania. On
21 behalf of the entire Zynerba team, I'd like to thank
22 FDA for the opportunity to present at today's public

1 hearing.

2 There's an established FDA commitment to
3 quality and safety of cannabinoid products. FDA has
4 previously approved drugs containing CBD and THC,
5 thereby ensuring comprehensive oversight of the
6 products. The 2018 Farm Bill explicitly preserved
7 FDA's authority to regulate CBD products in
8 furtherance of the agency's mandate to protect the
9 public health.

10 All cannabinoid products should be held to
11 the same rigorous quality, safety and efficacy
12 standards established by FDA to protect the public.
13 The current landscape is marked by, one, proliferation
14 of cannabinoid-containing products and, two, confusion
15 about the legality of distribution and differences
16 between federal and state regulatory oversight of
17 cannabis and cannabinoids.

18 There are established risks with non-FDA-
19 regulated cannabis. Lab analyses demonstrate that
20 some non-FDA-approved, commercially available CBD
21 products do not contain what is listed on their
22 product labels. FDA's independent lab testing has

1 shown similar results.

2 In addition, CBD product testing has shown
3 the presence of THC at levels which may be sufficient
4 to produce a negative euphoric effect, particularly
5 among children. Common cannabis contaminants include
6 microbes in the form of bacteria and fungi, heavy
7 metals and pesticides.

8 Microbial contamination may occur during
9 improper preparation and storage of cannabis products
10 and can result in infections. Heavy metal
11 contaminants may be attributable to soil fertilizer
12 and/or cross-contamination during processing.
13 Pesticide use in the cultivation of cannabis products
14 is well established.

15 FDA should therefore continue to enforce
16 pharmaceutical compliant cGMP processes and testing
17 standards to ensure product quality and safety for all
18 commercially distributed cannabinoid products.

19 Pharmaceutical product development, evaluation and
20 processes are well defined in FDA and international
21 guidelines.

22 Testing limits and controls for each stage of

1 product development are established. Existing
2 pharmaceutical development, manufacturing and quality
3 assurance processes ensure product quality, label
4 accuracy and minimize the risk to public safety.

5 FDA should therefore continue to leverage the
6 existing robust regulatory framework in the oversight
7 of cannabinoids. There exists the FDA regulatory
8 oversight guidance, review and inspection and within
9 that, the good manufacturing procedures regulations,
10 the International Conference on Harmonization
11 Guidelines, U.S. Pharmacopeia and national formulary
12 standards and finally drug product track and trace
13 requirements.

14 Product quality manufacturing controls ensure
15 product identity, purity, strength, quality and label
16 accuracy. It's important to consider the control of
17 raw materials, solvents, the impurities, herbicides,
18 pesticides and fungicides.

19 Documented manufacturing processes and end
20 process testing are important considerations, as are
21 microbial testing, as is microbial testing to ensure
22 that acceptable levels are not exceeded. And then

1 finally, controlled storage conditions on this aspect
2 can safeguard against the impact of moisture like
3 packaging and oxygen exposure. Product stability and
4 shelf life testing is also a consideration.

5 In summary, FDA has a well-established
6 history of protecting the public health. Existing
7 regulations and processes governing the manufacture of
8 pharmaceutical products establish critical controls to
9 ensure necessary quality and safety standards are met.

10 This robust framework can and should be
11 leveraged in the regulation of all cannabinoid
12 products. Less stringent manufacturing and quality
13 standards would create an unnecessary public health
14 risk. Thank you. Any questions?

15 MS. CRISTINZIO: Thank you very much. We are
16 now on speaker number 84, Rosemary Mazanet.

17 DR. MAZANET: Good afternoon. I'd like to
18 tell you a little bit about Columbia Care. Columbia
19 Care is U.S.-based medical cannabis company. We're in
20 14 states. We're also in Europe now. We're licensed
21 for medical cannabis. We are largely vertically
22 integrated in each of those states. And the reason

1 why we have always been vertically integrated or made
2 every attempt is to control quality.

3 We learned early on that it was really
4 impossible to have a -- to understand what your
5 product really had been through unless you grew it,
6 manufactured it and had sort of chain of custody
7 throughout the whole situation in most states.

8 We are in states that largely are regulated.
9 We're in New York. In some states like New York, we
10 have a DEA Schedule 1 license around our manufacturing
11 plant. In some states like Florida, all of our
12 manufacturing is GMP. So we try to be as compliant as
13 we can with having very high standards for manufacture
14 in the medical cannabis space.

15 And the reason for that is because we are
16 undertaking more than a dozen IRB-approved trials in
17 the United States and Europe to try to look at
18 efficacy in these products. And we believe strongly
19 that you have to have the same product. You have to
20 eliminate variables if you're going to do any
21 meaningful research. So we have very formulated
22 products and those are what we test in patients,

1 apples to apples. We're not big fans, as you might
2 imagine, of flower because we feel that it's very hard
3 to have a dosable product.

4 So I'm a HemOnc by original training. I
5 actually have done drug development my whole life and
6 I became involved with Columbia Care back in 2013
7 because they were interested in doing clinical trials
8 with formulated dosable products in as many patients
9 as possible in the United States. And that's what
10 we're about.

11 But what I'm here today to talk about is
12 hemp, hemp CBD because we believe that that's an
13 important medication. Epidiolex has shown us that it
14 has a lot of potential. We're actually doing trials
15 globally with a high dose CBD formulation in psychosis
16 out of King's College, London. But again, quality is
17 really the issue here that we're concerned about.

18 I'm telling you something that you've heard
19 all day. I apologize for that. But I'm going to say
20 it again. Okay. We know, going back to 2015, the
21 first publication in JAMA that said that greater than
22 15 percent of the products evaluated had significantly

1 less cannabinoid content than labeled. Okay. You
2 know, that was 2015.

3 So we have another publication in 2017 that's
4 more disturbing. Only 31 percent of CBD extracts were
5 labeled correctly. Sixty-nine were labeled -- or 69
6 percent were labeled incorrectly. Forty-three were
7 under-labeled. Twenty-six were over-labeled. And
8 some of those actually had THC in them. So this is
9 pretty alarming if you actually read that JAMA paper.
10 There was THC in a good number of those products that
11 were sold as a CBD extract.

12 Now what that shows is just that people are
13 lazy. People will do an extraction of whatever plant
14 they have and they'll sell it. And until somebody
15 tells them that they can't do that, they will continue
16 to do it.

17 This past year, Forensic Science
18 International had a study that was published looking
19 at again not just contaminants. We're not talking
20 about microbes here. We're not talking about heavy
21 metals. We're talking about things that during the
22 manufacturing process, chemicals that got into that

1 product that shouldn't have been there.

2 And some of that was dextromethorphan, which
3 really is quite interesting when you think about how
4 that would have gotten into CBD extracted product.
5 Again, there were no quality assurances to make sure
6 that that happened.

7 You know, the national news has picked up on
8 this, the Philadelphia Inquirer, some Alabama papers.
9 But again, you know, I think the fact that potentially
10 dangerous CBD is sort of getting into the news is
11 something that should concern us all. And I think to a
12 large extent that's why we're here today.

13 You know, we're trying to make a legitimate
14 business out of the medical products that might be
15 available in the cannabis plant. And so, we need to
16 be credible and we need to get away from some of the
17 fantastic, if you will, things that we read.

18 There was a large study done in California
19 recently. I want to point out here that there are two
20 products that had absolutely no CBD in them at all.
21 If I were a parent of a child that had a seizure
22 disorder and I was not eligible for reimbursement to

1 receive Epidiolex and I was buying CBD, this would
2 make me sick. This is just really sad when we think
3 that there are people that rely on these medicines.

4 So moving forward, again, I think, you know,
5 singing again to the choir here, that the FDA guidance
6 should protect safety. GMPs should be required.
7 There should be standards for the levels in food and
8 dietary supplements. There should be labeling
9 requirements. And there should be restrictions on
10 disease claims. And thank you for being able to
11 present today.

12 PANEL MEMBER: Are you -- is your submission
13 -- does it propose specific levels for food and
14 dietary supplements? And if so, does it take into
15 account exposure across a broader -- a wide array of
16 products?

17 DR. MAZANET: We actually have many
18 formulated products that may differ because of that.
19 So I think when we put in some formal comments, I can
20 address that, yes. Thank you.

21 MS. CRISTINZIO: Thank you. Next up, we have
22 speaker 85, Alice Mead.

1 MS. MEAD: Good afternoon. I'm Alice Mead,
2 from GW Pharmaceuticals. We're here to express our
3 support for a strong and comprehensive regulatory
4 framework that first and foremost further encourages
5 development of cannabis-derived medications for
6 serious and life-threatening illnesses.

7 Next, ensures that CBD consumer products can
8 be safely used in a mass market setting that lacks
9 physician oversight. And finally, establishes clear
10 differentiation in dosing and concentration levels
11 between FDA-approved medicines and consumer goods.

12 We've seen that cannabis-derived derived
13 medications can change lives. Epidiolex is not only
14 the first cannabis-derived medication approved by the
15 FDA. It's brought new hope to thousands of families
16 with loved ones suffering from two life-threatening
17 forms of epilepsy, Dravet Syndrome and Lennox-Gastaut
18 Syndrome. And we're just scratching the surface with
19 Epidiolex.

20 There's tremendous potential in this plant to
21 treat many more severe illnesses. GW is researching
22 eight different disease areas. We're leading the way.

1 But without greater incentives, few companies will
2 follow us down the FDA pathway.

3 So why dose FDA approval matter? Because the
4 FDA approval process is the only way to answer
5 important questions about a drug, about the disease it
6 seeks to treat and safety considerations that are
7 unique to the patients who will take the drug.

8 For example, no one knew CBD is potentially
9 toxic to the liver until we conducted clinical and
10 preclinical studies. To answer such questions, we've
11 spent the past 20 years researching this plant.

12 Along the way, we've built an extremely
13 comprehensive scientific database on CBD. We know
14 that CBD causes drug-induced liver injury. Therefore
15 physicians are instructed carefully to monitor liver
16 function with blood tests when treating patients with
17 Epidiolex.

18 We also know that CBD has powerful drug-drug
19 interactions with other medications like warfarin, a
20 common blood thinner. This can cause these other
21 drugs to have stronger or weaker effects than
22 intended.

1 GW and non-GW studies alike tell us that CBD-
2 rich extracts can cause a number of other side effects
3 such as sleepiness, which can be a problem when
4 driving.

5 That brings me to the issue of unknowns.
6 There is still so much we do not know about CBD. It
7 has not been tested in a number of vulnerable patient
8 populations such as pregnant women and patients over
9 55. In fact, concerns about fetal toxicity in lab
10 rats prompted FDA to require us to do more studies in
11 fetal toxicity.

12 Our research shows that negative side effects
13 from CBD begin to appear at 1 mg/kg of body weight, or
14 about 70 mg per day for an average adult. These side
15 effects appear at relatively low levels probably
16 because CBD affects multiple systems in the body. And
17 people will ingest CBD from multiple sources. And
18 therefore there should be wide safety margins when
19 setting concentration limits and daily serving levels.

20 That brings me to my last point, which I
21 guess I should have been clicking all this time,
22 shouldn't I? My last point is THC. It's a myth that

1 CBD products will have only trace amounts of THC.

2 The 0.3 percent limit from the Farm Bill
3 could be interpreted to allow, for example, a small
4 gummy bear to have as much as 12 mg of THC. That
5 means that two gummy bears could deliver more THC than
6 smoking an entire marijuana cigarette.

7 In closing, we recognize that there are
8 patients suffering from serious ailments outside of
9 Dravet and LGS who feel as though in the absence of an
10 approved cannabis medication, using unapproved
11 cannabis products is their only option. But this is
12 not ideal.

13 That's why we support a strong regulatory
14 framework for cannabis products that encourages robust
15 research, maintains the integrity of the FDA approval
16 process for medicines and brings more FDA-approved
17 medicines to patients. Thank you.

18 (Applause.)

19 MS. CRISTINZIO: So we have a slight change
20 in the agenda here, and I'm sorry it's not reflected
21 in the printed version that you have. We have number
22 85a, as you see, Mr. Marwan Moheyeldien presenting

1 from Maryland Packaging next. And then, after him, we
2 will resume in numerical order. Thank you.

3 MR. MOHEYELDIEN: Thank you so much. My name
4 is Marwan Moheyeldien. I'm the CEO of Maryland
5 Packaging and COO of Fuchsia Foods. Maryland
6 Packaging is the largest food co-manufacturer in the
7 mid-Atlantic. I'm sorry. One second to advance.

8 So we're the largest co-manufacturer in the
9 food. We manufacture for Fortune 100 companies. We
10 manufacture for startup brands. We've been in
11 business since 1983. We produce food and beverage
12 that are consumed by millions of consumers on a daily
13 basis.

14 Maryland Packaging is PCQI-certified, FDA-
15 registered for 20 years without a single violation,
16 USDA legend facilities, two of them in the state of
17 Maryland, SKF-certified, preventive control program-
18 compliant, food defense-compliant, Homeland Security-
19 certified. We are kosher. We're halal. We're
20 organic. We're third party-audited. We are HPP
21 authority. We are HARPC-compliant, HACCP-compliant
22 and certified FSMA-compliant and certified and we are

1 GMP-certified. So I think we can say that we are very
2 heavily regulated and we're very heavily compliant.

3 We came across CBD because we have a
4 tremendous amount of clients that are coming to us to
5 be able to start manufacturing products for them with
6 CBD. When we looked at the model of being able to
7 manufacture for these clients, we started realizing
8 very quickly that we have two issues that we have to
9 deal with.

10 One of them is how are we going to ensure
11 that the product that we are going to manufacture is
12 going to be safe. And number two, how are we going to
13 make sure that the product that is being received by
14 us to manufacture is going to be safe?

15 On our Fuchsia website, which is our own CPG
16 brand, we decided that we were going to actually put a
17 claimer that says our stand is very clear on CBD. We
18 take the same stand as the FDA.

19 And we posted the paragraph that the FDA came
20 up with stating that it is considered -- if it's being
21 sold as any kind of medicinal purpose, it is a drug
22 and should be sold as such. And if it's being sold,

1 it's basically illegal.

2 So what did we decide on doing to be able to
3 make sure that we are compliant? One thing that we
4 know is the following. The industry is so large, it's
5 right now \$600 -- I'm sorry, it's \$600 million
6 industry. And it's going into \$2 billion in the
7 retail industry.

8 We've had multiple meetings with the health
9 department from the state of Maryland which complies
10 for the FDA. The actual meeting with the health
11 department when they came and sat with me and they
12 said, well, you have to be careful because the FDA has
13 not approved for you to manufacture. So when you
14 submit the labels, we're going to take the same stance
15 with the FDA that you can't manufacture it.

16 And my response to them, well, under Consumer
17 Protection Act and as a consumer, I'm going to ask the
18 FDA to go in and basically recall anything on the
19 shelf in the state of Maryland if you're telling me
20 that it's illegal to supply it or illegal to sell it.
21 The response was you're giving us anxiety. Well, you
22 know, I'm sure we are.

1 But at the end of the day, if the FDA -- I've
2 been down this. We're the largest HPP facility in the
3 Mid-Atlantic. And when we started the HPP, we had the
4 same arguments with the FDA. Eventually I became the
5 foremost authority on HPP in the Mid-Atlantic and I
6 became the CASA speaker on behalf of the government as
7 well as the FDA.

8 All we are asking for is we are asking for a
9 fair, level playing field. We intend -- if we are
10 going to use CBD and we're going to manufacture it,
11 it's very simple to be able to control it.

12 Our interest is any kind of CBD that we bring
13 in to use in our manufacturing, we're going to have it
14 tested for pesticides, heavy metal, confirm that it is
15 0.3 -- below 0.3 THC, not 0.03. I'm going to have to
16 talk to my people -- accurate CBD measurements as
17 advertised.

18 Once we find out that the product that we
19 plan on using complies, then we will use it in
20 manufacturing. Before our product is released, our
21 lot number will go to a third party laboratory to be
22 able to confirm the same exact parameters. That COA

1 from the lab would be published on the Internet for
2 inspection by any government agency and any consumer.

3 All we want to do is we want to make sure
4 that we are a responsible manufacturer in the
5 industry. But we have to have a path. We have to
6 know where you guys are going to stand because if we
7 receive a letter telling us that we can't operate
8 under any circumstance, we expect you to do the same
9 thing with every other manufacturer.

10 The last thing is my concern is if we don't
11 have a provisional kind of license allowing
12 manufacturers or responsible manufacturers like us to
13 operate, all the FDA is going to do is going to drive
14 those manufacturers underground and you're going to
15 have a black market to be able to put this product in.
16 You can't control the product on the shelf. And as
17 long as people want it, people are going to
18 manufacture it.

19 So my request is to be able to find a path
20 for a provisional license for certain companies that
21 meet certain criteria to be able to manufacture and we
22 will self-police ourselves under the supervision of

1 the FDA or any agency that chooses to regulate us.
2 But we want regulation and we welcome it. So please
3 find a path for us to be able to provide safe products
4 for the consumer.

5 MS. CRISTINZIO: Thank you.

6 MR. MOHEYELDIEN: That's it. Thank you.

7 MS. CRISTINZIO: Next, we have speaker
8 number 86, Stephen Mueller.

9 MR. MUELLER: My name is Stephen Mueller.
10 I'm the founder and CTO of Mile High Labs. Mile High
11 Labs is a largescale hemp extraction and purification
12 company that produces thousands of kilograms of CBD
13 every month. Through our customers, that CBD goes
14 into maybe 10 million products every month.

15 Our production facilities and headquarters
16 are in Colorado. We also have international offices
17 in the UK and New Zealand.

18 You know, we really believe in and are
19 committed to and have invested in this industry in a
20 really significant way. We employ more than 130
21 people. We've spent many tens of millions of dollars
22 on hemp that has gone to American farmers. We've

1 spent tens of millions of dollars on equipment and
2 infrastructure.

3 So our company is really focused on
4 manufacturing of CBD ingredients. And that starts
5 with our process expertise and our engineering team.
6 And we've designed and built largescale customized
7 extraction and purification equipment that
8 specifically is tailored to this industry.

9 The second key component of our manufacturing
10 is our commitment to quality and compliance. We
11 manufacture according to GMP standards, 21 CFR parts
12 111 and 117 and we've been audited by third parties
13 for compliance to these GMPs. We have strict
14 specifications on all incoming components and finished
15 products and each material is tested using validated
16 in-house methods for compliance and specification.

17 You know, this has been talked a lot about
18 today. But the size of the CBD market is exploding
19 right now. Many other presenters have talked about
20 that today. But it's estimated that up to 64 million
21 Americans have used CBD in the past 24 months. So
22 regardless of the existing regulations, this thing is

1 taking off and we really want to make sure that it's
2 done in a way that's safe for the consumer.

3 You know, here are some of the common issues
4 that we see in the market, and these have kind of been
5 covered as well. Mislabeled products. Some of the
6 presentations I saw today were pretty astounding in
7 terms of just how mislabeled they are. Facilities
8 that aren't operating under GMPs. This is one of the
9 biggest issues that we see out there.

10 If you don't have the proper controls in
11 place per the GMP guidelines, you're really at risk of
12 shipping unsafe product to the consumer. And many
13 manufacturers don't have access to accurate test
14 methods, either in-house or through contract labs.

15 The level of inconsistency that we've see
16 with some of the contract labs and third-party labs is
17 really -- is pretty astounding.

18 So one of the problems today is that a lot of
19 the manufacturers don't actually understand what they
20 need to do to make a safe and consistent product for
21 the consumer. Consumers also don't have confidence in
22 the products themselves and don't understand which

1 manufacturers they can look to, to buy a safe product.

2 And really, our position is that the good
3 manufacturing practices already outlined by the FDA
4 are really the baseline for production of a quality
5 and consistent ingredient and we think that this
6 should be applied to all CBD manufacturers.

7 So new dietary ingredient notification should
8 also be required for all CBD dietary supplements.
9 This is already outlined in FDA guidelines and we
10 think that CBD fits into those existing guidelines.

11 The main focus of the discussion today seems
12 to be around CBD. But a lot of the products on the
13 shelf also contain many other compounds, so other
14 cannabinoids, terpenes, degradants and we think that
15 the FDA should evaluate all of these separately
16 instead of trying to combine all of the non-THC
17 products under one category. I think there's so much
18 variability in the types of products out there that
19 it's very difficult to regulate or to control
20 consistency of the product. We can isolate and purify
21 these compounds and formulate products with them that
22 are more consistent.

1 So the heart of quality control is the
2 ability to characterize and test raw materials and
3 final products. Here's a list of some of the critical
4 quality attributes that we think should be controlled
5 for all of the materials and finished products that
6 CBD manufacturers are dealing with.

7 You know, one thing in particular I want to
8 point at here is using validated test methods, per the
9 GMP guidelines, and really being able to produce
10 accurate test results. This is one of the biggest
11 issues that leads to some of the label claim issues
12 and other problems in the industry.

13 The third-party labs are using generic test
14 methods and the method really should be validated for
15 each sample matrix. It's not appropriate to use a
16 method that was validated for CBD content in hemp and
17 also use that method for testing products containing
18 CBD without performing studies to demonstrate the
19 applicability of the method to the sample matrix.

20 Right now most of the industry uses contract
21 labs who are testing products using generic methods
22 that have not been validated for that particular

1 sample matrix. You know, being an agricultural
2 product of hemp, we also need to look at heavy metals
3 and microbial contamination.

4 So I want to commend the FDA for bringing
5 together all of the stakeholders to work together
6 towards a solution. We believe strong regulation
7 enacted quickly will benefit consumers and improve the
8 industry. Thanks for the opportunity. Any questions?

9 PANEL MEMBER: Yeah. Just one follow-up
10 question. So your slide four, you talked about
11 regulating use in dietary supplements, foods and
12 cosmetics at lower strengths.

13 I didn't know if you had an idea for how we
14 would go about identifying that lower strength that
15 would be appropriate for those uses and any thoughts
16 you had with that would be really helpful.

17 MR. MUELLER: So I think you'd need to look
18 at some of the safety data out there in the studies
19 that have been done. You know, as an ingredient
20 manufacturer, we're not making consumer products that
21 have guidelines on how much can be taken. But you
22 know, we think this is an important route for kind of

1 the broader public outside of pharmaceutical drug
2 applications. Thank you.

3 MS. CRISTINZIO: Thank you. Next we have
4 speaker number 87, Aaron Secrist.

5 MR. SECRIST: Good afternoon. My name is
6 Aaron Secrist. I'm the vice president of quality and
7 regulatory affairs for NOW Health Group. As a
8 responsible manufacturer of legal dietary supplements,
9 NOW Health Group is very concerned about the current
10 state of affairs with regards to hemp and hemp-derived
11 products such as CBD.

12 The current approach taken by FDA, which
13 seems to be best described as unofficial enforcement
14 discretion, does little to promote and protect the
15 public health, the primary mission of the agency.

16 By not enforcing the current statutes, the
17 agency has encouraged irresponsible or, at best,
18 uneducated and uninformed companies to manufacture and
19 market CBD and other hemp-derived products without
20 understanding in many instances the identity of the
21 CBD ingredients or hemp-derived ingredients that
22 they're putting in the products and without any safety

1 studies performed on these ingredients that they use
2 in the products that seem to vary so widely in the
3 marketplace, as we've seen today.

4 We respectfully ask the FDA to do one of two
5 things: either enforce the current statutes and hold
6 the companies responsible for manufacturing and
7 marketing these illegal products or we urge the
8 secretary to exercise his authority under current
9 statute to allow hemp-derived products such as CBD to
10 be recognized as legal dietary ingredients, provided
11 that an NDIN is submitted and all other applicable
12 federal laws are met.

13 This will encourage responsible companies who
14 follow the law, such as NOW Health Group, to
15 potentially enter the market through the front door
16 and perform the requisite safety studies, method
17 validation, clinical studies and submit an NDIN for
18 agency review to ensure that safe and effective
19 products are available to the American public. This
20 is in keeping with the FDA's mission and our company's
21 mission and values.

22 We also respectfully ask the FDA to ensure

1 that the rule of law is upheld by barring any company
2 illegally marketing CBD or other hemp-derived dietary
3 supplements from submitting an NDIN for a period of
4 time equal to the time that their products have been
5 illegally marketed.

6 If the FDA simply opens the door to hemp-
7 derived ingredients and products containing CBD by
8 exercising the secretary's authority without such a
9 provision, then it effectively encourages companies to
10 flout the law in the future, as the only consequence
11 would seem to be a three- to five-year head start in
12 the marketplace over companies who choose to follow
13 the law.

14 We also respectfully ask the FDA to continue
15 to explore the idea of master files relative to the
16 NDIN process. We believe that this will help provide
17 some IP protection to the companies that spend the
18 precious resources of time and money to ensure the
19 identity of the potentially new dietary ingredient,
20 along with the requisite safety studies necessary to
21 demonstrate to the agency that the ingredient is safe
22 under the conditions of use.

1 We do not believe that the agency should
2 accept self-affirmed GRAS as a way to circumvent the
3 NDIN process as it relates to CBD and other hemp-
4 derived ingredients. We also believe that it's very
5 important for the FDA to ensure that there's federal
6 preemption for any pathway forward for hemp-derived
7 ingredients such as CBD as potential new dietary
8 ingredients.

9 Varied and often contradictory state law
10 makes it nearly impossible for responsible companies
11 to enter the marketplace, which leads to subpar and
12 possibly unsafe products on the marketplace. Thank
13 you for your time.

14 MS. CRISTINZIO: Thank you. Next we have
15 James Sharkey, number 88.

16 DR. SHARKEY: Good afternoon. I'm Dr. James
17 Sharkey. A little bit about me, I have a doctorate in
18 biomedical sciences and I am the director of research
19 and development for hemp and CBD products for Dixie
20 Brands and I'm also --

21 MS. CRISTINZIO: Can you move closer to the
22 microphone please?

1 DR. SHARKEY: I'm sorry.

2 MS. CRISTINZIO: That's okay.

3 DR. SHARKEY: And I'm also the chief science
4 officer for Therabis, which is a pet supplement brand.
5 My talk today is going to primarily focus on the human
6 supplement aspect of our businesses. But the written
7 comments that we will be providing will also include
8 animals.

9 Dixie Brands, we're based out of Denver,
10 Colorado and we were one of the pioneers in the
11 medical cannabis industry, which naturally brought
12 along hemp and CBD products. We've been creating
13 these products since 2009 under the regulatory
14 environment of the Colorado -- state of Colorado,
15 which is one of the most mature hemp and cannabis
16 markets in the United States.

17 The reason why I'm employed there, unlike
18 others in the space, is that we are very research-
19 emphasis, very heavy research emphasis and providing
20 products that are safe and have a degree of efficacy.

21 Recently we just announced actually yesterday
22 that we partnered with a major university veterinary

1 school to perform a clinical study on efficacy with
2 safety in canine joint health.

3 So I'm going to proceed to go to -- now,
4 we've heard today that there is a dearth of research
5 in the space, specifically regarding safety. It's
6 true and it isn't true. In the United States, it
7 absolutely is true that very little of this work has
8 been produced in the United States.

9 The majority of this are products from
10 overseas. And I've selected just a few studies to
11 show that we have side effect -- chronicling of side
12 effects in humans, in oral administration since 1973
13 as well as across a broad range of dosages.

14 Now I just learned today from GW
15 Pharmaceutical that they have shown adverse events as
16 low as 1 mg/kg. It's in a bit of conflict and that is
17 not publicly available. So I would strongly encourage
18 that, for the benefit of all of us stakeholders, that
19 these type of studies be made publicly available so
20 that we can see and actually produce products, given
21 if it is -- if the FDA does take a path towards a
22 supplement category, that we can actually operate and

1 provide safe products because there are a lot of us
2 out there who do this, do want to ensure safety.

3 So beginning with Carneal, that was a
4 relatively small study. But 40 healthy adult males
5 and a dosage of 15 to 60 mg. So roughly that is sub 1
6 mg/kg. Hollister was 200 to 100. The more
7 interesting one would be Consroe, which was a 15-week
8 study in Huntington disease patients at 10 mg/kg/day
9 that reported no significant side effects.

10 But the more recent data we have is the
11 Epidiolex safety trial and the extended access
12 program. A total of 607 patients were in the safety
13 arm of the extended access program. Dosages got up to
14 between 25 and 50 mg/kg/day and the dose range
15 corresponded to 20 mg/kg/day for the study and 200 mg
16 per day for the maintenance dose in a 10 kg child.

17 Primary findings, it was well tolerated.
18 However, they did show some drug interactions, which
19 we absolutely have to be concerned with because
20 previous mouse work has shown inhibition of cytochrome
21 P450s. And this was with clobazam and valproate.
22 Valproate is known to have hepato -- to damage the

1 liver and clobazam is known to have existing
2 somnolence. As a matter of fact, the CBD of clobazam
3 was predicted and characterized by Geffrey in 2015.

4 Then earlier today we learned from a previous
5 group about this hepatotoxicity in mice. A lot of
6 hard work has gone into that. But in reality, the
7 test article they did, did not resemble anything that
8 would be seen in a human being in the market.

9 Specifically regarding the THC levels and the
10 fact that the residual solvents weren't characterized
11 to a sufficient degree for a limit of quantitation.
12 So we need some additional data and need to make sure
13 that these studies accurately represent the products
14 we're doing.

15 And then, here are just some conclusions
16 based upon this. The FDA has done a clinical trial, a
17 Phase III clinical trial and approved a drug in a
18 vulnerable patient population of children. That is
19 the most robust safety trials that exist. Further, we
20 have empirical -- not empirical data, but anecdotal
21 data and a lack of reporting of side effects in the
22 general populace.

1 This lends to a degree that a concentration
2 of 1 to 2.8 mg/kg, which would be the consumer
3 available dose, that these supplements would in fact
4 be relatively safe in an adult -- health adult
5 population. Thank you for your time.

6 MS. CRISTINZIO: Thank you. Speaker number
7 89, Priyanka Sharma?

8 DR. SHARMA: Thank you. Good afternoon to my
9 industry colleagues and distinguished guests. It is
10 truly an honor and a privilege for us to be here
11 today. We'd like to thank the Food and Drug
12 Administration for providing us with this platform
13 today and for hosting this public hearing on cannabis-
14 derived compounds.

15 My name is Dr. Priyanka Sharma, and I'm
16 joined here by Pulak Sharma. We're co-founders of
17 Kazmira. I'm going to be explaining the left-hand
18 side and Pulak will be talking about the remaining
19 information.

20 Kazmira is a biotechnology manufacturing
21 company operating in Colorado producing THC-free CBD
22 raw extracts derived from industrial hemp. Our

1 products are consistently free of residual solvents,
2 heavy metals, pesticide and microbial contaminants, to
3 name a few.

4 We develop these raw ingredients for product
5 manufacturers who produce finished goods which are
6 distributed online and within retail channels. We
7 believe that setting high product quality standards
8 will enable development of finished products that are
9 safe for consumers.

10 Industrial hemp manufacturers throughout the
11 U.S. have already implemented significant quality
12 control and stringent manufacturing standards in the
13 current processes of extracting the hemp biomass into
14 oils containing a variety of cannabinoids.

15 Today we would like to discuss three quality
16 metrics already followed closely by hemp-derived
17 product manufacturers: consumer safety, quality
18 management systems and validated testing.

19 With added support from federal regulatory
20 agencies, we can continue to create a brighter future
21 state for the hemp-derived products industry. At
22 Kazmira, we have focused our manufacturing processes

1 on meeting the current applicable standards of CBD raw
2 materials. This enables our customers to give
3 consumers a product with non-detect levels of THC.

4 Working with regulatory agencies, we would
5 support development of guidelines for consumer product
6 specifications.

7 Second, current quality management systems
8 allow complete traceability from farm to product.
9 Many of the manufacturers here today have obtained ISO
10 9001 and are working towards self-regulating cGMP
11 compliance certifications.

12 To further standardize process controls,
13 infrastructure to support higher quality control on a
14 federal level needs to be provided. We as
15 manufacturers would support guidance on obtaining
16 FSMA, GFSI or other food safety management compliance
17 practices.

18 Third, cannabis-testing laboratories are
19 available today to manufacturers where contaminant
20 testing is performed on raw materials and finished
21 products. Cannabinoid purity analysis, residual
22 solvents, heavy metals, pesticides and microbial

1 contaminants are among the testing performed currently
2 on these products.

3 Manufacturers and testing laboratories would
4 support a collaboration between industry and federal
5 regulatory stakeholders to develop federal compliance
6 guidelines and standardized testing methods for CBD
7 products.

8 MR. SHARMA: Thank you, Priyanka. Performing
9 at the highest level of manufacturing and product
10 quality standards is going to give us stronger
11 consumer safety infrastructure.

12 First there will be increased quality
13 transparency with consumers being aware of contents of
14 their hemp-derived products through updated packaging
15 and labeling requirements. This will spark a healthy
16 debate that encourages education on product quality.

17 Second, enabling a pathway for acceptance of
18 CBD oils through the right channels as a dietary
19 supplement and a food ingredient will create
20 accountability with all stakeholders and drive deeper
21 transparency and trust with consumers.

22 This has been successfully replicated with

1 ingredients such as fish oils. As for the CBD
2 industry, this model has been defined with successful
3 deployment by the Colorado Department of Public Health
4 and Environment.

5 Finally, ingredient safety will drive the
6 conversation of product safety with rigorous process
7 control, quality management and high compliance
8 standards that enable higher quality products
9 consumers can trust. For example, this can be pursued
10 through USP monographs for dietary supplements.

11 Thank you very much for your valuable time
12 and enabling this engagement to start the conversation
13 on this important subject. We hope that with the
14 presentations today, the regulatory agencies got a
15 glimpse of the industry stakeholders' vested interests
16 in making processes and standards for consumer safety.

17 We look forward to continuing this dialog and
18 creating a sustainable pathway for manufacturers to
19 serve consumers with the highest quality and safety
20 standards for cannabis-derived compounds and products.

21 Thank you.

22 MS. CRISTINZIO: Thank you. Our last

1 presentation before the break, number 90, Thuy Vu.

2 MS. VU: Good afternoon. My name is Thuy Vu
3 and I am -- I serve as the director of operations and
4 regulatory affairs for Hammer Enterprises integrated
5 solutions, located in Evergreen, Colorado.

6 Hammer Enterprises is one of the largest
7 vertically integrated industrial hemp companies in
8 Colorado and we serve as a custom white label
9 manufacturer offering a full spectrum of products for
10 oral ingestion, inhalation and absorption.

11 Hammer Enterprises is committed to strict
12 quality control guidelines, ethical standards and high
13 integrity to deliver pesticide-free, chemical-free and
14 preservative-free pesticides -- I'm sorry,
15 preservative-free products. Hammer Enterprises is
16 devoted to setting the highest standards in the
17 industry promoting public health, public safety and
18 environmental stewardship.

19 My perspective is unique in that I started my
20 career as a lead foodborne illness outbreak
21 investigator for the Denver Department of Public
22 Health and Environment, Public Health Inspections

1 Division.

2 After cannabis legalization in Colorado in
3 2010, I took the initiative to become the first
4 environmental health investigator to specialize in
5 marijuana investigations, spearheading inspections,
6 investigations and enforcement of the Denver marijuana
7 industry, implementing the first food safety recalls
8 of marijuana-infused products and the first foodborne
9 illness outbreak investigation of a licensed marijuana
10 operation in 2014.

11 In addition to my regulatory background, I
12 have five years' experience in the private marijuana
13 industry as well as the industrial hemp industry,
14 specializing in cannabis extraction and refinement
15 processes, concentrated infused products
16 manufacturing, food safety concerns and quality
17 control of cannabis and cannabis derivatives and
18 cannabis-infused products.

19 Colorado has successfully regulated the legal
20 marijuana and industrial hemp program. The Colorado
21 Department of Agriculture regulates the regulation --
22 the registration and cultivation of industrial hemp,

1 requiring all plants cultivated in the registered land
2 area meet the standard identity of no more than 0.3
3 percent THC on dry weight basis, as well as setting
4 forth criteria for pesticide usage.

5 In July of 2017, the Colorado Department of
6 Public Health and Environment announced a new
7 industrial hemp policy recognizing all parts of the
8 industrial hemp plant, including cannabidiol as a food
9 ingredient. CDPHE's industrial hemp policy is the
10 first of its kind in the nation and it's the most
11 progressive program applying current good
12 manufacturing practices to a new food ingredient.

13 Excuse me. Let me get to the right slide.
14 Okay -- as a new food ingredient. CDPHE's industrial
15 hemp policy is the first of its kind in the nation and
16 it's the most progressive program applying current
17 good manufacturing practices to a new food ingredient
18 and for a new emerging industry.

19 Hammer Enterprises played a pivotal role in
20 the successful implementation of CDPHE's industrial
21 hemp program, committing to a professional partnership
22 with CDPHE as well as other government and regulatory

1 agencies in efforts to advocate for informed, balanced
2 and fair regulations for the new industry.

3 CDPHE's industrial hemp policy requires all
4 parts of the plant utilized in food to be sourced from
5 a state with an established or approved hemp program
6 or a country that inspects and regulates the commodity
7 to ensure its safety for human consumption.

8 The producer or grower must be in good
9 standing and compliant with the governing laws of the
10 state or the country of origin and the raw material
11 and finished products must be tested to ensure that it
12 meets the standard of identity for industrial hemp and
13 that documentation must be available upon request.

14 The policy also outlines labeling
15 requirements citing all products meet both state and
16 federal labeling guidelines by identifying hemp as an
17 ingredient, the CBD potency, including the statement
18 FDA has not evaluated this product for safety or
19 efficacy, as well as clearly stating that no health
20 benefit claims are to be made on the label or the
21 extension thereof.

22 In order for these products to be considered

1 approved sources, CDPHE requires a manufactured foods
2 registration of all industrial hemp operations. At
3 Hammer Enterprises, we lead the industry by
4 voluntarily adhering to the strictest guidelines for
5 quality control with a robust testing protocol of all
6 products throughout the extraction, purification and
7 manufacturing process.

8 As a vertically integrated operation, we have
9 transparent oversight and complete control over every
10 step of the process, from propagation to cultivation
11 to extraction, refinement and purification and the
12 manufacturing of finished products, achieving full
13 chain traceability.

14 All manufactured products are accompanied by
15 a product specification sheet and a certificate of
16 analysis, either from our in-house proficiency tested
17 analytical laboratory or a third-party laboratory.

18 While Colorado -- sorry. While Colorado marijuana
19 enforcement division has the list of solvents approved
20 for marijuana extractions, some of which are not
21 approved solvents for the production of human food.
22 CDPHE requires the industrial hemp industry use only

1 approved food solvents.

2 These extracts can be further refined into
3 various forms of concentrates used to produce products
4 for ingestion, inhalation and absorption.

5 Challenges are to be expected in any emerging
6 industry that has little to no regulatory oversight.
7 Conflicting regulations from state to state, no
8 current standardized AOC testing methodologies for the
9 various matrices allowing for variances in potency
10 testing results and the lack of guidance from a higher
11 authority.

12 While some markets are still budding and
13 others like Colorado progressive and radical in its
14 approach to the regulation of industrial hemp, there
15 lies one common theme: the desire and duty to ensure
16 safety, consistency and quality of the manufacturing
17 products containing cannabis and cannabis-derived
18 compounds which can be attained by creating a
19 legitimate regulatory framework to streamline
20 definitions, standards, required testing and full
21 chain traceability.

22 At Hammer Enterprises, we are setting this

1 standard by pursuing our ISO 9001, 22000 and 17025
2 accreditations. We have an onsite PCQI and follow
3 cGMPs and FSMA guidelines to ensure the safety,
4 consistency and quality of all manufactured products.

5 We conduct -- we conduct batch testing of all
6 of our raw materials, intermediate ingredients and
7 finished products for cannabinoid potency, terpene
8 profiles, residual solvents, mycotoxins, heavy metals,
9 pesticide residues, moisture analysis, water activity
10 and microbial, which includes total yeast and mold,
11 total plate count, total coliform E. Coli and
12 Salmonella.

13 We also have preliminary nutritional analyses
14 of our raw CBD extract, CBD extract oil to split
15 isolate and finished products. Thank you.

16 MS. CRISTINZIO: Thank you so much for your
17 comments. At this time, we are going to take a 15-
18 minute break. We will see you back here at 3:30.

19 (Whereupon, the foregoing went off the
20 record.)

21 MS. CRISTINZIO: Please take a seat. We're
22 about to begin. Thank you, everyone. We are ready to

1 move onto a new category. It is the coveted "Other"
2 category. First up, we have speaker number 91, Aubrey
3 Adams. Thank you, Aubree.

4 OTHER

5 MS. ADAMS: Thank you for this opportunity.
6 My name is Aubree Adams, and I'm a former Colorado
7 mom. I moved to Houston, Texas this past summer
8 because marijuana changed my home.

9 My son started using marijuana edibles in the
10 eighth grade, soon after legalization. He was self-
11 harming. We did not know he was using marijuana
12 because the industry makes these products in deceptive
13 forms to disguise use.

14 By February 2015, my son was irrational,
15 paranoid, repeating things that did not make sense
16 and, one night, he was so violent towards my younger
17 son that my younger son ran barefoot through the snow
18 to get away from him. He attempted suicide and was
19 hospitalized. When he was discharged, he was still
20 suicidal and I took him back to the ER where I was
21 told it's just marijuana and was sent home.

22 Within a few days, my son was hospitalized

1 again in a different town because there were no
2 available beds in our town. He told me he was using
3 dabs and he knew they were making him feel crazy and
4 he was trying to quit. He described dabs as strong
5 marijuana and called them crack weed. Dabs are mass
6 produced, marketed and called medicine.

7 I volunteered my family for crisis
8 intervention with the Department of Social Services
9 because I could not find treatment for marijuana
10 abuse. My son had developed the pediatric disease of
11 addiction. And by the next year, not only was he
12 using marijuana, he was using meth and heroin.

13 Marijuana kills. It's a gateway to more
14 drugs and pharmaceutical drugs. My son allows me to
15 tell his story because he wants the nation to know
16 that marijuana is deadly, harmful and can change you
17 forever with delusional thinking, hallucinations and
18 increased risk for suicide, depression and addiction.

19 My husband also allows me to tell his story.
20 He read that marijuana would treat his panic attacks.
21 But marijuana harmed him and now he suffers from
22 severe depression, anxiety and suicidal thoughts.

1 My old community of Pueblo, Colorado has pot
2 scholarships for every high school senior. It's a
3 brilliant marketing plan by the predatory marijuana
4 industry to groom their future users. It's a way to
5 advertise to kids under the radar.

6 One out of three Pueblo high school seniors
7 now uses marijuana and they have a 27.6% chronic
8 absenteeism rate. There is a marijuana head shop next
9 door to an alternative high school where kids can see
10 shiny bongs and pipes and clothing and advertising
11 glorifying and normalizing marijuana. They even have
12 a person waving a sign saying come get your free pipe.

13 The number one cause of death ages 10 to 24
14 in Colorado is suicide. The main drug the victims are
15 testing for is marijuana, ages 10 to 19. In Pueblo,
16 Colorado, we are exposed to marijuana smell and smoke
17 everywhere we go, in schools, in stores, driving down
18 the road, in our own homes and on our own property.

19 Seventy percent of the marijuana shops in
20 Colorado recommend marijuana to pregnant women. So my
21 mom and I hung baby bibs on the marijuana shops in
22 Pueblo that says don't hurt our future, Colorado kids.

1 It's a campaign by the Marijuana Accountability
2 Coalition.

3 These are some of the people that have been
4 killed by the effects of marijuana in the state of
5 Colorado. Marijuana-induced suicides, marijuana-
6 induced psychotic murders and people killed by
7 marijuana-impaired drivers.

8 Here is a quilt from Moms Strong of more
9 people that have been killed by the effects of
10 marijuana, including marijuana psychosis and we even
11 have a marijuana-induced cardiac death.

12 Marijuana industry advertises psychotic
13 experiences as being a bonus. The ad says, ever been
14 so high you've shredded a pizza? We'll take you
15 there. Well, our kids have been so high they've
16 wanted to kill themselves and others.

17 Legalizing marijuana has made it more
18 dangerous than ever. It is now a weaponized assault
19 on the brains of our loved ones. Colorado has allowed
20 a full criminal organization to flourish with pretty
21 store fronts to sell their poison under the disguise
22 of medicine with false claims, no warning and no

1 accountability.

2 Colorado has allowed products to be marketed
3 in the highest potency levels ever known and Colorado
4 has allowed a predatory industry to profit of our
5 children's demise. For the marijuana industry to
6 survive, they need more and future users. Those users
7 are the youth of our country.

8 Colorado has now turned into a third world
9 country. We have criminal organizations from all over
10 the world living in our neighborhoods. Why have drug
11 dealers been allowed to break federal law for so long?

12 Every day I try to forgive those that have
13 allowed this to happen. Drugs are winning the war on
14 drugs and the war is now in our homes and in our
15 neighborhoods. I am a witness to the fall of America
16 and THC is the weapon of our destruction.

17 I hope -- I hope the House of Representatives
18 in Illinois is listening to the testimonies from the
19 industry. It is very obvious tax and regulation is
20 not working and the people here are poisoning the
21 people of Colorado. And it is my wish that federal
22 law be enforced. Thank you.

1 (Applause.)

2 MS. CRISTINZIO: Thank you.

3 MS. ADAMS: I do have -- I have a minute, so
4 I would like to just keep --

5 MS. CRISTINZIO: No, I'm sorry. You're
6 actually over.

7 MS. ADAMS: Oh, I'm over?

8 MS. CRISTINZIO: Yeah.

9 MS. ADAMS: I'm so sorry.

10 MS. CRISTINZIO: That's okay.

11 MS. ADAMS: Thank you.

12 MS. CRISTINZIO: Next up, speaker number 92,
13 is Susan Audino.

14 DR. AUDINO: Good afternoon. Thank you for
15 the opportunity to address this critically important
16 need to create a regulatory pathway for CBD and other
17 cannabis products.

18 My name is Dr. Susan Audino and my testimony
19 here is built upon my expertise as an analytical
20 chemist and in testing methods. I'm also an A2LA lead
21 assessor and an instructor to many ISO standards. I
22 believe you are familiar with A2LA's dedication to

1 quality control testing. And I'm also a board member
2 of the Center for Research on Environmental Medicine
3 here in Maryland.

4 I serve on several expert advisory panels for
5 the cannabis industry and international organizations
6 such as an including AOSC and ASDM. My consulting
7 firm serves chemical and biological laboratories,
8 including those that test cannabis.

9 With that as a background, I'm going to stay
10 in my lane here today and ask you to focus on the role
11 that adequate product testing plays in protecting
12 patient safety. Of course testing and efficacy go
13 hand in hand. We've been hearing that all day.
14 However today I will focus on efficacy only in passing
15 and instead highlight the safety benefits associated
16 with adequate testing.

17 I believe that medical cannabis and cannabis-
18 based products have a place in the lives of patients.
19 However, to be clear, I do not believe that they
20 should be used freely and at the sole discretion of
21 the public. Rather I believe they need to be
22 introduced and used responsibly and cautiously by all

1 parties -- patients, physicians, the FDA and all other
2 regulatory bodies.

3 All patients, particularly those that are
4 immunocompromised and children, need to be cautious in
5 the adoption of these products and await the results
6 of solid and reputable testing.

7 For example, has science-based testing
8 accurately and precisely analyzed a product's
9 ingredients? Has it evaluated the product's potential
10 therapeutic benefits and risks of toxins or other
11 ingredients causing adverse effects? How do we know
12 how much is in there? How do we know how much is too
13 much or how much is too little?

14 As we know, rigorous testing can answer
15 questions such as these, empowering patients and
16 physicians to make truly informed decisions.

17 As with other products, cannabis-derived
18 products should be developed using and under the
19 processes central to and authorized by the FDA.
20 Product manufacture also requires the scientific
21 integrity of third-party testing labs to ensure that a
22 product meets the expectations displayed on its label

1 and in its marketing efforts.

2 This needs to be demonstrated for every
3 product, on every label, every time. My firm provides
4 scientific and technical guidance to cannabis
5 dispensaries, testing labs, medical personnel and
6 regulatory bodies.

7 We promote active research towards the
8 development of official test methods and we advocate
9 strongly for appropriate clinical research and product
10 development consistently -- consistent within the
11 rigors of the FDA processes.

12 For decades, centuries actually, there have
13 been countless anecdotal reports promoting the
14 benefits of cannabis and cannabis-based materials,
15 although advancing scientific evidence needs to catch
16 up with these attestations. The transparency and
17 openness with which you're conducting today's hearing
18 and soliciting additional testimony is a relief.

19 I say this because now more than ever the
20 public is gambling with its health. Product marketing
21 is far ahead of the science needed to substantiate
22 product claims and the media frenzy around CBD-based

1 products is rapidly expanding the use of unregulated
2 substances that people are ingesting without clear
3 indication of known benefits and risks.

4 This is a very frightening situation. Today
5 there are still many unknowns about the cannabis
6 plants and in particular its interactions with the
7 brain and other organs in order to allow these
8 unregulated CBD products with or without THC to be so
9 easily accessible.

10 Research is slowly emerging from the shadows
11 and must rationally and aggressively continue on. And
12 here are two more facts that could make you lose some
13 sleep. Makers of CBD and cannabis products are
14 susceptible to deception by laboratories that purport
15 to do science-based testing.

16 In fact, some laboratories don't even perform
17 quality control analyses of products for which they
18 are charging the manufacturers.

19 Second, there are product manufacturers that,
20 when faced with state-mandated requirements,
21 intentionally hire laboratories because of their
22 reputation for doing substandard and ineffective

1 product testing.

2 Patients and other consumers are at greatest
3 risk from this negligent activity, and clearly you
4 know that. Again, I commend you for today's hearing.

5 I close with good news. You have stepped
6 into these waters before. The FDA has created an
7 orderly process that brings benefits to all of
8 society. And the FDA can tame this current Wild West
9 of testing by requiring true quality standards.

10 For that to happen, we need regulators who
11 are well-informed developing regulations that are
12 science-based and consider the intricate
13 interdependencies of accurate and reliable third-party
14 testing, perhaps developing control standards would be
15 a focus of a future FDA hearing.

16 When that day arrives, patients across the
17 U.S. will applaud that effort as well. Thank you.

18 MS. CRISTINZIO: Thank you, Susan. Our next
19 speaker is James Beck, speaker number 93, from the
20 Parkinson's Foundation.

21 DR. BECK: Hi, there. Can everyone hear me?
22 Great. As my slides --

1 MS. CRISTINZIO: Just one second while we
2 pull your slides up.

3 DR. BECK: Great. No problem. I want to
4 thank you for the opportunity to speak today. I'm
5 James Beck. I'm the chief scientific officer with the
6 Parkinson's Foundation. A little louder? It's
7 deceiving.

8 So while my slides are coming up, the
9 Parkinson's Foundation is the largest community for
10 those living with Parkinson's Disease. And there are
11 a number of individuals in the United States have PD.

12 When the slides show up, I'll show you a map
13 of the United States depicting the prevalence of those
14 with Parkinson's Disease in the U.S., based upon a
15 current report that we had published recently.

16 MS. CRISTINZIO: Sorry about that. I can see
17 your slide from my desk. But that's not helping
18 anyone else here. Just one second. No? Try again.

19 DR. BECK: Perfect. Okay. Well, I'll start
20 again. So I'm from the Parkinson's Foundation, which,
21 as I mentioned, is the nation's largest community for
22 those living with PD.

1 Nearly a million people live with PD,
2 underlining the urgency for what we do as an
3 organization. This chart of the United States shows
4 deep blue states which have more people with PD than
5 the lighter colored states, based upon a recent report
6 that we published as a group.

7 Many of you on the panel and in the room may
8 not know what Parkinson's Disease is. It's a
9 neurodegenerative disease primarily characterized by
10 loss of dopamine neurons that can lead to motor
11 symptoms that include tremor at rest, bradykinesia,
12 which is slowness of movement, or rigidity.

13 Many approved therapies already address these
14 current symptoms. And levodopa shown up there on the
15 right is that green pill is one of the classic
16 examples. However, people with PD have many other
17 symptoms that are not well-addressed by current
18 approved therapies, problems with sleep, cognition,
19 autonomic dysfunction, mood disorders, et cetera,
20 which is why those in our community are seeking
21 alternative ways with which to control these symptoms.

22 And cannabis is not surprisingly one of those

1 choices. And when we surveyed our PD neurologists at
2 our centers of excellence throughout the U.S. and the
3 world, we found that 95 percent of them report being
4 asked about medical cannabis from their patients.

5 That, along with the changing in the
6 legalization in the United States, led to the
7 Parkinson's Foundation to gather key stakeholders in
8 at a meeting in Colorado earlier this spring.

9 The goal here, by bringing together people
10 with Parkinson's Disease, neurologists who specialize
11 in PD, epileptologists, people who specialize in MS,
12 is to understand what could cannabis be used for when
13 it came to Parkinson's Disease.

14 What are the gaps in knowledge? What are our
15 safety concerns? What are health effects? And the
16 idea here is to guide the patient as we wait for
17 formal guidance from the government and further
18 research and also to develop a research plan for
19 moving forward with understanding how cannabis can be
20 useful.

21 Key takeaways are, not surprising, that
22 cannabis is unlikely to help the motor aspects. This

1 is the tremor that current approved therapies are able
2 to help.

3 It may be helpful at a targeted level for
4 non-motor symptoms, the sleep, the anxiety issues.
5 Bottom line is we really need more research to
6 understand the utility of cannabis in Parkinson's
7 Disease. There's just not a lot known and the quality
8 of research is rather limited that's available.

9 Diving deeper into some of the non-motor
10 aspects, this survey that was again done in 2015
11 asking neurologists what they thought cannabis could
12 be useful for. In blue shows where they think it
13 could be a benefit and orange shows where neurologists
14 thought it could actually cause harm.

15 Superimposed upon this is from a focus group
16 in the patient community identifying their priorities.
17 Pain, anxiety and sleep are issues that people with
18 Parkinson's Disease are dealing with and are seeking
19 cannabis as a form of treatment.

20 But cannabis is a drug. And like any other
21 drug, it has side effects that we need to be concerned
22 about. Many of the side effects for cannabis are also

1 symptoms of Parkinson's Disease itself. So the issue
2 here is that individuals who may utilize cannabis as
3 self-treatment may be making their own PD symptoms
4 worse.

5 Up there are dizziness and low blood pressure
6 or hypotension. If a person with Parkinson's Disease
7 who was using cannabis too much led to a fall at the
8 age where people with PD have Parkinson's Disease is
9 in the late 60s, early 70s, it could be catastrophic.
10 And that's the last thing we want.

11 The other thing to just point out is that
12 many of these adverse effects or side effects were
13 discovered within a healthy population. It's
14 important to consider a neurodegenerative population
15 when trying to understand how side effects could be
16 different in this community.

17 Routes of administration are a challenge.
18 Inhalation is clearly the most rapid way with which to
19 deliver it. But using raw plant material can lead to
20 difficulties in dosing.

21 Oral forms are great. But they have a
22 delayed effect and it's compounded by the fact that

1 most people with Parkinson's Disease have an issue
2 with gastroparesis, which is delayed gastric emptying
3 and slow colonic motility, which can further compound
4 any type of titration or even understanding how this
5 can get delivered in an effective way.

6 Our community is concerned about lack of
7 standards that has been talked about here, side
8 effects and whether there's sufficient safety research
9 that accompanies cannabis.

10 Take-home messages from our key stakeholder
11 meeting is that we need objective safety and
12 tolerability assessments at various stages of
13 Parkinson's Disease covering the symptoms as well.

14 We need more research within the
15 neurodegenerative community. We need an evidence-
16 based approach for treating and targeting symptoms.

17 And last but not least is what's been brought
18 up before. We need ready access to the study drug for
19 research in human subjects. It's too difficult right
20 now to obtain the medication in order to use for
21 people with Parkinson's Disease and other diseases
22 areas. Thank you for your time.

1 PANEL MEMBER: I had a question.

2 DR. BECK: Yes?

3 PANEL MEMBER: When you talk about cannabis
4 use in Parkinson's patients, are you thinking
5 primarily of the higher THC products or of the low
6 THC, higher CBD products?

7 DR. BECK: So it's a mix. The problem is
8 that many people with PD are trying to choose low THC,
9 high CBD is what's often recommended if they're able
10 to get the information because it's less psychoactive.

11 But you go to a dispensary and it could be
12 hit or miss depending on what they could get. And so,
13 people who have high THC cannabis could lead to
14 problems with psychosis or delusions which are already
15 problems with people with PD. Any other questions?
16 Thank you.

17 MS. CRISTINZIO: Thank you. The next speaker
18 is Scott Coates.

19 MR. COATES: Thank you. Good afternoon. I
20 am Scott Coates, the senior director for the AOAC
21 Research Institute. That's a division of the AOAC
22 INTERNATIONAL, and I also serve as the program leader

1 for the cannabis analytical science program.

2 Before I start my presentation, I want to
3 make an observation. We've probably had at least a
4 dozen, maybe more, testimonies where there was
5 concerns about label accuracy. And that comes as no
6 surprise to me because we don't have any reference
7 methods.

8 And without having reference methods, we
9 don't know whether the label is accurate or the
10 testing laboratory is accurate. You don't know. So
11 we need to have reference methods. And that's one of
12 the things that I think the analytical science program
13 can help us with.

14 So just a little bit of background on AOAC
15 INTERNATIONAL, we have a long history in food safety
16 and involvement with USDA and FDA. We're consensus
17 builders. We bring people and scientists together to
18 decide on what the correct methods are, and that's an
19 important function that we serve is that we publish
20 the official methods of analysis.

21 So two years ago, in response to the concern
22 from the states, we responded to regulators and we

1 have taken action to convene experts and approve
2 consensus methods for analysis of cannabis and hemp in
3 feed, food, plant materials.

4 Those would be reference methods that
5 everyone could use so that the testing laboratory and
6 the producer could be using the same validated method.

7 We start by developing standard method
8 performance requirements. We call them SMPRs for
9 short. We started in 2017. We have one for cannabis,
10 cannabinoids and cannabis concentrate and one for
11 dried plant materials, one for chocolates and one for
12 pesticides and cannabis.

13 Those documents give in great detail what
14 cannabinoids and how many of the cannabinoids and at
15 what level we're going to be testing.

16 We use those as a call for methods and we
17 have two official methods now for cannabinoids in
18 dried plant materials.

19 After we did that exercise, we realized that
20 that was too slow. We did two official methods, two
21 reference methods in two years. Too much stuff was
22 going on. So we just decided to develop CASS.

1 So CASS's objective was to facilitate a forum
2 where the science of cannabis analysis could be
3 discussed, develop and publication of cannabis and
4 hemp-specific methods and standards, identify and
5 develop cannabis and hemp reference materials,
6 establish cannabis and hemp proficiency testing
7 programs and provide resources and education to the
8 regulators responsible for establishing rules and laws
9 for hemp.

10 We do have a policy, because it's paid for.
11 We do not advocate for or against the legalization of
12 cannabis. Our mission is consistent with ensuring
13 public health, and we do not accept any funding from
14 any organization involved in the cultivation or
15 manufacturing of cannabis or hemp.

16 We currently have three projects. The first
17 one is microbiology in cannabis and they're focusing
18 on aspergillus. A second one is the cannabinoids as
19 consumables and their initial focus is on
20 cannabinoids, in particular CBD and THC and hemp plant
21 material. They're also missioned to give some kind of
22 recommendations on reporting of total THC and also

1 recommendations on how to calculate dry weight.

2 And a third working group is the one that
3 reviews target limits of quantitation for pesticides.
4 They all currently got started in May and they are
5 doing their work and we expect to have some results by
6 the end of the summer.

7 So those are the first three that we got
8 started with. But we have many particular other
9 options. Potency, pesticide residues, biological
10 contaminants, chemical contaminants, untargeted
11 testing profiles and method validation guidelines.

12 So what AOAC is doing, what we have been
13 doing for 125 years, is set the standards for
14 development of reliable analytical methods and what
15 we're doing now is applying that to supporting
16 programs for cannabis and hemp in food products and
17 plant materials. And we feel that is critical. Thank
18 you.

19 MS. CRISTINZIO: Any questions from the
20 panel? Thank you so much.

21 MR. COATES: Thank you.

22 MS. CRISTINZIO: Next up, we have speaker

1 number 95, Daniel Fabricant.

2 DR. FABRICANT: Thank you. Good afternoon.

3 I think I may be the only speaker here who was once
4 part of the marijuana taskforce. So, it's good to see
5 some of you again. I don't necessarily miss some of
6 those meetings, and I can't imagine what -- I can't
7 imagine what the next one is going to be like.

8 Now I represent the Natural Products
9 Association, the oldest and largest trade association
10 in the dietary supplement space. We represent about a
11 thousand companies in 10,000 storefronts nationwide.

12 I think looking at how we got here, we've had
13 about 1,500 products come on the market over the past
14 three years. So clearly there's market confusion, so
15 much so that I think we have a letter from a senator,
16 a U.S. senator, which I'll submit for the record,
17 where -- and this man has served since 1993,
18 cannabidiol producer industrial hemp is considered by
19 the Food and Drug Administration to be a dietary
20 supplement and therefore legally used.

21 So if the Senate is not getting it right, I
22 think there's a pretty high chance that the rest of

1 America isn't getting it right and there's a lot more
2 that needs to be done in terms of consumer education.

3 So while that's certainly one way to resolve
4 the issue, I think the bigger way is this morning we
5 heard from Dr. Sharpless that this is completely
6 uncharted territory for the agency. That's not
7 exactly accurate.

8 Currently active pharmaceutical ingredients
9 are in nutritional products, dietary supplements,
10 botanicals at levels that are established below an
11 HHE, things like red yeast rice, *Monascus purpureus*,
12 snake root and those products are allowed to stay on
13 the market as dietary supplements.

14 That would seem to be, at least in the short
15 term, because regulation writing, especially in this
16 environment, and legislative action in this
17 environment, which I think is deemed at best
18 challenging, may be difficult.

19 So FDA can at present, using an HHE process,
20 establish a safe harbor, if you will, until other
21 science comes online. And this isn't completely new
22 territory for the agency. And other agencies have

1 looked at CBD specifically and exposure CBD daily.
2 WHO report has safe use up to 600 mg per day. No
3 place preference and no indication of hepatotoxicity
4 at those levels.

5 Mouse studies indicate somewhere between 8 to
6 10 mg/kg. That's including a safety factor. So for a
7 70 kg human, that would put the dosage range about
8 that 600 level.

9 So currently none of this is happening. And
10 furthermore, products aren't being screened for THC,
11 which is something the agency can do. There's no
12 planned activity code that I'm aware of that the
13 agency is asking for funding to look at THC in
14 products which would seem to be at odds with the
15 public health mission of the agency.

16 So with that, I think it's incredibly
17 important and you've heard from many people that time
18 is of the essence that the agency establish a level
19 via an HHE, allow for something to happen in the
20 interim while a regulation is being written or a
21 statutory solution is being sought.

22 And in the meanwhile, this is, while a

1 confusing issue, it's not an impossible issue. This
2 is food toxicology. I think there's a lot of streams
3 being crossed here. I think when you look at the
4 science, you hear a lot about drugs. You hear a lot
5 about how these interact.

6 But we're talking about food toxicology.
7 These are products that should be used by healthy
8 populations. And so, you saw a recent study that said
9 hepatotoxicity of a cannabidiol-rich cannabis extract
10 in the mouse model. Well, this mouse model actually
11 used a mouse that's used for cancer bioassays. Tumor
12 was not an endpoint of this study.

13 And this mouse is so popular, it's actually -
14 - Dr. Sharpless' lab used to use it at NCI in the
15 mouse bioassay program for cancer. So I think looking
16 at models like this in my time of running the division
17 of dietary supplements and we saw food toxicology
18 routinely on dietary supplements, we never saw any
19 sort of animal models where the animal was already
20 compromised.

21 So I think that that's important to note,
22 that folks aren't getting the issues crossed. We're

1 talking about use in a healthy population and the
2 science should reflect that. And there's quite a bit
3 already in the science that does reflect that.

4 So in closing, again, I think there's plenty
5 of data out there that the agency can already use. A
6 lot of smart people at the agency. A lot of smart
7 people on this panel. A lot of people with background
8 in toxicology.

9 It would seem to be that the exposure level
10 drives this discussion and an unwillingness to set an
11 exposure level doesn't seem to make a lot of sense for
12 an agency charged with the public health. So with
13 that, I'm happy to take any questions.

14 PANEL MEMBER: Hi. I'm wondering if you have
15 any thoughts on labeling issues related to dietary
16 supplements to address some of the risk factors and
17 some of the risks you're seeing.

18 DR. FABRICANT: I mean, I think you --
19 Sharon, you see standard for products with caffeine.
20 Another joy we had at CFSAN. You saw levels for
21 pregnancy, for children, things like that.

22 So I think those are generally labeled away.

1 For adulteration, it's the use specified in the
2 labeling or conditions -- normal conditions of use.
3 So I think that's imparted into 402, into the law.
4 Thank you.

5 MS. CRISTINZIO: Thank you. Next up, we have
6 Jacqueline French, from the Epilepsy Foundation.

7 DR. FRENCH: Good afternoon. Thank you so
8 much for allowing me to make remarks today. I'm Dr.
9 Jaqueline French.

10 I'm the chief medical officer of the Epilepsy
11 Foundation, as well as a professor of neurology at NYU
12 School of Medicine in the epilepsy program and I do
13 see many people with uncontrolled epilepsy. So I come
14 here from both of those perspectives.

15 Next slide, please. I guess I can do it.
16 There we go. So the Epilepsy Foundation is the
17 leading national voluntary health organization that
18 speaks on behalf of the approximately 3.4 million
19 Americans with epilepsy and seizures. We foster the
20 wellbeing of children and adults affected by seizures
21 through research programs, educational activities,
22 advocacy and direct services.

1 Epilepsy, make no bones about it, is a
2 serious and potentially life-threatening disease. And
3 unfortunately, despite all of the therapies that are
4 available right now, one-third of people with epilepsy
5 do not have control of their seizures. Many of these
6 are children. Many of them are young children.

7 Individuals with uncontrolled seizures live
8 with continued risks of serious injuries. There is a
9 condition called sudden unexplained death in epilepsy
10 that can take people's lives. There's also the
11 possibility of status epilepticus, which is continued
12 seizures without stopping that can also be deadly.

13 For these reasons, I think that I speak in a
14 unique position because CBD, we've been told, is not a
15 drug. But we in the epilepsy community, obviously we
16 know it is a drug and it is a lifesaving drug. It's
17 been proven in randomized controlled trials of
18 Epidiolex that CBD in high enough concentrations can
19 stop seizures.

20 And people who are in my community know that.
21 They've heard that. They understand that and they are
22 looking for answers for their uncontrolled seizures.

1 So I'm just going to give you a little story,
2 Laney's story. Laney was diagnosed with a type of
3 epilepsy called juvenile myoclonic epilepsy as an
4 adolescent in 2015.

5 She had already failed eight other seizure
6 medications and had been told that therefore there was
7 only about a 1 percent chance of ever getting control
8 of her seizures.

9 She was started on CBD in September of 2017
10 and this is not Epidiolex because Epidiolex is not
11 approved for her type of epilepsy. And she stopped
12 having convulsions and has not had one since four days
13 after starting the product.

14 And she is by no means alone. She uses a
15 currently unregulated product. And believe me,
16 listening to all of the other speakers today, that
17 scares the bejesus out of me. But so far, it's been
18 successful for her.

19 So what happens if you, for example, go along
20 the lines of what was just suggested and take all of
21 the CBD off the market other than what has a low
22 concentration? Laney and all the other Laney's in the

1 world will suddenly lose access to the product that
2 they've been using. And that literally could cause
3 her and others to lose their lives.

4 So as much as I am afraid of what we have
5 now, I am more afraid as a representative of my
6 community of losing it. If she needed to get -- to,
7 you know, take Epidiolex, it would be \$32,000 per year
8 because it would be off-label for her.

9 She takes Haley's Hope, which is a form of
10 CBD that she gets that's been grown for this very
11 purpose. And she pays \$400 a month for that, which is
12 still a lot of money, but it's affordable for her
13 family.

14 So CBD has been proven to be an effective
15 treatment for the most severe forms of pediatric
16 epilepsy. And I don't know that there's very many
17 other circumstances where you have a drug that is
18 lifesaving as a medication and also available as a
19 dietary supplement.

20 And in the best case scenario, obviously
21 everybody would take the pharmaceutical grade product.
22 But they just don't have access for it. It's not

1 feasible for everyone.

2 So there are many, many people with epilepsy
3 that are being medicated and often with their
4 physician's assistance with CBD oil from various
5 sources. So abrupt removal of CBD from these
6 individuals could lead to seizure worsening, injury or
7 death.

8 And the second thing that I think is very
9 important for me to say is that these people are
10 unaware of the variability of the drug they may be
11 taking, although they look for the best supply. Some
12 people seek it out and are unaware of the risk of
13 liver injury and the potential for serious drug
14 interaction.

15 So as the Epilepsy Foundation, we would like
16 you to preserve access to CBD for those who need it as
17 a lifesaving medication. But it is absolutely
18 essential that there is consistency or people
19 understand the consistency of their product, create
20 some manufacturing standards, make sure that the
21 horrible other things such as mold that might be in
22 there are not in there and also increase availability

1 of important information such as the potential side
2 effects and drug interactions. And also, I totally
3 agree that the access to this product for research is
4 extremely important. Thank you.

5 PANEL MEMBER: I think you just said that,
6 you know, in an ideal world, you would like the
7 pharmaceutical quality of an Epidiolex-like drug to be
8 more widely available.

9 But obviously you're saying preserve -- what
10 I'm hearing you say is to preserve the other forms of
11 it. And I guess my question for you is how would --
12 how does preserving those forms affect companies that
13 might want to develop the pharmaceutical.

14 DR. FRENCH: Well, the issue is it's a little
15 complicated. But there are probably a thousand
16 different forms of epilepsy and nobody is ever going
17 to have FDA approval for every single one of them.
18 And that's true of all the other drugs that are on the
19 market of course.

20 And again, I mean, you know, what would
21 happen if the other approved drugs -- valproate we've
22 heard, clobazam and other things -- were also

1 available as a dietary supplement and people were
2 taking them? It would be chaos.

3 So I didn't -- you know, I'm not saying that
4 this situation is the one I would have picked. But,
5 you know, if that were true, many of those people
6 would be taking it. And if you yanked it away from
7 them, they would get horribly worse.

8 So the situation is what it is. Many people
9 are taking it and they need to have access to it now
10 because no matter how many other manufacturers get FDA
11 approval, they'll never get approval for everything.
12 Thank you.

13 MS. CRISTINZIO: Thank you. Our next speaker
14 is Jeffrey Gitto, from Vanguard.

15 MR. GITTO: Hello. Good afternoon, members
16 of the committee. My name is Jeffrey Gitto. I'm an
17 active attorney in the cannabis space for about six
18 years, which is a very long time in the cannabis space
19 for lawyers. Good to see a mix of lawyers on the
20 panel too because I'm not going to be high science on
21 this one.

22 But what I wanted to do was present to the

1 committee the legal pathways that, in my opinion,
2 would be more an immediate effect for the public to be
3 more confident in purchasing these products.

4 One is a little more esoteric. I'm actually
5 going to go through the three right now and then we'll
6 go through them. But there's three, suggesting the
7 FDA take a tripartite approach to the regulation of
8 cannabis-derived products.

9 A public health approach, consistent with the
10 FDA core principles of innovation and practical risk
11 versus rewards. Two, the duality of market paths
12 dietary supplements and prescription-based uses.
13 Three is respect state determinations of regulating
14 in-state commerce under minimum federal standards.

15 I won't get too much into commerce and
16 dormant commerce clauses because that might get a bit
17 too much. But to start off, number one, a public
18 health approach. Here context must be given to
19 cannabis' long history. We are not speaking of a more
20 esoteric version of such back to BCBC eras.

21 But specifically the history of the U.S. and
22 more specifically the relationship of the plan and

1 what was considered to be its beneficial uses in the
2 marketplace as an agricultural product, the context
3 being you have to clear understand the past to
4 understand the future.

5 The FDA holds a unique source of power in
6 regards to public health. It is important that the
7 committee recognizes this beneficial agricultural
8 product that has been around for millennia, at least
9 outside the confines of a post-prohibitionist
10 mentality, alternatively focused on research, product
11 accountability, tracking and standardizing consistency
12 by the FDA in tandem with the USDA and state oversight
13 down to the farm level.

14 Data analytics of supply chain is -- as
15 everybody has heard the echoing of that -- crucial for
16 traceability and safety. Regulating cannabis at a
17 distance, at least at the moment, will allow the
18 integrity of the currently 33 states and District of
19 Columbia to continue their medical programs, as Mr.
20 Fabricant and others have mentioned, the medical THC
21 regime that each state has implemented has taken many
22 state-specific factors into consideration for both its

1 constituents, the state's needs and working within the
2 regulated market.

3 I put a timeline here, but it's rather
4 complicated. But you guys can review it later, of
5 course. The second approach is a dual regulatory
6 approach similar to alcohol. At least on the
7 precipitous of a post-prohibition, the only other time
8 the United States has seen this was with alcohol.

9 So to subject non-psychoactive cannabis-
10 derived products to the two proven regimes that
11 already exist.

12 Impose similar minimum standards as there is
13 upon alcohol and tobacco such as purity, dosage,
14 consumer age, known labeling with medical claims,
15 health warnings, et cetera, on cannabis-derived
16 products, more speaking of non-psychoactive of course.
17 And regulate the products under the proven systems
18 already in place at the federal and state level.

19 I've heard a few questions from the panel
20 about incentivizations, required prescriptions. I can
21 get into incentivizations if you guys would like my
22 opinion on that.

1 For higher doses purity of cannabinoid and
2 subject such approval to abbreviated review process,
3 thereby increasing incentives for the research which
4 assists in the necessary data collection.

5 With data being collected by the states and
6 Canada, it will not be so much as just proving what
7 may be harmful, the known about the plant, but also
8 the unrealized potentially, the known unknown, if you
9 will.

10 For the moment, farmers should only be able
11 to isolate specific cannabinoids on a prescription
12 dosage purity level with the benefits of insurance,
13 medical industry and FDA support. And the inverse
14 would be social, religious, familial support groups
15 for the people who may abuse that from a dietary
16 supplement aspect.

17 Third is to clarify the confusion. As we all
18 know, having one drug violate the FD&C Act, CBD, and
19 the same drug not violate the act, Epidiolex, in a way
20 that would be understood from an agency level down to
21 the state and federal enforcement departments as well
22 as producers, vendors and consumers.

1 And then three may be controversial to some.
2 It's to allow the states to guide and support state
3 legislation, regulation in tandem with the USDA for
4 the farmers and the FDA. Each state should be allowed
5 to regulate both their respective non-psychoactive and
6 THC cannabis markets while operating under FDA minimum
7 standards and guidelines.

8 The state's commerce may be required to stay
9 within the state to be exempt as a temporary
10 compromise to accommodate this theory. If so,
11 companies who wish to operate in multiple states would
12 need to be based out of each state.

13 If any intrastate pacts are made, transfers
14 of raw plant materials, flower would need to be
15 agriculturally exempt through the act, the
16 agricultural act, in crossing state lines, allowing
17 farmers access to larger out of state markets.

18 I did not mention in the beginning. I
19 represent quite a few hemp farmers and THC farmers as
20 well as hemp seed cultivars. The industry will be
21 better kept inherently within the states while the FDA
22 and other agencies learn more about the challenges and

1 successes through the states, with the states always
2 being their own experiences in each of themselves.

3 The FDA's workload can be more focused on its
4 current regime of regulatory experience. Each state
5 has agricultural departments that must comply with the
6 USDA. States can regulate and enforce according to
7 minimum federal standards with their own thresholds as
8 they do with other heavily regulated industries like
9 alcohol, tobacco and gambling.

10 Plus they are collecting the tax revenues in
11 order to fund this. Cannabis is actually taxed more
12 than alcohol and tobacco and gambling.

13 MS. CRISTINZIO: Sorry, sir. You're quite
14 over. Can you wrap up, please?

15 MR. GITTO: Oh, am I quite over? Sorry. I
16 was into it.

17 MS. CRISTINZIO: Please don't forget to
18 submit all your comments to the docket.

19 MR. GITTO: Absolutely. Thank you so much.

20 MS. CRISTINZIO: Thank you.

21 MR. GITTO: Any questions? I thought I could
22 get into the Tenth Amendment there for a second.

1 Thank you.

2 MS. CRISTINZIO: Mayne another time. Next up
3 we have Brian Malkin.

4 PANEL MEMBER: Garrett Graff, yeah.

5 MS. CRISTINZIO: Sorry about that. I'm ahead
6 of myself. Garrett Graff.

7 MR. GRAFF: No problem at all. Good
8 afternoon, and thank you for allowing us all the
9 opportunity to speak before you here today.

10 My name is Garrett Graff. I am the managing
11 attorney of Hoban Law Group, a Denver-based law firm
12 that almost exclusively serves both the marijuana and
13 the hemp industries.

14 We have been extensively involved for several
15 years now with respect to helping set definitive
16 parameters around regulatory guidance at the state and
17 local levels, as well as at the federal level.

18 So with respect to this afternoon's
19 commentary, four takeaway points. First, to compel
20 and request that the FDA provide interim guidance as
21 it continues to evaluate regulatory schemes in the
22 forthcoming months and years. Second, the need to

1 reconcile and unify existing state regulations.

2 With respect to the 2014 Farm Bill, perhaps
3 both a good and bad thing is that it encouraged states
4 to create regulatory schemes. But now with federal
5 oversight through the 2018 Farm Bill, there's great
6 need to reconcile and unify those.

7 Third, in order to so reconcile state and
8 local laws, we can use existing FDA mechanisms to do
9 so. Product classifications, testing, labeling and
10 other standards are all applicable and able to be
11 extrapolated here to hemp products. There is no need
12 to reinvent the wheel.

13 And fourth, for the answers to -- in order to
14 get answers to questions that are yet unanswered, we
15 need to encourage research because to date it's been
16 stifled in many respects by federal agency rhetoric,
17 including that from the DEA.

18 With respect to the existing marketing and
19 sales of hemp products, there again are existing
20 mechanisms already in place. Labeling conventions for
21 foods, supplements, cosmetics and other product types
22 already regulated by the FDA are sensible and provide

1 an appropriate way to disseminate information to
2 consumers.

3 Warnings, such as those for use with
4 medications or when suffering from other medical
5 conditions or when pregnant, many other conventional
6 warnings of those types may be well applicable here
7 too for hemp products as well and can be replicated.

8 Secondly, manufacturers have a great onus in
9 these industries already. So you look at calcium,
10 vitamin C and other supplement manufacturers.

11 In many respects, it's their requirements or
12 their obligation to comply with FDA requirements and
13 to disseminate information to consumers. There should
14 not be any different standards adhered to or applied
15 to hemp product manufacturers.

16 And lastly, as I commented before, we have
17 this great need to reconcile state laws. States like
18 Colorado and their department of health have
19 implemented regulatory schemes that treat hemp
20 products just as if you're manufacturing any other
21 food or dietary supplement product. Excuse me. The
22 same registration is used. We need not any different

1 registration regulatory scheme, but rather can simply
2 use the same registrations, the same GMP requirements
3 and all of the same typical methods for the existing
4 product types.

5 Next, with respect to the manufacturing of
6 hemp products for public consumption, again, GMPs are
7 in place for foods, supplements, cosmetics and other
8 product types. Solvent-based manufacturing is not
9 new. Plant-based products are not new.

10 There are -- there is no need to specifically
11 regulate hemp differently akin to how vapes or tobacco
12 or other product types have been regulated by FDA in
13 one-off ways in the past. But instead this fits
14 squarely within existing regulatory schemes for
15 products.

16 Testing, there's been commentary so far today
17 with respect to the availability of testing. There
18 are testing companies that are testing food additives
19 and dietary ingredients and finished products and have
20 been doing so for decades. And they are applying
21 those same exact standards, knowledge and wherewithal
22 as to hemp products today. For potency, for

1 contaminants, for heavy metals.

2 Now again, I don't expect everything to be
3 perfect. I ordered food this morning at my hotel and
4 there were bits of plastic in it. So clearly not all
5 regulation is perfect. But those same standards can
6 be applied to hemp products in successful way, in a
7 sensible way and in a way that provides confidence and
8 certainty to both consumers and regulators alike.

9 I note on the slide before you with respect
10 to terminology -- and I note that the panel has asked
11 questions about terminology being used. Currently
12 there's approximately four different types -- four
13 different phrases widely used: full spectrum hemp
14 extract, broad spectrum hemp extract, isolate, CBD in
15 this case or perhaps other cannabinoids in other
16 cases, and hemp seed oil for those products derived
17 from hemp seed.

18 Now I also note importantly as well that the
19 panel should not just be considering CBD. That's of
20 course the hot topic for today. But there's over a
21 hundred cannabinoid compounds within cannabis. So
22 these are issues that we're going to have to replicate

1 time and time again or we can take this opportunity to
2 try and handle that for all the different cannabinoids
3 now.

4 With respect to those various phrases, full
5 spectrum represents a full representative profile of
6 the entire cannabis plant and the compounds and
7 cannabinoids that are in. Broad spectrum is a broad
8 but not yet full representative profile. Isolates of
9 course mean isolated profiles and hemp seed oils.

10 And lastly, with respect to research, you
11 know, obviously there's been a great deal of research
12 presented here today and that's a testament to those
13 that have conducted that research. But yet there are
14 still those that are rejecting the ability to do and
15 conduct research.

16 We have clients that have been requesting to
17 do so for years and institutions of higher education
18 that remain -- continue to cite DEA and other rhetoric
19 saying that IND applications are required. Now, while
20 none of us may agree with that or some of us may not
21 agree with that statement, that rhetoric is still out
22 there. And so, clear and definitive guidance from the

1 FDA that would encourage, not stifle research would
2 answer the questions yet unknown. Thank you for your
3 time this afternoon.

4 MS. CRISTINZIO: Thank you.

5 (Applause.)

6 MS. CRISTINZIO: Next we have Brian Malkin,
7 from Arent Fox.

8 MR. MALKIN: Good afternoon. All right.
9 Good afternoon. My name is Brian Malkin. I'm an
10 attorney. And today I'm not speaking -- I'm speaking
11 on my own behalf. I'm not speaking on behalf of my
12 firm, any client or association.

13 I'm a food and drug attorney and an IP
14 attorney. My background's biochemistry. I worked at
15 the agency. I've worked at FDA and IP boutique firms
16 and currently I'm at Arent Fox.

17 And one of the things I'm active in now in
18 some bar association where there's a direct
19 relationship to cannabis is the New York State Bar
20 Association. I'm the co-chair for the committee on
21 cannabis law. I also am the chair for the food, drug
22 and cosmetic law section and I'm also involved in

1 their activities on legislative affairs. And for the
2 Food and Drug Law Institute, I'm also on a new
3 committee they have, the cannabis-derived products
4 committee.

5 So there's increasing interest obviously now
6 with FDA and FDA attorneys looking at how FDA is
7 regulating cannabis. And within cannabis law from
8 such as myself, my current firm, there's a cannabis
9 industry group which we're seeing happening more and
10 more at different law firms as there are more and more
11 products in the space.

12 So this is the overview I'm going to talk
13 about today, sort of how I got involved in cannabis
14 and FDA law, what I'm seeing happening in terms of the
15 overlay of cannabis clients and FDA and the
16 interaction there, what that relates to in terms of
17 the questions that are coming up in law firms that
18 have these cannabis industry groups or dealing with
19 cannabis clients and what kind of guidance I would see
20 that's helpful for FDA to spell out as you're looking
21 at lawmaking right now.

22 So I got involved back in 2015 as the chair

1 of the food, drug and cosmetic law section. Someone
2 approached me and said, you know, there's a new law
3 within medical marijuana in New York. What kind of
4 program can you do in your FDA group? And I was like,
5 I didn't know. It's not an FDA-regulated product at
6 that moment.

7 I said let's do something on ethics of
8 representing cannabis clients because there's a lot of
9 ethics issues that come in which gives the interplay
10 between federal and state laws because federal law was
11 saying it was illegal, state laws were saying it was
12 legal. So we thought that was a good topic to talk
13 about at the time.

14 Also what we started seeing is that within
15 our association, there were different programs. Every
16 section was doing it different. They're different
17 legal disciplines. So it's not just food and drug.
18 It's IP. It's labor law. It deals with real estate.
19 You know, there were all these different disciplines
20 that were coming into play.

21 And so, what I saw, there was a need that we
22 had to create some sort of thought leadership in the

1 space of cannabis generally. FDA is just one part of
2 that.

3 And so, back in June 2017, I pitched to the
4 state bar to create a committee and it was approved.
5 And so, now we have a committee on cannabis law. And
6 I'm a co-chair for that. And we also added an
7 academic advisor, the first professor who wrote a
8 textbook for law schools on cannabis law.

9 So this is the mission of our committee and
10 essentially what we're really trying to do is provide
11 good thought leadership within the space for laws as
12 well as advising other lawyers who want to get into
13 the space to properly advise their clients in terms of
14 what's going on in regulatory law. And that's
15 relevant here in terms of what FDA is considering to
16 do for cannabis and CBD-related products.

17 So far we've put on a number of CDLE
18 programs. This is giving a little bit of an overview
19 of the ones that had some interplay with FDA and you
20 can take a look at those sort of later.

21 What has happened since 2015 and that initial
22 program, what I'm seeing happening is there's an

1 increasing client base. First there was a lot of
2 international activities going on in regulation
3 because there wasn't a lot of guidance in what you
4 could do in the U.S. Everything was considered
5 illegal.

6 And so, the research had to be done overseas.
7 And there was a lot of frustration. The University of
8 Mississippi was the only source. It was a difficult
9 source to get ahold of the product. It was not a very
10 high quality source for doing cannabis research.

11 And so, and then there's the interplay
12 between whether it was legal or not. And so, again,
13 it was very frustrating and there's banking issues and
14 marketing issues for the products that were very
15 complicated.

16 So now what's happened since the Farm Bill
17 that came into play is that basically more companies
18 want to enter the market. Their first goal is to
19 enter the state friendly markets and then interstate
20 commerce. And that's fine. They're looking for more
21 FDA review and guidance. I want to sort of get
22 actually in terms of -- my time is coming into place -

1 - what kind of questions we see would be helpful for
2 FDA to give guidance on.

3 So a lot of the questions now is like what is
4 legal. We get that question all the time. Is what
5 I'm doing legal? Can I do this? Is it appropriate?
6 We're struggling with definitions about CBD extract,
7 broad, full spectrum, things like we've talked about
8 earlier today.

9 What is hemp extract? Is it from the hemp
10 seed or from the plant? That's not clear all the
11 time. What does THC-free mean? What are these --
12 what kind of laboratory tests are appropriate to use?
13 Are they state testing authorities?

14 Are there some national authorities for that?
15 What kind of intermediary processing comes into play?
16 If your THC level above 0.3 percent in your biomass,
17 what does that mean? Can you transport that in
18 interstate commerce or not?

19 And then, what kinds of products can be used
20 in FDA-regulated products? So these are some things
21 where we thought FDA could be helpful with the dosage
22 forms, whether there's need for allergen testing,

1 guidelines for cGMPs that are relevant to cannabis,
2 specific to it.

3 Import/export implications with the Border
4 Patrol and advertising as FDA relates to the THC and
5 developing more uniform labeling standards. Thank
6 you. Any questions? All right. Thank you.

7 MS. CRISTINZIO: Thank you. Next we have
8 speaker number 100, Robert Morgan.

9 MR. MORGAN: That's not mine, no. That's
10 mine. Thank you. Thank you, and good afternoon. My
11 name is Bob Morgan, and on behalf of ASTM
12 International, I would like to thank the FDA for
13 giving us the opportunity to provide some comments
14 concerning our scientific and consensus-based driven
15 efforts to develop technical standards that advance
16 the safety, manufacturing and product quality of
17 cannabis products and processes.

18 ASTM International was established 120 years
19 ago to enable industry, consumers and regulators to
20 work in public and private collaboration in the
21 development of consensus standards that ensure product
22 quality and performance while protecting the consumer

1 and the environment. Over this time, ASTM has
2 developed nearly 13,000 standards for 90 different
3 industry sectors. Over 6,000 ASTM International
4 standards have been adopted or referenced in
5 regulations in the United States and around the world.

6 ASTM standards are known and trusted for
7 their technical quality and relevance because they are
8 developed in an open and transparent form, with all
9 stakeholders having an equal voice in the process.

10 These standards range from ensuring the
11 performance of jet fuel used in airplanes to the steel
12 and concrete used in our infrastructure, as well as
13 for the safety of children's toys.

14 ASTM and the Food and Drug Administration
15 have a long history of working together for the
16 development of standards for all types of medical
17 devices. As an active stakeholder, the FDA
18 contributes its technical and regulatory expertise to
19 help inform and shape ASTM consensus standards because
20 they can be developed more efficiently by a
21 collaborative effort among regulators, manufacturers
22 and users.

1 They can be more easily updated to reflect
2 changes in technology or new product development and
3 because they can be recognized and utilized globally
4 as international standards.

5 In response to a request for standards from a
6 cannabis cultivator, ASTM met with key industry
7 stakeholders and, in 2017, formed committee D37 on
8 cannabis. The scope of this technical committee is
9 the development and maintenance of standards and
10 guidance materials for cannabis and its products and
11 processes.

12 D37 has grown to 600 members from 14
13 countries representing all aspects and components of
14 the cannabis and hemp industries. Partnerships have
15 been created with key industry organizations bringing
16 in research and stakeholder participation.
17 Subcommittees on cultivation, laboratory testing,
18 quality management, processing and handling and
19 transportation have been actively working on standards
20 for their part in this industry.

21 To date, ASTM has developed six full
22 consensus standards addressing water activity,

1 cleaning and sanitation, packaging and labeling, waste
2 management and managing hazard analysis critical
3 control points.

4 Our efforts are already having an impact as
5 U.S. states are working towards referencing the water
6 activity standards, ensuring product stability in the
7 marketplace.

8 In addition to these approved standards, the
9 stakeholders are driving dozens of standard test
10 methods that will impact laboratory testing for
11 pesticides, residual solvents, heavy metals,
12 cannabinoid and terpene analysis, compliance auditing
13 as well as security and transportation processes.

14 Our newest subcommittee on industrial hemp
15 has opened the door for the many issues of hemp as a
16 food supplement and as a construction material.

17 The efforts of ASTM members clearly
18 demonstrate a commitment to raise the bar for this
19 industry through consensus standards that ensure
20 product quality and safety.

21 Moving forward, ASTM committee D37 is eager
22 to work with the FDA and others from state and federal

1 regulatory bodies and all stakeholders on the
2 development of high quality consensus standards that
3 support every step in the production and processes for
4 these emerging class of products.

5 Thank you for this opportunity to share these
6 comments, and I look forward to answering any
7 questions you may have. Thank you.

8 MS. CRISTINZIO: Thank you. Next, we have
9 Sheri Orlowitz, speaker number 101.

10 MS. ORLOWITZ: Good afternoon. I'm Sheri
11 Orlowitz, and I'm honored to be here and I'm pleased
12 to be representing MPP in my role as an officer and
13 board member.

14 I'm a businesswoman. I'm a former Justice
15 Department lawyer who was recruited through the honors
16 program. And I'm a former federal prosecutor who was
17 charged with enforcing the drug laws.

18 We change lives. That's a pretty bold
19 statement. But for the past 25 years, MPP has been
20 working to decriminalize cannabis because cannabis has
21 ruined more lives than people use cannabis today. We
22 need and we welcome the FDA regulation and we suggest

1 that the FDA take note of the state markets and the
2 state regulatory schemes as a starting point.

3 As MPP's legislative counsel said to me, the
4 FDA should pave the cow path. So today, I'm going to
5 give you a little view of the cow path, our broad
6 recommendations and how we might be able to assist.

7 Changing state laws. It's hard to fathom how
8 fast things are changing today. Yesterday 33 states,
9 including 10 states that are adult use cannabis.
10 Today Illinois just passed adult use, 46 against, 66
11 for.

12 The landscape is unbelievable. The reality
13 is cannabis is used by millions of people. One report
14 estimates that close to 25 million people are using
15 cannabis today. They're doctors. They're lawyers.
16 They're legislators. They're Fortune 500 CEOs. In
17 fact, perhaps there are some FDA administrators and
18 some of the most successful people in the world.

19 What we know over the 80 years that cannabis
20 has been illegally -- has been used illegally, there
21 have been few reported incidents of serious adverse
22 effects.

1 To the contrary, they are far outweighed by
2 more and more evidence that cannabis has many
3 legitimate medical and wellness uses, as well as for
4 recreation, with less deleterious effects than
5 alcohol.

6 Unprecedented change. Cannabis moved from
7 the back alleys to beautiful dispensaries and this is
8 an opportunity for oversight and control by the FDA.
9 But we caution against an unduly restrictive scheme
10 that can drive another illegal and unsafe market.
11 That is something we do not want.

12 We have already seen incidents of synthetic
13 CBD using rat poison ingredients which hundreds of
14 people, I've been told, died from. This is something
15 that must stop. No more back alley dealing.
16 Retailers should have confidence in what they are
17 selling and the populace needs to have confidence in
18 what it is buying.

19 Regulation now falls largely to the states.
20 And again, that is where MPP has done most of the
21 work. Our knowledge of the state and regulatory
22 schemes that we have helped create over the past few

1 decades is unparalleled.

2 We have been assembling a council of experts
3 which includes scientists, some former FDA, academics,
4 lawyers as well as industry people from outside the
5 U.S. who have no stake in the U.S. regulatory scheme
6 to help us understand the landscape and shape our
7 advocacy work.

8 We've taken great pains to assemble this
9 council so that there are people without conflicts of
10 interest in the current U.S. regulatory scheme.

11 The broad range of products is mindboggling
12 and gives rise to so many dichotomies in the states.
13 Some states allow flower. Some states don't allow
14 flower. Some states allow infused drinks. Some
15 states don't allow infused drinks.

16 Aside from the state and federal illegal
17 dichotomy, I give you an example in California which
18 arose out of an FDA edict which just threw more
19 confusion into the way. CBD from hemp was illegal for
20 food products. But CBD for marijuana was legal from
21 food products -- in food products, excuse me.

22 Now how can that be enforced? As far as I

1 have researched, there is no test that can discern the
2 difference between CBD from marijuana and CBD from
3 hemp. FDA. FDA looms large over all of the states.
4 These -- wrong page. So we suggest that the FDA work
5 hand in hand with the states and not against the
6 states.

7 Consider we agree with Commissioner
8 Gottlieb's statement in early April. The path that
9 the FD&C allows for such substances to be added to
10 foods or marketed as a dietary supplement is first by
11 the FDA issuing a regulation through notice and
12 comment rulemaking allowing such use and through
13 bifurcating the regulation of cannabis to both drug
14 pathway and supplemental pathway at lower doses, the
15 FDA can provide Epidiolex a protected path and provide
16 for usage for health, wellness and recreational use.

17 As we go forward, MPP is a veteran of the
18 drug war and 25 fighting it has made us experts. We
19 know overregulation created the largest illegal
20 industry and this war has cost more and created more
21 American casualties than all wars combined. So we
22 give the following recommendations. We recommend a

1 dual path be created for cannabis. We recommend --

2 MS. CRISTINZIO: Briefly, please, because
3 you're over.

4 MS. ORLOWITZ: Okay. Thank you very much.

5 MS. CRISTINZIO: Thank you.

6 PANEL MEMBER: Can I just ask a quick
7 question? You said that you have a vast knowledge of
8 all the state laws and regulations. If you have
9 compilations and analyses or comparisons of those laws
10 that you can put on the record, that would be very
11 useful for us.

12 MS. ORLOWITZ: In fact, we were going to
13 allow -- ask that you allow us to provide a
14 comprehensive report on the state laws along with some
15 recommendations of how to proceed. If you would like,
16 we would be happy to submit such.

17 PANEL MEMBER: Yeah. Thank you.

18 MS. ORLOWITZ: Thank you.

19 MS. CRISTINZIO: Thank you. Next up, speaker
20 number 102, is Steve Mister.

21 MR. MISTER: Good afternoon. I'm Steve
22 Mister, with the Council for responsible Nutrition.

1 CRN is the leading trade association representing the
2 dietary supplement and functional food industry. We
3 start with the acknowledgement that we hear FDA's
4 position.

5 FDA currently considers CBD to be prohibited
6 for use in dietary supplements and foods because of
7 the exclusionary provision of section 321, a provision
8 that's somehow referred to as the IND exclusion.

9 This provision was included in DSHEA to
10 protect the commercial interests of pharmaceutical
11 firms and to incentivize drug development by assuring
12 that years and millions of dollars of research for a
13 drug would not be diminished by allowing food and
14 dietary supplements to come in and use an article if
15 it was first studied as a drug.

16 It's important to realize that this provision
17 is grounded in protecting the commercial interest of
18 pharmaceutical research, a worthy objective. But it
19 is not a safety question, but rather a race to market,
20 or more appropriately, a race to investigate.

21 Even so, Congress gave FDA the discretion by
22 statute to permit an article to be used in food and

1 supplements irrespective of the race to investigate
2 because it foresaw circumstances that might arise that
3 would justify mutual use and deny an indefinite
4 monopoly to a drug company should that article have
5 other intended uses than just the drug claim.

6 So it is worth reiterating that the IND
7 exclusion is not a safety question. FDA has plenty of
8 processes and standards in place to examine the safety
9 of any ingredient and it should use those tools and
10 aggressively demand evidence of safety. But the
11 initial determination of whether CBD is a dietary
12 ingredient is not a safety question. It's a
13 commercial one.

14 FDA needs to trust its own processes for
15 examining safety in due time with respect to the
16 requirements for each of the regulatory channels where
17 CBD would appear, whether food, cosmetic, supplement,
18 OTC drug or prescription medication.

19 One of the advantages of considering the
20 definitional issue first and independent of the safety
21 consideration is that it allows FDA to more quickly
22 clear up the regulatory confusion and then consider

1 safety for each individual product rather than trying
2 to adopt a "one size fits all" broad safety standard
3 dosage ceiling across all of these products.

4 Such a broad safety standard developed at the
5 beginning of the process would be ill-fitted for the
6 vast range of CBD-containing products that are already
7 in the market.

8 It would fail to provide flexibility as new
9 research emerges and it would not take into account
10 the wide range of dosage forms, delivery systems,
11 dosage levels, cautionary level statements and other
12 differences among all of these products that would
13 factor into whether individually they would be
14 considered safe.

15 For FDA and for industry, consumer safety is
16 always job one. But that doesn't mean that
17 sequentially it's the first job we do. Providing a
18 predictable and lawful path to market is.
19 Particularly when it comes to products that are
20 already in the marketplace, FDA needs to act swiftly.

21 The agency must also act boldly to assure
22 that products comply with the rules for whatever

1 regulatory lane they are swimming in. If a CBD-
2 containing product is marketed as a dietary
3 supplement, if it contains a dietary supplement
4 statement of identity on the label, if it carries a
5 supplement facts box, then the marketer of that
6 product has implicitly signaled to FDA and to
7 consumers that it should be held to the regulatory
8 framework for dietary supplements.

9 And so, these products should be made in a
10 facility that is registered with FDA. They should be
11 subject to GMP inspection. The label should comply
12 with all general regulations for supplements. The
13 marketer should have a system in place for reporting
14 adverse events.

15 All CBD-containing supplements should be
16 treated as new dietary ingredients, subject to
17 notification. And then, questions about identity of
18 the product, identity, purity, potency and composition
19 should be addressed with adequate characterization of
20 the product in the NDI notification and then followed
21 up with product testing.

22 And FDA should strongly enforce these

1 category-wide requirements on these CBD requirements
2 as they would for any dietary supplement, using the
3 range of tools provided by DSHEA like warning letters,
4 import alerts, product seizures, mandatory recall and
5 even criminal sanctions to send a clear message.

6 FDA will still have the opportunity to
7 evaluate safety though. And while I will not get into
8 specific safe levels identified in the ongoing
9 research, FDA should find some comfort that well-
10 respected authoritative reviews have already found CBD
11 to be safe.

12 Demanding adherence to the NDI notification
13 requirement in DSHEA will give FDA, in due time, the
14 ample opportunity to insist upon, to analyze and to
15 evaluate the safety data that's specific to each
16 product.

17 Indeed, CBD research has already generated
18 several systematic reviews that support the potential
19 of CBD to be used in the general population without
20 the requirement of the intervention of a health
21 professional. These early studies have found CBD to
22 be well-tolerated and appropriate for use.

1 Ironically if a company submits an NDI
2 notification today to FDA, complete with all of that
3 safety data, it would have the notification returned
4 because the ingredient is not recognized as a
5 legitimate dietary ingredient.

6 But if the FDA creates a predictable path to
7 market, then the safety research that the agency so
8 craves will materialize because then the nutrition
9 community, academia and government agencies like NIH
10 will all join in the symphony of research.

11 So, and then I'm going to provide you with
12 some references to some of those safety data. In
13 summary, CRN urges FDA to act quickly and decisively
14 to resolve the definitional issues by conducting a
15 notice and comment rulemaking to allow hemp and hemp-
16 derived CBD to be used in food and dietary supplements
17 and, in the meantime, to demand that products that are
18 marketed as food or dietary supplements comply with
19 all of the requirements long-established and expected
20 of any product in those channels. Thank you.

21 PANEL MEMBER: Given your knowledge of the
22 dietary supplement industry, I'm curious of your

1 opinion about whether you believe that most of the
2 supplements, particularly the CBD supplements, are
3 produced by companies that already exist.

4 In other words, it's an additional product to
5 an existing facility, or whether you think there'll be
6 numerous additional facilities that will need to be
7 inspected.

8 MR. MISTER: Well, I think that's the irony
9 of the CBD situation in the marketplace that has
10 exploded over the last three years. Typically when a
11 new ingredient comes to market, it comes through
12 existing companies who are already in the dietary
13 supplement space. And as a result, they're well-
14 equipped and familiar with all of those requirements.

15 I believe what's happening in the CBD space
16 is that the majority of these companies who are
17 bringing CBD to market as supplements are not
18 companies that are traditionally in the supplement
19 space. So they're not even aware of the requirements
20 to have an adverse event system in place, where a
21 dietary supplement company that's been in this space
22 knows well that that's been around since 2008. So I

1 think that is creating an added requirement why the
2 agency needs to be aggressive in enforcing the other
3 requirements for supplements.

4 PANEL MEMBER: Do you have any estimates of
5 how many additional facilities you think are out there
6 beyond what we're aware of with these existing dietary
7 supplement facilities?

8 MR. MISTER: I would have no way of knowing
9 that. Thank you.

10 MS. CRISTINZIO: Thank you. Our next speaker
11 is Matt Sica, speaker number 103.

12 MR. SICA: I'm Matthew Sica. I'm the
13 accreditation manager at ANAB, responsible for
14 cannabis labs. ANSI National Accreditation Board is a
15 recognized international body that does assessment
16 activities around the world to various standards.

17 We're asking that FDA consider the adoption
18 of the international conformity assessment model
19 pertaining to testing activities for the cannabis
20 space. This testing may include aspects such as
21 content of cannabinoids, pesticides, heavy metals and
22 microbiological organisms.

1 ANAB encourages the use of accredited
2 laboratories, 217025, the international standard for
3 the general requirements of competence of
4 laboratories. We respectfully ask FDA to consider not
5 using terms such as meeting the requirements of or in
6 compliance with 17025. We stress that conformity
7 assessment and accreditation to 17025 is more
8 appropriate as it includes an independent review of
9 the competence of the laboratory.

10 Acting as impartial entities, internationally
11 recognized accreditation bodies evaluate the
12 competence of the lab. The accreditation body
13 approach and assessments provide a credibility to the
14 conformity assessment activities such as testing and
15 that goes beyond a self-declaration of meeting the
16 spirit of the standard.

17 The conformity assessment model is structured
18 to give confidence through the attestation of
19 competence. Accreditation is the formal recognition
20 of competence of the laboratory to carry out specific
21 activities in accordance with the standard as
22 described in a scope of accreditation.

1 Accreditation provides the attestation that
2 laboratories offering testing have technical
3 competence and impartiality to check conformity of
4 products to relevant specifications.

5 Lab accreditation provides a ready means for
6 customers to identify and select reliable testing
7 services. The competence is determined through an
8 ongoing cycle of assessments, onsite and offsite, by
9 technical competent experts and through participation
10 in proficiency testing on an ongoing basis.

11 The conformity assessment model provides
12 several levels of impartiality throughout the process.
13 Regulators may set requirements for specific products.
14 The producers of those products use testing services
15 to determine conformance to specific requirements.

16 Conformity assessment bodies, in this case
17 laboratories, test the products where those conformity
18 assessment bodies are assessed for competence by the
19 accreditation bodies. This is strengthened when
20 accreditation bodies are peer-evaluated and are
21 members of mutual recognition arrangements among
22 accreditation bodies. In the United States, there are

1 several ILAC signatory accreditation bodies to promote
2 choice through an established competitive market.

3 Accreditation is based on the laboratory
4 demonstrating compliance with specified requirements
5 for competence, independence and impartiality.

6 Competence is determined through the experience and
7 technical skills of the staff, as well as review of
8 equipment and the methods utilized.

9 Independence is determined through a review
10 of the business framework of the accredited body and
11 any related bodies to show autonomy between the
12 laboratory and organizations to which it provides
13 service.

14 Impartiality is demonstrated through the
15 absence or management of conflicts of interest with
16 the laboratory to whom they are providing the
17 services.

18 Benefits of accreditation include for
19 regulators the use of the conformity assessment model
20 can support implementation of national legislation to
21 confirm compliance with standards and accepted
22 requirements, reduce bureaucracy by eliminating a

1 number of administrative obligations and limit costs
2 and resource needs by reducing the need for regulators
3 to employ their own specialized assessment personnel.

4 For consumers, it can create trust, where
5 consumers have confidence that the market is enhanced
6 knowing that products and services they choose are
7 regularly evaluated and checked by independent and
8 competent third parties.

9 For business, accreditation can boost
10 efficiency where accurate measurement and testing
11 performed in accordance with best practices can help
12 limit errors and control product costs and
13 contributions. By relying on accredited tests,
14 regulators --

15 MS. CRISTINZIO: Sir, please wrap it up.
16 Please wrap up.

17 MR. SICA: Yeah. Regulators obtain
18 independent evaluation which is a transparent process
19 and allows for the product to go through. Please
20 consider the use of ILAC MRA signatories.

21 MS. CRISTINZIO: Thank you for that. Please
22 submit the rest of your comments to the docket for

1 consideration. Our next speaker is David Steinberg,
2 104.

3 MR. STEINBERG: Okay. I guess I've got the
4 microphone right. I'm David Steinberg. I am the
5 founder of Steinberg & Associates. We are a
6 consulting firm that deals in the chemistry and
7 regulations of cosmetics and topical drugs.

8 I titled my presentation "The Coming Crisis,"
9 and that may give you a slight comment which is to
10 explain why I think it's a crisis and why I'm so
11 concerned.

12 My wife and I have a 38-year-old son who,
13 when he was five months old, was diagnosed with
14 infantile seizures. He outgrew this because he got to
15 be two years old. So it became Lennox-Gastaut
16 Syndrome and you've already heard something about
17 this. I'll talk a little bit more about it later.

18 I thought by now someone would have put this
19 slide up. But no one did. What is CBD? I haven't
20 heard anyone say what it is. I've heard everyone talk
21 about it. CBD is a chemical. It has a CAS number.
22 It's commonly called CBD. It has an IUPAC name. It

1 has a definitive structure right here, which you've
2 already seen.

3 Oh, I went the wrong way. This is what CBD
4 looks like. I don't know how many of you have ever
5 seen pure CBD. Not too many people. It's horrible.
6 I sort of describe it as a mixture of molasses with
7 soft margarine. It is yucky is the best way to
8 describe it. It sticks to everything. As a chemist,
9 it's very difficult to handle.

10 As you know, we've already heard that it has
11 an approved legal use that came out last June. The
12 important comment that I want to make here is on the
13 label it is not stable after being opened for 12
14 weeks. It's available by prescription only.

15 The other term I hear constantly is CBD oil
16 and I have no idea what CBD oil is. Every company
17 that I've asked about what it is, I heard a different
18 story, the term. And I have a typo mistake here. It
19 should be CBD oil. It has become generic. I've asked
20 manufacturers what is it. Well, it's CBD in oil.
21 Petroleum oil? Mineral oil? Sesame oil? Not
22 disclosed. So this has become a generic term and this

1 has led to some of the crisis that I am concerned
2 about.

3 At the Lennox-Gastaut Foundation meeting
4 three weeks ago in Seattle, I was talking to many
5 parents of children with LGS. And some of them were
6 taking the legal drug and some of them for other
7 reasons were taking the generics, which claim to have
8 the same effect. And their children suffered from it.

9 But they told us it was CBD oil, just like
10 the real stuff.

11 Okay. This, everyone knows the uses of CBD.
12 So what is CBD? Does it have specifications? Do we
13 have solvents present? What is the purity? The
14 sample that I showed you before was measured at about
15 98.2 percent purity. What are the contaminants? Does
16 it have THC in it? What trace contaminants are? And
17 of course we have the unintended use of imitations
18 which have caused all sorts of bad consequences.

19 Okay. My principal chemistry issue with CBD
20 is that it's not stable. Everyone needs to understand
21 it's not stable. It has a maximum temperature of
22 about 25 degrees Celsius, which is 77 degrees

1 Fahrenheit. Above that, it starts to break down or
2 form other compounds. You can't store it cold because
3 below 4 degrees Celsius, around 39 degrees Fahrenheit,
4 you have other problems.

5 It is packaged in dark brown glass. We now
6 have a place for recycled beer bottles. It is not pH
7 very stable. It's stable most at about 6.5 to 7.
8 That's not where we want to use it in cosmetics. Most
9 cosmetics are lower than that. The degradation
10 products possible include THC. So stability is a
11 critical question.

12 So what I want to say is that the FDA needs
13 to establish specifications for CBD. Get a USP
14 monograph and have that be the law of the land for any
15 use of CBD, whether it's in foods, drugs, cosmetics or
16 in dietary supplements.

17 So here it is. Let's have the percent of CBD
18 on the label and also, because of the instability of
19 it, the date of the manufacture of the CBD raw
20 material on the label. Thank you.

21 (Applause.)

22 MS. CRISTINZIO: Thank you very much. Our

1 next speaker is Youn Lee, 105.

2 DR. LEE: Hi. My name is Youn Ok Lee and I'm
3 a social scientist at RTI International, a nonprofit,
4 independent research institute and I --

5 MS. CRISTINZIO: Please move the microphone
6 down a little bit.

7 DR. LEE: And I've led many studies in
8 tobacco regulatory science. However, today I'm going
9 to be presenting data from my NIDA-funded study of
10 adult cannabis user behavior. I just wanted to
11 acknowledge my collaborators and funding source.

12 And I'll just start by saying what everybody
13 has said before, which there are many, many cannabis
14 products currently available on the market. The
15 degree to which the mode of administration of cannabis
16 may affect both individual and population health risks
17 is currently unknown. And national surveys do not
18 capture this range of cannabis product on the market,
19 which severely limits the population surveillance
20 necessary to monitor the population health effects
21 that may occur as a result of some of these products.

22 Furthermore, prior studies show that

1 concurrent use of cannabis and tobacco is prevalent.
2 But less is known about the potential effects of this
3 concurrent use of cannabis with tobacco or nicotine.
4 Such co-use may complicate the regulatory approach
5 needed for such products.

6 And finally, there's reason to expect that
7 the use of the range of the available cannabis
8 products varies by subpopulation, in part because of
9 the ease of targeted digital marketing, many brands
10 and retailers can increasingly tailor and target
11 market to specific groups in the population.

12 For example, here are a couple of
13 screenshots. You see the brand Kandypens at the top,
14 which I think is clearly positioned to appeal to
15 younger adults. And then below, you have a CBD
16 product line whose ad features older individuals and
17 explicitly markets to what they say seniors and
18 veterans with a discount.

19 So my purpose is threefold. First, I wanted
20 to look at what types of cannabis products are used by
21 consumers, especially those in mature markets.
22 Second, I wanted to know does preferred THC versus CBD

1 concentration vary across sociodemographic groups.

2 And third, I wanted to look at what motives for use
3 are associated with high CBD products compared with
4 high THC products.

5 So just very quickly in the interest of time,
6 we collected original data. We surveyed 2,978 past
7 30-day cannabis product users in the legally -- the
8 recreational legal states at the time of survey. We
9 collected this data in November and December of 2018
10 using a protocol approved by the RTI IRB. It was a
11 convenience sample, but we did calibrate based on past
12 30-day cannabis use using the 2016-2017 BRFSS.

13 All right. So results. So here you can see
14 the 30-day prevalence of each type of cannabis product
15 that we measured along the bottom. Now one thing to
16 note is that these categories are not mutually
17 exclusive. So they won't total to a hundred percent.
18 But you can see by the percentages that these indicate
19 a high degree of multi-product use. A large
20 proportion of our adult sample reported using multiple
21 modes of cannabis administration in the past 30 days.

22 Overall, if you look at the left side, you

1 can see that joint, edible, pipe and vape were the
2 most prevent reported products, though many current
3 cannabis users did also use or co-use with tobacco as
4 well, indicated by the yellow bars.

5 So we can see evidence of the co-use that's
6 been reported in prior surveys and show some of the
7 relative prevalence that may be driving the
8 introduction of nicotine-cannabis products onto the
9 market.

10 Now here we added information about use
11 frequency, indicted by the orange line. You can see
12 that shows the average number of days in the past 30
13 each product type was used. And so, I won't go
14 through all of the results.

15 But you can see for pipe, for example, it was
16 the most frequently reported number of days at 11.5
17 days of the past 30 compared to 4.3 days of the last
18 30 for co-vaping with nicotine. But there's a decent
19 amount of variation here that should be considered
20 when assessing the health effects, dose or exposures
21 of these different modes, certainly when people are
22 using multi-modes.

1 So we also wanted to examine cannabis product
2 type and demographic characteristics. So here you can
3 see as an example we were comparing people who
4 reported they usually use a high THC, low CBD product
5 versus a low THC, high CBD product versus equal
6 amounts of THC and CBD and we included I don't know
7 because in this case I think the response of I don't
8 know can be meaningful because there may be knowledge
9 gaps in the public that need to be addressed with
10 proper public education.

11 We see relatively high percentages compared
12 to don't know responses to other items in the survey
13 which suggests that many consumers may not really know
14 some of these differences.

15 MS. CRISTINZIO: Please wrap up.

16 DR. LEE: Oh, all right. Let me go really
17 quickly then. So finally I just wanted to share some
18 of the motives and show you that they differ a bit by
19 the high THC, low CBD, especially you treat a health
20 problem. You'll see that those scores are higher for
21 the CBD responses.

22 So just to wrap up, our data suggests that

1 regulation of cannabis involves understanding
2 variation among products and consumers or users.
3 Protection of public health requires considering
4 population health in addition to individual health and
5 this can inform approaches for regulating these
6 products in the protection of public health.

7 Thank you. And we look forward to doing more
8 research like this in support of the decision-making
9 of you and other stakeholders.

10 PANEL MEMBER: Just a question. Will those
11 data be available in the public docket in any greater
12 detail? That would be really useful information for
13 us.

14 DR. LEE: We can submit some summary, I
15 believe.

16 PANEL MEMBER: Thank you very much.

17 MS. CRISTINZIO: Thank you. Our next speaker
18 is in the "Patient" category. We have James Werline.

19 PATIENTS

20 DR. WERLINE: Good afternoon. My name is
21 James Werline. Greenwich Biosciences supported my
22 travel, but I have not been paid for my time.

1 I took off of work and traveled here today
2 from San Antonio, Texas because I feel it is important
3 for the FDA and the public to understand what an FDA-
4 approved CBD oil has done for my daughter and family.

5 I am a husband and father of a child with a
6 rare disease known as Sturge-Weber Syndrome. And I am
7 also a Doctor of Pharmacy. So I look at today's
8 hearing issue, a regulatory pathway for cannabis and
9 cannabis-derived products, through two lenses, one as
10 a pharmacist, the other as a dad.

11 Those two lenses provide me with a single
12 clear vision for what I believe the FDA must do to
13 support the needs of people with rare diseases, people
14 like my daughter, Camilla.

15 In this photo, my wife Marla is holding
16 Camilla. We will celebrate her second birthday in
17 about six weeks. Camilla is as sweet as any little
18 girl you'll ever see. She's also a fighter. Camilla
19 started having seizures when she was only nine months
20 old.

21 When a child has debilitating seizures, the
22 entire family suffers. As time went on, her seizures

1 increased to 20 to 25 attacks every day and were
2 considered drug-resistant. We tried to ease Camilla's
3 suffering and we fought to give her every chance to
4 have a better quality of life through a combination of
5 treatments.

6 At one point, we were pumping six medications
7 into our little girl twice a day, every day and still
8 the seizures continued. My worries grew significantly
9 because I didn't know if Camilla's development delays
10 were due to her disease or the medicines prescribed as
11 treatment.

12 My wife and I took Camilla to some of the
13 country's leading pediatric neurologists and
14 epileptologists. She underwent all the tests you can
15 imagine. We received three different diagnoses for
16 three different types of epilepsy and we didn't have
17 an answer and neither did the doctors. We even
18 considered a brain surgery that is too complicated and
19 too gruesome to describe during my brief time with you
20 today.

21 As the months dragged on, our frustration
22 turned to desperation. About a year ago, my wife and

1 I thought about trying CBD oil on Camilla. We planned
2 to drive from San Antonio to Colorado to buy a CBD
3 product from a dispensary. Desperation can make you
4 do some crazy things.

5 For the first time during Camilla's illness,
6 we were considering giving an untested, unproven,
7 unregulated product to our little girl. Sure, there
8 were anecdotal reports of children with epilepsy
9 getting better with CBD.

10 But I wouldn't know how to monitor for
11 interactions or how to adjust other medications that
12 she was already taking and who knows what would be in
13 the bottle that we bought and gave to Camilla. Its
14 ingredients and its impurity would be unknown. It
15 could contain THC or toxins or other substances that
16 could worsen her condition. And that is today's world
17 of unregulated and inadequately controlled CBD oil.

18 On Thanksgiving eve, just six months ago, we
19 have Camilla her first dose of Epidiolex, which the
20 FDA had recently approved as the only prescription CBD
21 medication. And we watched in wonder as our prayers
22 were being answered right before our own eyes.

1 I am forever grateful to the FDA and the
2 company that invested in the clinical trials and
3 manufacturing processes needed to bring a new
4 medication to patients and families like ours.

5 I'm not testifying to promote the product.
6 But I have to share that Camilla hasn't had any
7 seizures since she's been on the medication. She's
8 also been able to wean off of five medications and
9 continues to reach new development milestones. Even
10 now, after living her best life for the past six
11 months, it still seems unbelievable.

12 FDA determined that the company demonstrated
13 safety and efficacy to the agency's satisfaction and
14 that means that families like ours can have
15 conversations with our doctors to determine if a
16 product is indeed the right drug for the right patient
17 at the right time.

18 FDA, I'm asking you to accept your
19 responsibility and exercise your authority to
20 meaningfully assist patients, their families and
21 health professionals with a few simple yet important
22 questions.

1 What is in a bottle containing CBD that is
2 purchased in a retail store or online? What does a
3 label say about what's in that bottle? And what can
4 it do to the patient, both good and bad? These are --
5 well, there are families out there that will benefit
6 from FDA-approved prescription CBD medications just
7 like we have.

8 Patients and their healthcare professionals
9 should have as much information and assurances as
10 possible in order to make informed decisions about a
11 substance that might be beneficial. They deserve to
12 have a clear vision for navigating their individual
13 health journey. Today they're flying blind. They
14 don't know what they're taking or what they're giving
15 to their little girl or boy.

16 FDA, please require that these drugs are
17 subject to robust clinical trials and good
18 manufacturing processes to demonstrate safety,
19 efficacy and purity. Every patient deserves a chance
20 to receive the same blessings that our family has
21 received over the last six months. Thank you for your
22 time.

1 (Applause.)

2 MS. CRISTINZIO: Thank you. Next up, we move
3 to the "Public Safety" category. We start with number
4 107, Heather Despres.

5 PUBLIC SAFETY

6 MS. DESPRES: I'd like to thank you for
7 giving me the opportunity to speak here today. My
8 name is Heather Despres, and I am the director of
9 patient-focused certification at Americans for Safe
10 Access. It is a nonprofit organization whose mission
11 is to ensure safe and legal access to cannabis for
12 therapeutic and research.

13 The patient-focused certification program is
14 an independent compliance program whose goal is to
15 ensure that cannabis businesses are operating in
16 compliance with state regulations as well as other
17 regulations.

18 Today I'd like to present to you information
19 about manufacturing and product safety as it relates
20 to validated analytical testing, product standards and
21 safety concerns. We will be presenting comments based
22 on everything that we present here today in much more

1 significant detail.

2 One of the questions presented centered
3 around current standards needed to address safety
4 concerns related to manufacturing of cannabis and
5 cannabis-derived products. And we would like to
6 address this by identifying industry standards that
7 already exist.

8 The American Herbal Products Association and
9 the American Herbal Pharmacopeia have issued best
10 practices for cannabis business, including
11 cultivation, manufacturing, distribution and
12 laboratory operations. From these standards, the
13 patient-focused certification program was created in
14 order to ensure compliance.

15 In addition to these standards, we would
16 recommend that personnel working in the cannabis
17 industry and regulators inspecting these businesses
18 have the education and training needed to safely
19 perform the job that they are hired to do and that to
20 ensure that there are adequate numbers of inspectors
21 available to support the industry.

22 Validated analytical testing is a key factor

1 in ensuring safe products. Mandatory testing is
2 required in almost every state that has a cannabis
3 program and yet this testing is not consistent from
4 state to state.

5 This is a table of a subset of over 70
6 different pesticides that are required to be tested
7 for in various different states. And as you can see,
8 only six are the same throughout. Also all of the
9 limits are different. So for operators working in
10 various states, there's not consistency.

11 With consistent testing and limits, the
12 safety profile of cannabis products can get better.
13 Some of the major safety concerns for cannabis and
14 cannabis-derived products are the use of pesticides
15 and solvents in cultivation and manufacturing.

16 The majority of recalls that have been issued
17 have been for the use of non-permitted pesticides or
18 for exceeding the limits of allowable pesticides.
19 Four different states have applied for a special local
20 needs registration, none of which have been approved
21 by the EPA. The type of solvents approved for use
22 also varies by state.

1 For example, some states will permit the use
2 of hydrocarbons such as butane, while others will only
3 permit the use of carbon dioxide. Additionally, the
4 equipment used in cannabis extraction is often
5 operated at high pressures and requires specific
6 training for safe operation.

7 We would encourage that operators be required
8 to obtain this special training prior to being able to
9 use the equipment.

10 While pesticides and solvents are major
11 concerns, the potency of THC-rich products is also a
12 concern. People have varied reactions to this, to the
13 THC present in cannabis and cannabis-derived products
14 as many factors may play into how this person reacts,
15 including their weight and rate of metabolism, the
16 amount and type consumed, the method of consumption
17 and their personal experience with cannabis.

18 Some states require that products containing
19 THC be tested for homogeneity and we would encourage
20 this type of testing for all products, not just THC-
21 rich products.

22 Proper testing with representative sampling

1 will ensure that products are labeled accurately,
2 allowing the consumer to know exactly what
3 cannabinoids and how much are in the products that
4 they are consuming.

5 There are many challenges facing the cannabis
6 industry. However there are solutions available. We
7 have worked with state regulators to develop and
8 implement these standards and we look forward to
9 working with you together to help implement these
10 standards as well. Thank you.

11 PANEL MEMBER: Just one quick question. You
12 mentioned recalls. Any data that you have on the
13 recalls that have occurred in states or the processes
14 surrounding it would be greatly appreciated, if you
15 could submit that.

16 MS. DESPRES: We do plan on submitting that.

17 PANEL MEMBER: Fantastic. Thank you.

18 MS. DESPRES: Thank you.

19 MS. CRISTINZIO: Thank you. Our next speaker
20 is John Redman.

21 MR. REDMAN: Good afternoon, and thank you
22 for allowing me to speak today. I'm John Redman. I'm

1 the CEO of Community Alliances for Drug Free Youth.

2 We're a non-for-profit organization based out
3 of California that focuses -- that was created during
4 the parent movement of the late '70s/early '80s and
5 focusing on youth drug prevention. We focus and
6 support sound drug policy not only at the local, but
7 state, national and international levels. CADFY holds
8 consultative status at the United Nations and we work
9 on global drug policy at that level.

10 We're not here to really discuss or argue the
11 merits of the medicinal use of CBD. What we are
12 concerned about however is the amount of THC that will
13 be allowed as an adulterant within CBD products that
14 negatively impact our youth.

15 If you take a look at this picture, I took
16 that only weeks ago in my hometown. That is water
17 that's being sold to businesses and homes that says it
18 has CBD products in it and I have no idea what's in
19 it. We have no idea what the THC levels are. And it
20 is vastly unregulated compared to our municipal water
21 that I don't drink.

22 Our request for action is that the FDA should

1 proceed with extreme caution and treat any levels of
2 THC as unsafe, especially for vulnerable populations.
3 And to protect the public health and safety, we urge
4 the FDA to prohibit THC in CBD containing consumer
5 goods, that is any amount.

6 I won't go over all of the concerns of the
7 harmful effects of CBD -- or THC, I mean. You've
8 heard that ad nauseam today. But suffice it to say
9 that we know that THC significantly impacts youth much
10 more than adults. And the question is how much THC is
11 too much.

12 We have no idea of the THC amount percentage
13 by weight consumed that causes dependency or
14 addiction. We have no idea of the THC amount that
15 causes first-time episodic psychosis or other chronic
16 adverse health effects. We also know that THC
17 permanently changes brain structure in the developing
18 mind.

19 One thing to look at is how much THC is too
20 much. If we take a look at some of the states, or if
21 we just take a look at Oregon, Oregon has stated that
22 5 mg of THC will produce psychoactivity. So that

1 means no more than 5 mg of THC in a serving. But when
2 we take a look at the hemp bill, we have 0.3 percent
3 by dry weight.

4 Well, what does that mean? If you take a
5 look at a joint that contains 63 mg, 17 mg of THC is
6 ingested into the body. An edible that contains 50 mg
7 packaging, a serving is 5 mg of THC.

8 If you take a look at a 30-count bottle that
9 can have 360 mg in a single 4 g CBD gummy bears, those
10 can have -- a single gummy bear can have 12 mg of THC
11 for a CBD product. For 30 mL bottles that contain CBD
12 oil, that could contain 82 percent mg in a single
13 serving of 2.73 percent. All you do have to take two
14 servings and you're over Oregon's limit.

15 Some available products, I looked on the
16 website. Here's one product on the left that has 2.8
17 mg. If you multiple that times the 0.3 percent you
18 get at the bottom what they say is 84 mg of THC in
19 that CBD product. Another one, that 2.89 percent of
20 THC, you have 86 mg.

21 When we take a look, it's been said that all
22 we have to do is just put an age limit on it. It

1 didn't work for alcohol, folks. It didn't work for
2 tobacco. We know that putting age restrictions on
3 products doesn't work and we also know that the most
4 abused drugs in our youth, number one, alcohol, number
5 two, tobacco. It's not going to be any different for
6 marijuana products.

7 The three things that come together to
8 increase youth use is attitude, advertising and
9 availability. I've heard all of those talked about
10 today. All three of those will create a perfect
11 storm.

12 All one has to do is look at the permissive
13 drug policies of certain states that have legalized
14 marijuana and look at the higher youth use rates in
15 those states than those that don't have it. And yes,
16 we have the data on that.

17 Our request for action is the FDA should
18 proceed with extreme caution and treat any levels of
19 THC as unsafe, especially for vulnerable populations.
20 To protect the public health and safety, we urge the
21 FDA to prohibit THC in CBD-containing consumer goods,
22 any level.

1 Please treat this as a drug and not as a
2 commodity. Please look at this as a public health
3 issue and not as a profit issue. We urge the FDA to
4 look at this and strictly regulate it. Our youth
5 deserve it. Our nation demands it. Thank you.

6 (Applause.)

7 MS. CRISTINZIO: Thank you. Our next speaker
8 is Denise Valenti.

9 DR. VALENTI: Good afternoon. I know it's
10 been a long day. But I've found it pretty exciting
11 because I've learned quite a bit from many of the
12 previous testimonies, and I hope you have also.

13 I'm Dr. Denise Valenti. I'm an optometrist.
14 I'm a CEO and president of IMMAD. IMMAD is Impairment
15 Measurement Marijuana and Driving. Our current
16 funding source comes from NIH, NIDA in the form of an
17 SBIR. We have our first prototype of a technology
18 that is intended for roadside use by law enforcement.
19 And it works quite well. It measures the retina using
20 a visual field technology in a virtual goggle,
21 smartphone and Bluetooth response.

22 However, it is my previous roles in previous

1 careers for which I am offering my testimony today.
2 Prior to doing research, I spent 20 years as a
3 clinician specializing in vision loss and blindness.
4 Under that capacity, I did see many multi-handicapped
5 children, much like some of the children you have
6 heard described today. They are complex and the
7 parents are very challenged in identifying treatments
8 and care for their children.

9 I'm also a parent. I stopped seeing patients
10 because, at the age of 36, after I had my family, I
11 was diagnosed with idiopathic familial dilated
12 cardiomyopathy. It's familial because even though the
13 clinicians had determined I was beyond the potential
14 of risk of having the disease, I had lost a 17-year-
15 old sister to cardiac health and a 19-year-old sister
16 to cardiac death.

17 When I was diagnosed, I couldn't walk up a
18 flight of stairs. I was worked up for a heart
19 transplant. But that's not the worst.

20 Two years later, the next generation. The
21 oldest child in our family was diagnosed. He was 15
22 years old. He died three months later. So it was

1 with horror we realized that the disease that we
2 thought was only affecting one generation was
3 autosomal dominant. It meant my two-year-old had a 50
4 percent chance of potentially not surviving to the age
5 of 21.

6 So I know the desperation and the feelings of
7 some of these parents that would do anything and go to
8 any lengths to solve and improve the health of their
9 children. And I would never suggest that these
10 severely impaired children that are having some of
11 their quality of life significantly improved by CBD go
12 off the CBD.

13 But we do need to do more research because
14 there are side effects that are treatable. One of
15 them is that there is increased pressure in the eye
16 with CBD. While we often hear about marijuana being
17 able to lower the pressure in the eye, that's only
18 with THC, only with THC. We never hear about the CBD
19 causing an increase in the IOP.

20 The very research papers that were put
21 forward by proponents to advocate for glaucoma as one
22 of the treatment -- diseases to treat with CBD

1 actually had research in them demonstrating that CBD
2 elevates the pressure of the eye.

3 Glaucoma is painless. Glaucoma is a disease
4 that it creeps up on you and steals your vision and
5 you don't know it before it's too late. Why is CBD
6 potentially doing this? Well, there are cannabinoid
7 receptors in multiple parts of the eye, every layer.
8 It's in the retina. That's why we're able to identify
9 vision loss and develop technology. But it's also in
10 the anterior chamber.

11 In neurologic systems, and particularly in
12 the eye, THC and CBD tend to have opposite effects.
13 And the THC acts on the ciliary body as does the CBD.
14 But they can do it in opposite ways. The one human
15 study that I talked about earlier found a dose-
16 dependent response. And these doses, relative to what
17 we hear about are being used to treat many diseases,
18 aren't that high.

19 These are some of the doses that are
20 suggested for many diseases. As you can see, they are
21 beyond the dose of risk, the 40 mg that was found in
22 this study.

1 However, there are additional studies. There
2 is a rabbit study that I don't cite here. On the
3 other hand, a colleague of mine, when I wanted
4 somebody to look into this, used some of his funding
5 to investigate it further and he definitely found CBD
6 causes an elevation in IOP in his mouse model.

7 We need to investigate this further. Again,
8 I'm not suggesting that anybody go off a lifesaving
9 drug. But if there is an elevation of IOP, it can be
10 treated. But we don't really know exactly what's
11 happening in humans.

12 I'm concerned that there is going to be a new
13 generation of needless vision loss because we did not
14 look closely at CBD. Thanks.

15 MS. CRISTINZIO: Thank you.

16 DR. VALENTI: Oh, there's a good ending. My
17 son was negative. And we developed a mouse model for
18 my own disease and we developed treatments for me.

19 (Applause.)

20 MS. CRISTINZIO: Any questions?

21 PANEL MEMBER: Absolutely please submit your
22 data. Thanks.

1 MS. CRISTINZIO: Thank you. Our next speaker
2 is Shawn Hauser.

3 MS. HAUSER: Hi. Good afternoon. I'm Shawn
4 Houser. I'm an attorney with the Vicente Sederberg
5 LLP and here today on behalf of the Cannabis Trade
6 Federation.

7 The Cannabis Trade Federation is a national
8 coalition of cannabis businesses representing all
9 aspects of what has primarily been a state-based
10 marketplace. Our companies include large multistate
11 operators who have been subject to stringent
12 regulations under these state systems for the better
13 part of the past decade.

14 We're eager to share today with the FDA data
15 arising from our many years of operation and our views
16 on federal regulation.

17 We believe the appropriate regulation of
18 products containing lawful cannabinoids already exist
19 under the framework of DSHEA and that the data arising
20 out of these state-regulated regimes supports such
21 regulation. The evidence of CBD safety is clear, as
22 acknowledged today and by agencies such as the World

1 Health Organization and DEA and their findings that
2 CBD is safe, well-tolerated and non-addictive.

3 State-controlled cannabis regulatory regimes
4 provide years of evidence demonstrating that
5 consistent quality products containing cannabinoids
6 can be safely and transparently sold in a manner like
7 dietary supplements.

8 Our operators are familiar with the
9 complexities of issues faced by consumers, regulators
10 and businesses when compliance means navigating a
11 patchwork of state regulations and differing legal
12 interpretations.

13 However, whether right or wrong, the current
14 situation has created a perceived regulatory vacuum
15 and it opens the door to bad actors and allows for
16 substandard products, often available to the most
17 vulnerable of our population.

18 We produce products containing lawful
19 cannabinoids and desire to market these products. But
20 the lack of a federal pathway for regulation,
21 particularly the refusal to accept NDI notifications
22 for CBD and other regulatory impossibilities, remains

1 a barrier to proper regulation. Our industry is ready
2 to meet FDA requirements and, in many cases, already
3 complies with the elements of FDA regulations.

4 In virtually every regulated state market,
5 most businesses are required to apply for and obtain a
6 state and local license for each facility they
7 operate. These facilities are subject to rigorous and
8 regular inspections by various agencies. These state
9 regulatory frameworks increasingly require the
10 implementation of cGMP systems for the manufacturing
11 of cannabis products.

12 For example, cannabis businesses in Florida
13 must employ cGMPs, pass a food safety GMP inspection
14 by a nationally accredited certifying body. If they
15 don't pass, they can't process until they demonstrate
16 corrective action. Similarly, New York requires CBD
17 supplement manufacturers to adhere to FDA standards
18 for the production of CBD products, including cGMP and
19 packaging and labeling.

20 Truth in labeling is at the core of our state
21 cannabis regulatory regimes. In addition to
22 comprehensive labeling regulations in most states,

1 many states like Indiana, Utah and Texas require that
2 hemp -- CBD product labels include scannable bar codes
3 linked to information regarding the manufacture of the
4 product such as batch IDs, ingredients and a link to
5 certificates of analyses.

6 Use of independent third-party testing labs
7 to verify label content for each production batch is
8 standard. Using accredited and independent testing
9 laboratories to confirm the accuracy of labeled
10 information including potency and to ensure compliance
11 with state requirements helps ensure consumer
12 confidence in the product being sold by standardizing
13 the analysis procedure and eliminating the risk of
14 bias.

15 Warning labels for vulnerable subgroups,
16 particularly children, is a virtually universal
17 requirement in our state-regulated cannabis regimes,
18 with labels generally requiring both written
19 statements and symbols indicating the presence of
20 cannabinoids and instructions that the products be
21 kept away from children. As demonstrated by the
22 chart, these requirements are effective.

1 In California and Colorado, product
2 manufacturers have achieved an average 90 percent
3 passage rate for mandatory testing for label accuracy
4 in the presence of microbial, pesticide and heavy
5 metal contaminants. This data demonstrates that
6 cannabis manufactures can and do comply with DSHEA-
7 like standards to protect consumer safety.

8 Many states also follow the FDA's approach
9 with recall and adverse event reporting, requiring a
10 review and investigation of consumer complaint that
11 extends to all relevant batches and records.

12 Based on investigative findings arising out
13 of adverse event reporting, manufacturers and
14 regulatory authorities issue public notifications and
15 recall the affected products where appropriate.

16 In sum, cannabis products can be safely
17 regulated under the existing DSHEA framework and,
18 where products are intended for non-medicinal
19 purposes, it's appropriate to regulate them as such.
20 The years of data from these state regulatory regimes
21 are a very important source of data for the agency to
22 consider in determining the appropriate regulatory

1 pathway here.

2 We stand ready as the Cannabis Trade
3 Federation to advance to the next level with FDA an
4 effective regulation of cannabinoid products to ensure
5 consumer safety.

6 MS. CRISTINZIO: Thank you.

7 PANEL MEMBER: Hi. As we've asked in other
8 instances, if your organization has a report that
9 details some of those findings at the state, could you
10 make sure that they get into the docket?

11 MS. HAUSER: Absolutely.

12 PANEL MEMBER: Thanks.

13 MS. CRISTINZIO: Great. Our next speaker is
14 speaker number 111, Dana McMurchy.

15 RETAILERS/DISTRIBUTORS

16 MR. MCMURCHY: Yes. Thank you for inviting
17 me. I'm here in Washington by your invitation. My
18 challenge is will you listen. The authority that I'm
19 given to speak comes from the constitution of the
20 United States of America which grants me and every
21 person I this room the right to life, liberty and the
22 pursuit of happiness.

1 Why did I start that way? I believe that a
2 balanced endocannabinoid system is fundamental for
3 human life. That's why I ended up supporting Yes on
4 788 in Oklahoma. We also demand liberty to decide
5 what laws and regulations we're willing to live under
6 without interference from anyone, including law
7 enforcement because they don't create law. We do.

8 Oklahoma has a population of under 4 million
9 people. In the vote that we gave -- that we did, we
10 surpassed all election turnouts for any kind of vote
11 and there were 507,000 voters that approved medical
12 cannabis.

13 So I represent those voters. Those are
14 people in chronic pain, in despair over their opioid
15 dependence, patients with MS, lupus, Alzheimer's,
16 Parkinson's, cancer or the veterans with PTSD.

17 We're joining 32 other states that have
18 already approved cannabis either recreational or for -
19 - sorry, medically or for reasonable adult use. I am
20 the voice of the people without the money to buy or
21 influence the practices of medical provider.

22 You might have noticed that I was a

1 pharmaceutical and medical device rep. So I have a
2 lot of experience in that area.

3 And then, not to gain -- I'm the voice of
4 people who do not have the money to gain privileged
5 access to the FDA and the demands of people for access
6 to cannabis and our parents and grandparents who are
7 the number one use of medical cannabis.

8 And if you look, American College of
9 Pediatrics, Journal of Prevention Medicine and
10 national survey on drug use shows that in youth, most
11 of that use has gone down with a slight use there.

12 So why did I get so involved in this? Ten
13 years ago, if you told me I'd be promoting medical
14 cannabis, I'd have said nonsense, there's no medical
15 proof. They just want to get high.

16 And then, I found this patent in addition to
17 much other research. We funded this information.
18 This is Patent Number 6630507 and I assume that you
19 all know this really well. But I'm shocked and
20 constantly impressed that people do not know about
21 this.

22 We funded it from the department of health

1 and human services. It was assigned in the United
2 States and it was assigned in 2003. Okay. What do
3 they claim? They claim that cannabinoids are
4 antioxidants and neuro-protectants.

5 So that now makes sense as to why it can have
6 application in a wide variety of oxidative diseases
7 such as ischemic, age-related -- I don't know anybody
8 who's getting younger -- inflammatory and autoimmune
9 diseases.

10 They have particular application as neuro-
11 protectants. And I will specify that in this case
12 they took the THC out. They made some changes. But
13 they're claiming on behalf of the American people that
14 this has potential in 2003. 2003.

15 I had to do educational seminars. I had to
16 debate physicians who said what's the urgency, what's
17 the emergency. The opioid crisis that we face, the
18 number of deaths in the U.S. exceeds what we lost in
19 World War II. Okay. Twenty-two veterans committed
20 suicide. Twenty-two today. Twenty-two tomorrow. And
21 cannabis prohibition has been a big part of the
22 problem.

1 So proceedings of the National Academy of
2 Sciences, 1995 -- that's a long time ago. CBD and THC
3 is antioxidants and neuro-protectants. The
4 endocannabinoid system is our master balancing and
5 homeostasis system and it was discovered in the 1990s.
6 How come our doctors don't know about this? Only 13
7 percent of physicians are trained in the
8 endocannabinoid system in medicine right now.

9 We demand a new model, not the pay-for-play
10 science funded by corporate money. We have paid the
11 price of corporate greed and I carry some weight on
12 that. The opioid crisis. That's how I got to retire
13 at age 50. It pays really, really well.

14 Sixty percent of our U.S. biomedical research
15 is funded by the for-profit pharmaceutical industry.
16 And of course this is the best slide of all. March
17 1973, cannabidiol and other cannabis compounds could
18 reduce hippocampal seizures. It took 45 years using
19 the model we currently have to reach patients. I'm
20 thrilled that Epidiolex got approved. But I beg you
21 not to wait 45 years for the next one.

22 And you asked about full spectrum hemp oil.

1 It's not CBD. It's cannabidiol, terpenes, flavonoids,
2 fatty acids, vitamins and minerals. Okay. And I
3 think it's important that we regulate cannabis as
4 generally regarded as safe and the regulations should
5 match other products out there. And I just think this
6 is helpful.

7 MS. CRISTINZIO: Please wrap up.

8 MS. MCMURCHY: Yes. Thank you. I'm the home
9 grower who makes my food -- sorry, my food my first
10 and best medicine. I trust -- oh, sorry. Okay.

11 And we the people in the United States have
12 claimed back our rights to this whole plant medicine
13 from generally ill-guided federal policy, not
14 necessarily just the FDA. I'm not saying you guys did
15 that. But we require and respectfully require the FDA
16 to respect our common voices and self-governance.

17 MS. CRISTINZIO: Thank you.

18 (Applause.)

19 MS. CRISTINZIO: We are now on speaker 112,
20 Valentina Milanova.

21 MS. MILANOVA: Good afternoon. Thank you for
22 the opportunity to be here today. We are Valentina

1 Milanova and Dr. Harry Baxter from Daye. We are a UK-
2 based female health company. And we are delighted to
3 present our research on CBD-coated feminine hygiene
4 tampons as well as the quality standards we're
5 implementing in our supply chain and manufacturing.

6 Let's start with the supply chain. The CBD
7 we use is extracted through a proprietary process
8 capable of separating all cannabinoids from one
9 another. Importantly the process fully removes -- oh,
10 I think there's an issue with the clicker. Oh, there
11 it is.

12 Importantly the process fully removes any and
13 all traces of THC, THCA, making the end extract
14 suitable for medical and consumer uses. The
15 advantages of the method are that the synergetic
16 effects of CBD, CBN and CBG are retained while THC is
17 fully removed to ensure that the tampons do not cause
18 a high. Importantly the extract prepared in this way
19 has no impurities and no traces of solvent.

20 Further we're using cottonized industrial
21 hemp fibers to make up the absorbent body of our
22 tampon. To achieve cottonization, the fiber is soaked

1 in purified water and then treated with high voltage
2 electric process, separating and softening individual
3 fibers.

4 The advantages of using cottonized hemp are
5 that the porous structure of the fibers allows for
6 improved absorption and moisture retention, thus
7 reducing the size of the tampon and the likelihood of
8 vaginal abrasions which often occur from the insertion
9 and removal of a dry tampon. We take great care to
10 ensure our tampons are produced safely by introducing
11 clean room manufacturing and gamma ray sterilization.

12 Vaginal applications of CBD are quite novel.
13 And here is what we know so far. Unlike other forms
14 of CBD, vaginally applied CBD works by binding to
15 cannabinoid receptors in the vaginal epithelium,
16 working locally and mechanically. Oops, sorry.

17 The endocannabinoid system is being
18 discovered in many organs, including the vaginal
19 canal, where it plays an important physiological role,
20 as we have heard today. A few promising studies in
21 rats, rabbits and human volunteers so far have shown
22 the lubricating and skin conditioning properties of

1 topical CBD.

2 These are advantageous for vaginal use again
3 as the dry surface of tampons is known to cause
4 abrasions in the vaginal canal which are associated
5 with a heightened risk of toxic shock syndrome.

6 Moving on to how we -- sorry. Is there are a --

7 DR. BAXTER: Where are we pointing the
8 clicker?

9 MS. MILANOVA: It's not working. The next
10 slide should be about manufacturing standards. Should
11 we click? Yes, down please. Further down. Down.
12 Down. Down. Here it's perfect. One up. Thank you.

13 All right. How we ensure quality in our
14 supply chain. So first we have three years agreements
15 for the supply of CBD and cottonized hemp which
16 ensures that we get a consistent quality of raw
17 materials and can build long-term relationships with
18 our partners.

19 Second, each and every batch of CBD that we
20 receive is tested in two independent labs for
21 concentration, toxic shock syndrome, staph,
22 Escherichia coli, candida, total anaerobes, total

1 yeast, arsenic, nickel, lead and mercury.

2 Third, we have strict conformity agreements
3 with our suppliers, ensuring that they are
4 incentivized to continuously provide the best quality
5 product or face liability.

6 Moving forward to manufacturing standards, if
7 I can have the next slide please, we use FDA-approved,
8 medical grade machine parts in all of our proprietary
9 CBD tampon coating machines which are housed in ISO 8,
10 Grade D certified clean rooms. We also sterilize the
11 CBD-coated packaged tampons -- perfect. We sterilize
12 the CBD-coated packaged tampons using gamma rays,
13 ensuring no harmful bacteria or contamination are left
14 on the tampon surface when it reaches the consumers.

15 Next slide, please. Shelf-life testing and
16 stability are really important questions when it comes
17 to CBD. We've conducted accelerated shelf-life
18 testing on our raw materials as well as the finished
19 products to ensure that our CBD tampons have a 12-
20 month shelf-life.

21 To ensure product stability in natural
22 consumer environments, we wrap our tampons in medical

1 paper with a lacquer finish and then place them in
2 heat-sealable, airtight plastic pouches.

3 When it comes to labeling -- next slide,
4 please, thank you -- we have clear indications on our
5 packaging and in informational pamphlets on the risk
6 of toxic shock syndrome as well as the risk of CBD
7 allergies.

8 We don't recommend that first-time tampon
9 users employ the CBD tampon and we limit sales to over
10 18-year-olds. We can do that through our e-commerce
11 business model -- as the data on CBD's impact on the
12 development of the vaginal tract is still limited.
13 We're currently thinking about marketing our product
14 simply as CBD tampons, with the view of expanding to
15 soothing, lubricating and finally cramp-fighting as we
16 obtain regulatory approvals and more peer-reviewed
17 clinical data.

18 At present, we will not be making any medical
19 claims with regards to our products. It's important
20 to note here as well that we've received clearance
21 from the European Medicines Agency to market our
22 products in the EU.

1 Dosing is another issue in CBD products, as
2 we heard today, that deserves further research. How
3 we chose the dose that we use today was based on
4 extensive peer-reviewed literature reviews as well as
5 volunteer trials with self-reported efficacy outcomes.
6 That's the next slide. Thank you. Next slide.

7 MS. CRISTINZIO: Please wrap up.

8 MS. MILANOVA: So from the studies that we've
9 seen so far, CBD was tolerated really well in all
10 volunteers with no signs of toxicity or serious side
11 effects. The reported minor side effects that we had
12 included tiredness and diarrhea. Finally --

13 DR. BAXTER: And finally, we are prioritizing
14 high quality research to ensure our products are safe
15 and effective. We've demonstrated that CBD suppresses
16 E. coli, Staph aureus and E. coli growth at
17 therapeutic levels in vitro and we have completed
18 preclinical trials including CBD showing that it does
19 not irritate vaginal epithelium and is pH-balancing.

20 Finally, we have undertaken extensive
21 volunteer trials with CBD-coated tampons which were
22 well-tolerated and so far have shown no adverse

1 events. In our oncoming research pipeline, we are
2 currently undertaking further preclinical trials with
3 animal models to interrogate other potential rare
4 adverse events.

5 We are currently undertaking a double-blind,
6 multicenter RCT at an EMA-certified facility with 80
7 patients using CBD tampons for menstrual symptoms.
8 And finally, we are investigating the effect of CBD on
9 the vaginal microbiome using qualitative PCR analysis.

10 In conclusion, we look forward to working
11 with the FDA on ensuring a stable regulatory framework
12 for CBD, especially in women's health, is put in place
13 in the future. We will be submitting all our written
14 testimony and quoted research for submission.

15 MS. MILANOVA: Thank you. I'm sure you must
16 have questions.

17 PANEL MEMBER: Do you have data -- do you
18 have data on absorption through the vaginal mucosa?

19 MS. MILANOVA: So what we have data about is
20 CBD binding to endocannabinoid receptors in the
21 vaginal epithelium. And we're currently conducting
22 blood plasma tests to see the absorption of CBD

1 through the vaginal mucosa.

2 What we know is that in rat models, CBD is
3 well-absorbed through the skin. But what we've seen
4 in the vaginal canal from in vitro studies with
5 vaginal epithelium cells is that it tends to bind to
6 the endocannabinoid receptors.

7 DR. BAXTER: And we're currently undertaking
8 it in a rabbit model to assess vaginal absorption.

9 PANEL MEMBER: And were you saying that the
10 CBD coating was leading to a lower risk of TSS than
11 with standard tampons? I couldn't tell if that's what
12 you were saying or not.

13 MS. MILANOVA: So the research on toxic shock
14 syndrome shows that the main reason for it is the dry
15 surface of the tampon causing minor incisions on the
16 vaginal entrance and the vaginal walls from the
17 friction from the insertion and the removal of the
18 tampon. And through these incisions, bacteria can
19 enter the bloodstream and toxic shock syndrome
20 happens.

21 Now, there's two ways in which we believe
22 we're reducing the risk of toxic shock syndrome. The

1 first one is that by being infused with CBD on the
2 outer layer, on the protective sleeve of our tampon,
3 it's effectively lubricated, so significantly reducing
4 the risk of those ulcerations happening from friction
5 from insertion and removal.

6 And then second because we sterilize the
7 tampons using gamma rays which is the standard in
8 surgical tools. That's where we borrowed that from.
9 We ensure that there's no bacteria that could enter
10 through any ulcerations or abrasions.

11 MS. CRISTINZIO: Great. Thank you so much.

12 DR. BAXTER: Thank you.

13 MS. MILANOVA: Thank you.

14 MS. CRISTINZIO: Sorry for the technical
15 difficulties with your slides.

16 MS. MILANOVA: No worries. Thanks for
17 helping.

18 MS. CRISTINZIO: Our last presenter today
19 before we close is Craig Brand, from Folium
20 Biosciences, for five minutes.

21 MR. BRAND: Dale told me I could speak until
22 all of you fell asleep. But five minutes shouldn't

1 say that. Anyway, I literally asked -- my name is
2 Craig Brand. I'm general counsel for Folium
3 Biosciences in Colorado Springs, Colorado.

4 I asked to be the first speaker. That way,
5 when I sat down, I was literally the best speaker. So
6 I got moved all the way to the back where everything I
7 wanted to talk about is pretty much gone now.

8 So I would like to start off first by
9 thanking the FDA for this day, thanking the
10 stakeholders for this day, thanking all who are
11 listening on Wi-Fi for being present with us, thanking
12 all that are in the room with us. Thank you for
13 sharing your birthdays. Thank you for sharing beer
14 30. Thank you for all the time that everybody has
15 given to these issues.

16 Now, given the fact that almost everything I
17 did want to say has already been said or I should just
18 button my lips, let me repeat what I did hear. I did
19 hear that what we're here today to discuss is about a
20 product that is a pharmaceutical product or a dietary
21 supplement or a food ingredient or even a dispensary
22 product. Yes, it is.

1 I did hear that we're talking about issues
2 of adulteration, of diversion, of mislabeling, of
3 improper product manufacturing. Yes, we did. I did
4 hear us talk about safety, conformity, standards and
5 protocols. Yeah, we did that too.

6 I heard people mentioning about the farming
7 business, the genetic business, the harvesting, the
8 extraction, the production, the fulfillment and even
9 pharmaceutical interest. Yeah. We did that as well.
10 I heard people talk about competition, global
11 intervention. There's even, if you look just across
12 the pond, a new category for CBD called novel foods
13 that maybe the FDA needs to direct some attention to.
14 But yes, we did.

15 So we have an industry. We have an American-
16 made industry. Now, let's do everything we can that
17 we keep this American-made industry, that we don't let
18 this American-made industry go bye-bye to the world as
19 we know it.

20 Let's look to work in harmony, bring all of
21 what I just discussed, whether it's a pharmaceutical
22 product, a dietary supplement, a feed ingredient or

1 dispensary product, let's figure out a way to make it
2 work and let's come up with solutions.

3 So Folium Biosciences is located in part in
4 Colorado Springs, Colorado. There are -- I'm going to
5 give a shout out to all of the other Colorado
6 companies that came up here today and talked before me
7 because, one, they deserve the shout out and, two, I
8 love my state.

9 But all of us here are here for a single
10 purpose. There were people that came up and I heard a
11 lot of badmouthing about CBD. I heard badmouthing
12 about THC. Guys, it's an industry. It's a business.
13 We're all here to make it better. We're not here
14 because we want to do things wrong. We're in this
15 room. We're listening over the Wi-Fi. We're
16 listening over TV, whatever it is, because we're
17 trying to get it right. With you or without you,
18 we're moving forward and we're doing a really, really
19 good job.

20 So I ask you how many of you sitting on the
21 panel have even ever tried CBD. You don't have to say
22 anything. I ask you the following. How many of you

1 sitting on the panel have even come out to one of
2 Colorado's best or any other state's best and even
3 seen how the industry actually works? It should be
4 first base or home plate.

5 And I invite you, and I'm sure my Colorado
6 brethren would probably have no objection as well to
7 come out and see us. See what it is we do.

8 Folium Biosciences is one of the largest
9 seed-to-sale facilities in the entire world, with
10 facilities going around the world, with our product
11 going around the world. So it's first base for you.
12 It's the way that you get your answers to your
13 questions.

14 So I know that my time is almost up. But let
15 me say the following. All that we talked about today,
16 from the labeling issues, from the diversion issues,
17 from the adulteration issues, does it go on? Yes, it
18 does.

19 But let's not kid ourselves. It goes on in
20 every single business. For those who know me also
21 know that I was healthcare attorney of the year. I'm
22 a senior partner in one of the largest healthcare law

1 firms in the country. I also was CEO of a very large
2 pharmaceutical chain.

3 So there's a lot about the history of this
4 building, of what is done here that I have firsthand
5 knowledge about. So what happened, all you have to do
6 is look just a few years back.

7 Look to the illegal drug diversion issue and
8 look how the states got smart and created all the
9 solutions to counter that, to prevent that and to move
10 forward going forward in the future. And all of what
11 we saw here today, from the labeling issues, from the
12 people making improper products --

13 MS. CRISTINZIO: Please wrap up.

14 MR. BRAND: -- to people improperly
15 fulfilling, all of that has been answered. All we
16 have to do is look to the states and look to the laws
17 that they've written. Thank you very much.

18 (Applause.)

19 CLOSING REMARKS

20 MS. CRISTINZIO: Thank you. That concludes
21 the end of our public comment and formal presentation.
22 I want to remind everyone that the docket is still

1 open. It remains open until July 2nd. Please submit
2 comments to the docket. Thank you to everyone who
3 joined us in person today and on webcast. And this
4 concludes our public hearing. Thank you very much.

5

6 (Whereupon, the foregoing was concluded.)

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

CERTIFICATE OF NOTARY PUBLIC

I, KEVON CONGO, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



KEVON CONGO

Notary Public in and for the

STATE OF MARYLAND

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

CERTIFICATE OF TRANSCRIBER

I, BENJAMIN GRAHAM, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

BENJAMIN GRAHAM

&	1,100 238:9	490:19	19 18:20 70:18
& 6:17 7:13 9:21 14:17 16:5 18:4 18:18 81:5,8 101:20,22 102:6 102:16 155:19 447:5	1,500 189:17 290:7 395:13 1.4 120:10 10 18:11 51:10,21 52:5 58:22 84:16 96:19 132:10 203:2 211:12,14 237:19 273:21 277:7 282:22 292:1 302:12 314:9 318:8 319:22 347:14 359:8,16 375:13 375:15 397:6 430:9 10,000 78:19 395:11 100 141:1 207:3 212:21 232:3 239:1 270:16 342:9 359:6 425:8 101 429:9 102 434:20 103 442:11 104 447:2 105 451:1 107 462:4 10903 1:18 10:45 172:16 11 18:12 59:2 245:19 11.5 454:16 110 159:18 111 162:20 348:12 481:14 112 486:19 113 24:20 117 159:13,18 348:12 12 18:13 61:10 191:1 299:18 311:8,8 341:4 448:13 469:10	12,000 108:21 153:10 161:17 120 301:11 425:18 125 394:13 13 18:14 61:11 159:11 189:22 251:20 485:6 13,000 426:2 130 347:20 132 126:6 135 18:15 14 18:15 61:13 237:20 332:20 427:12 145 18:16 147 18:17 149 84:14 15 1:11 18:16 50:13 63:16 235:14 287:22 327:21 334:22 359:5,7 372:17 472:21 15.4 300:17 150 125:22 156 18:19 16 18:17 66:18 91:22 250:3 318:5 318:20 16,000 196:4 17 18:18 66:20 469:5 472:14 17004 502:14 17025 133:21 135:5 372:1 443:6 443:7 176 18:21 18 18:1,19 43:15 70:17 84:17 209:4 256:1,8 258:16 491:10 1896 156:2	1970 28:10 1973 358:12 485:17 1978 132:17 1983 342:11 1990 273:5 1990s 175:9 221:18 485:5 1993 395:17 1994 273:4 1995 485:2 1998 160:8 1:30 281:18 1st 169:5 2 2 18:3 27:6 108:20 262:8 344:6 2,000 107:8 206:11 289:9 2,281 78:17 2,978 453:6 2.7 51:11 2.73 469:13 2.8 361:2 469:16 2.89 469:19 20 18:5,21 63:2 72:11 159:22 174:2 181:22 201:1 223:7 227:3 238:1 239:18 245:18 270:17 299:16 319:2 339:11 342:15 359:15 458:1 472:2 20,000 289:14 200 51:8 116:9 359:6,15 200,000 52:7 125:11 289:8
0			
0.001 314:9 0.02 314:17 0.03. 345:15 0.1 295:20 313:18 314:2 0.10. 314:10 0.17 299:12 0.2 239:21,22 295:20 0.3 28:21 69:1 84:8 85:16,22 190:6,17 191:16 211:3 240:1,4 275:6 295:19 296:1,6 313:16 341:2 345:15,15 368:2 424:16 469:2,17 0.3. 313:22 0.4 292:2 0.5 299:12			
1			
1 18:2 28:12 29:2 63:3 86:5 93:21 94:7 119:16 148:14 210:10 226:15 272:7 280:18 283:13 296:5,7 302:12 320:4 333:10 340:13 358:16 359:5 361:2 402:7 1,000 161:16 279:2			

2003 79:3 484:2 484:14,14	23 43:17 188:5 190:16	30,000 175:2 233:14 289:14	402 400:3
2008 441:22	24 83:8 173:17 223:13 248:6	300 116:10	41 129:17 238:7
2009 77:22 357:13	306:1 311:4	300,000 222:21	42 18:10 132:12
201 86:5 272:21	318:15 348:21	301 105:5,8 106:10 273:2	43 135:8
2010 293:21 367:3	375:13	31 1:14,17 335:4	43.1 275:11
2012 42:18 78:8	24.2 300:17	32 104:13 482:17	430,000 140:21
2013 141:16 334:6	24/7 194:11,20 198:4	32,000 403:7	44 135:9 248:14
2014 204:18 367:10 414:2	25 57:17 87:14 189:11 211:14	321 435:7	45 41:6 137:13 190:18 193:17 485:18,21
2015 291:3 334:20 335:2 360:3 373:14 387:10 402:4 420:22 422:21	317:4 359:14 429:19 430:14 433:18 449:22 458:1	33 107:2 159:10 408:18 430:8	456 19:6
2016 283:21	259 19:3	33,000 153:10	46 142:13 430:10
2016-2017 453:12	26 18:7 91:6 248:10 251:7	33223 311:21	461 19:7
2017 312:15 335:3 368:5 392:9 402:9 422:3 427:7	27 61:18 92:15 94:1	334,000 43:12	47 144:18
2018 28:18 29:5 33:22 48:14 54:18 67:21 81:13 82:8 82:16 97:9 109:17 111:14 116:10 147:10 312:15 329:6 414:5 453:9	27.6 375:7	34 111:4 238:3 249:13	48 147:4
2019 1:14 27:6 49:3 110:9 116:11 160:19 312:15	272 261:18	3406507 1:20	481 19:8
20993 1:19	28 95:14	35 111:7 259:11 311:14	5
21 18:22 55:8,11 55:18,21 56:8 75:22 159:13 162:20 226:16 255:22 256:8 348:11 473:5	287 19:4	36 115:17 472:10	5 18:6 173:12 201:1 207:5,6 210:9 301:12,13 301:15 318:21 468:22 469:1,7
217025 443:2	29 98:9	360 469:9	5.2 318:7
21st 145:10	2c9 179:11,19	37 18:9 118:22	50 46:9 132:19 160:8 199:13 208:9 232:16 278:7 292:21 318:13 359:14 469:6 473:3 485:13
22 18:22 77:19 108:17 268:13	2nd 53:3 66:9 104:7 110:15 124:17 501:1	37.5 277:9	500 26:20 120:12 290:6 430:16
22000 372:1	3	373 19:5	500,000 319:22
227 18:22	3 18:4 53:13 72:4 260:2 295:18	38 250:3 447:12	501 19:9 53:13
	3,000 289:9	39 125:7 450:3	507 79:3
	3,500 132:18	3:30 372:18	507,000 482:11
	3.4 400:18	3a4 178:19 180:8	51 221:3
	30 23:7 51:21 101:19 169:4 206:10 222:19 237:22 251:1 284:2 311:14,14 453:7,12,14,21 454:12,17,18 469:8,11 496:14	4	51 221:3
		4 18:5 213:10 272:7 450:3 469:9 482:8	53 18:11 161:6
		4,355 247:14	54 166:5
		4,400 138:3	55 166:7 280:16 340:9
		4.3 454:17	57.9 201:13
		4.9 161:18	58 18:12 43:14 181:13
		40 62:5 63:6 129:16 228:20 249:12 311:5,8 315:5 359:4 474:21	
		400 51:7 237:12 237:18 403:11	

59 187:9	70s 388:9 467:4	9001 291:3 363:10	347:3 351:9 387:1
5th 92:8	71 258:22	372:1	390:9 410:10
6	72 263:17 297:21	91 373:2	414:10 430:6
6 18:7	298:1	92 378:12	460:8 465:8
6,000 426:3	73 268:7	93 383:19	473:17 474:8
6.4 211:8	75 260:20 261:9	95 386:3 395:1	abnormal 300:21
6.5 450:7	261:22 273:6	98.2 449:15	abrasions 488:8
60 48:2 107:14	315:6	99 148:13	489:4 495:10
192:6 228:20	75.3 275:16	a	abroad 268:17
232:16 261:9	750 83:1	a.m. 1:15	abrupt 404:5
292:21 300:18	76 287:13,15	a2la 8:12 132:16	absence 28:15
359:5	77 293:16 449:22	132:17 134:22	37:19 106:9 108:6
60,000 82:22	78 298:7	378:20	265:13 341:9
233:14 259:22	788 482:4	a2la's 378:22	445:15
600 344:5,5 397:2	79 208:21 303:3	aaron 14:2 353:4	absent 35:14
397:8 427:12	8	353:6	99:14 109:16
601 161:19	8 18:9 397:5 490:9	ab 252:20	absenteeism 375:8
607 359:12	80 27:13 261:10	abbreviated 410:2	absolutely 53:2
60s 388:9	310:19 430:19	abdicate 117:19	68:6 124:18 125:3
61 200:9	493:6	abdominal 275:12	169:16,19 231:6
62 204:5	800 26:22 270:16	abernathy 2:2	251:17 277:18
63 209:18 469:5	80s 467:4	21:7,7	281:11 309:15
64 216:6 248:11	81 316:20	abhors 37:22	310:8 336:20
348:20	82 469:12	ability 142:7	358:7 359:19
65 76:4	825 96:5	147:22 149:10	404:17 412:19
65.5 275:8	82nd 57:16	231:10 292:17	475:21 481:11
66 18:13 227:11	83 18:14 246:22	326:15 351:2	absorbed 184:20
261:12 430:10	328:17	418:14 502:7	494:3
6630507 483:18	84 332:16 469:18	503:7	absorbent 487:21
67 235:6	85 142:18 337:22	able 63:10 91:8,13	absorption 75:9
68 240:11	85a 341:22	97:12 126:19	185:18 366:10
69 335:5	86 261:19 347:8	148:5 152:5 163:1	371:4 488:6
7	469:20	183:20 218:4	493:18,22 494:8
7 18:8 108:17	87 353:4	223:7 231:12	abstain 223:7
450:7	88 356:15	239:8 240:13	abstracts 78:21
7.5 277:2	88.7 275:19	252:12 254:10	abuse 28:14 57:8
70 43:11 51:10	89 361:7	255:7,14 256:16	68:1 220:12 242:5
248:6 252:15	8:00 1:15	264:17,20 274:1	268:20 271:8,9,11
260:6 309:9	9	290:10 291:8	295:1 374:10
340:14 397:7	9 18:10 27:15	294:17 295:8	410:15
464:5	291:20 292:2,8	306:4 314:5 316:8	abused 470:4
700 93:8 120:10	90 229:16 309:9	337:10 343:5,6	abuses 191:22
233:15 239:4	366:1 426:2 480:2	344:2 345:11,22	academia 4:14
		346:15,19,21	10:6 18:9 37:16

176:11,15 187:8 220:8 440:9 academic 18:21 37:8 236:16 422:7 academically 192:17 academics 292:11 432:3 academies 183:10 academy 224:14 485:1 accelerate 225:18 accelerated 112:20 223:16 490:17 accept 167:14 247:4 356:2 393:13 460:18 477:21 acceptable 28:16 85:7 331:22 acceptance 99:6 224:20 364:17 accepted 167:10 445:21 accepting 82:10 access 16:13 33:18 34:17 47:2 55:1,3 55:6,7 75:14 111:15 112:13 118:4 123:6 132:5 133:19 152:10 175:4 194:11,20 195:21 197:13 216:19 217:7 221:21 225:8 267:2,7 287:6 326:2 349:13 359:11,13 389:18 403:1,22 404:16 405:3 406:9 411:17 462:10,11 483:5,5	accessed 23:7 accessibility 266:16 accessible 382:9 accessing 142:19 accidental 144:1 accommodate 411:10 accompanied 370:14 accompanies 389:9 accomplished 133:6,21 account 36:15 123:13 337:15 437:9 accountability 364:20 376:1 377:1 408:11 accountable 47:22 149:13 accounted 123:19 accounting 95:7 accreditation 16:3 132:15,18 133:21 133:22 134:16,18 135:5 442:13,14 443:7,11,12,19,22 444:1,5,19,20,22 445:1,3,18 446:9 accreditations 372:2 accredited 132:19 134:13 135:4 443:1 445:10 446:13 478:14 479:8 accumulates 45:22 accumulating 80:9 accuracy 121:17 251:15 314:20	331:4,16 391:5 479:9 480:3 accurate 74:4 134:8 239:2 303:16 319:10 345:16 349:13 351:10 383:13 391:9,10 396:7 446:10 502:6 503:5 accurately 188:15 222:11 306:5 360:13 380:8 466:1 acetaminophen 202:7,19 aches 127:8 achieve 118:7 201:16 487:22 achieved 53:19 57:15 119:16 299:12 480:2 achieves 317:21 achieving 370:12 acid 45:21 acids 45:21 234:8 486:2 acknowledge 112:4 159:20 451:11 acknowledged 113:12 114:13 476:22 acknowledgement 292:19 435:3 acne 276:18 acquired 191:10 207:6 259:14 acre 83:1,2 233:14 233:15 288:14,15 289:9 acres 161:17 289:8,8	act 28:10,18 31:21 65:18 93:21 105:5 108:2 111:20 112:19 113:6,15 114:10,15 117:2 117:21 120:22 121:12 144:6 188:19 241:16,17 273:4,5 296:2 313:15 344:17 410:18,19 411:15 411:16 437:20,21 440:13 acting 4:7 20:11 25:22 146:10 220:15 443:10 action 42:12 85:1 85:4 89:7 120:3 139:12 160:2,4 186:16 392:1 396:16 467:22 470:17 478:16 502:9,13 503:8,12 actions 77:4 112:17 120:6 170:6 active 27:14 81:18 81:21,22 98:4 100:1 105:13 125:22 173:6 177:2,3 178:18,22 179:17 188:16 207:12 253:1 310:21 311:6 381:7 396:8 406:17 419:17 426:17 actively 132:19 234:19 427:19 activities 121:8 235:14 400:21 420:1 423:2 442:16,19 443:14 443:21
---	---	--	---

<p>activity 108:20 209:9 324:8 372:9 383:3 397:12 427:22 428:6</p> <p>actors 477:15</p> <p>acts 270:6,7 474:13</p> <p>actual 186:11 189:5 190:9 191:11 199:11 228:12,14 229:2 263:12 315:4 344:10</p> <p>acute 41:10 213:17</p> <p>acutely 212:10</p> <p>ad 376:13 452:16 468:8</p> <p>adams 7:4 14:14 91:7,12,17,20,20 92:14 373:3,5,6 378:3,7,9,11</p> <p>adb 207:5,7</p> <p>add 302:22 328:11</p> <p>added 27:18,19 31:7 32:13 105:8 105:13,22 106:21 180:4 323:22 362:19 422:6 433:9 442:1 454:10</p> <p>addiction 57:9 173:12 243:2 271:11 374:11,18 468:14</p> <p>addictions 67:10</p> <p>addictive 104:21 173:13 222:18 243:6 477:2</p> <p>adding 31:21 111:21 304:2</p> <p>addition 22:17 23:8 78:22 79:11 84:13 131:9,14</p>	<p>151:6 186:7 210:22 211:17 217:1 266:16 272:13 330:2 367:11 428:8 456:4 463:15 478:21 483:16</p> <p>additional 25:19 46:7 61:3 66:8 75:13 88:9 90:11 129:3 155:7 168:10 212:21 257:10 320:8 327:12 360:12 381:18 441:4,6 442:5 475:1</p> <p>additionally 53:21 99:3 106:3 465:3</p> <p>additive 31:1 81:20 167:2</p> <p>additives 52:19 64:11 99:20 120:8 124:7,8 144:4 416:18</p> <p>address 35:2 53:10 109:12 115:12 117:2,20 119:4 120:3 131:5 150:15 182:3 285:4 302:7 337:20 378:15 385:13 399:16 463:3,6</p> <p>addressed 149:8 256:7 272:2 288:16 385:17 438:19 455:9</p> <p>addresses 213:5</p> <p>addressing 71:16 427:22</p> <p>adequate 78:10 134:4 157:5 181:9 379:11,16 438:19 463:20</p>	<p>adequately 146:20</p> <p>adhere 195:6 196:17 478:17</p> <p>adhered 415:14</p> <p>adherence 121:15 439:12</p> <p>adhering 370:4</p> <p>adjectives 214:22</p> <p>adjunct 192:9</p> <p>adjust 459:11</p> <p>administer 202:21</p> <p>administered 211:15 212:15,22 213:7 214:19 270:12,13 271:1 299:1</p> <p>administering 212:10 285:11</p> <p>administration 1:1,16 2:4,9,13,17 2:21 3:5,9,13,17 3:21 4:5,11 40:20 41:13 177:7 183:19 184:2,18 185:16 186:1,8,17 201:15 202:18 211:17,19 213:4 215:3 257:22 258:9 358:12 361:12 388:17 395:19 426:14 451:15 453:21</p> <p>administration's 20:4</p> <p>administrations 84:18</p> <p>administrative 22:20 446:1</p> <p>administrators 430:17</p> <p>admissions 222:21</p> <p>admit 208:16</p> <p>admitted 92:4</p>	<p>adolescent 402:4</p> <p>adolescents 224:22</p> <p>adopt 437:2</p> <p>adopted 314:6 426:4</p> <p>adoption 119:17 380:5 442:17</p> <p>adult 51:11 108:17 146:1 174:9 247:15 248:4,4,11 340:14 359:4 361:4,4 430:9,10 451:10 453:20 482:19</p> <p>adulterant 467:13</p> <p>adulterants 99:13 133:12 192:4 195:11,15 216:17</p> <p>adulterated 99:18 190:20 191:7,17 193:20</p> <p>adulteration 199:8 208:10 400:1 497:2 499:17</p> <p>adults 116:14,15 139:17 215:14 224:22 247:15,20 272:10,12 277:9 400:20 452:15 468:10</p> <p>advance 24:11 25:13 108:12 240:12,15 342:7 425:15 481:3</p> <p>advanced 37:20 84:12 311:12</p> <p>advancing 167:12 381:15</p> <p>advantage 82:20 82:21</p> <p>advantageous 489:2</p>
---	---	--	--

advantages 315:17 436:19 487:15 488:4 adverse 51:13 67:6,15,20 69:19 84:17 124:22 139:7 141:10 157:20 179:3 193:11 194:8,13 194:21 196:12,13 197:17 198:3 199:11,16,18 200:4 209:13 218:3 219:21 269:8,11 285:14 299:20,22 300:2,6 300:6,9,19,22,22 301:2,9,12,14,19 302:3,4,5 318:16 325:20 358:15 380:11 388:12 430:21 438:14 441:20 468:16 480:9,13 492:22 493:4 advertise 375:5 advertised 345:17 advertises 376:12 advertising 82:12 220:20 247:4 255:3 375:10 425:4 470:8 advice 251:4 advise 422:13 advising 119:6 422:12 advisor 3:7 21:11 422:7 advisory 95:19 379:4 advocacy 47:21 142:16 235:19 252:19 400:22 432:7	advocate 138:7 139:22 241:22 242:7 369:1 381:8 393:11 473:21 advocates 88:2 124:6 130:13 advocating 255:21 ae 301:4 aea 262:8 aes 300:5,11 301:5 afco 166:12,13,20 167:3,9,13,15 168:5,9,15,22 169:10 afco's 168:4 afco.org 169:7,8 afco.org. 169:11 afdo 156:1,1,2 157:10,14,16 159:10 160:20 affairs 2:6,8,12 20:9 21:22 22:3,4 192:12 298:12,16 321:12 353:7,10 366:4 420:1 affect 142:7 405:12 451:16 affiliated 192:17 affiliation 25:5 affirmation 273:7 affirmative 280:4 affirmed 356:2 affordable 403:12 aflatoxin 100:2 afraid 208:7,14,15 403:4,5 afternoon 103:1 252:17 268:8 282:3 293:17 310:20,21 328:18 332:17 338:1 353:5 356:16 361:8 366:2 378:14 390:19	395:2 400:7 406:15 413:8 419:3,8,9 425:10 429:10 434:21 456:20 466:21 471:9 476:3 486:21 afternoon's 413:18 ag 262:8 age 55:18,21 56:2 57:17 69:12 91:22 165:11 248:12,14 255:19 256:1,5,9 258:1,8,15 388:8 409:14 469:22 470:2 472:10 473:4 484:7 485:13 aged 149:3 agencies 83:19 88:11 89:3,9 166:14,15 182:18 204:1 312:16 362:20 363:4 365:14 369:1 396:22 411:22 440:9 476:22 478:8 agency 26:2 35:21 50:1 63:12 65:16 84:5 87:12 96:1 98:15 100:17 101:9 113:14 118:8 135:21 155:11 200:16 244:11 258:18 304:2 320:8 346:2 347:1 353:15,17 354:18 355:21 356:1 396:6,22 397:11,13,15,18 399:5,6,12 410:20 414:16 419:15	437:21 440:7 442:2 480:21 491:21 agency's 38:11 84:10 85:1 113:4 329:8 460:13 agenda 20:10,17 24:19,22 27:1 36:18 37:2 91:6 95:13 98:9 101:19 104:11,14 111:6 122:6 125:7 341:20 agent 297:20 agents 124:7 146:13 203:14 ages 67:5 375:13 375:15 aggregate 34:2 aggressive 38:3 174:10 442:2 aggressively 382:11 436:10 agnostic 313:8 ago 62:5 63:6 122:11 179:9 182:1 208:20 246:5 283:9 288:3 391:21 425:19 449:4 458:22 459:18 467:16 483:13 485:2 agonists 94:16 agony 58:14 agree 44:14 76:10 286:1 321:13 324:2 405:3 418:20,21 433:7 agreed 111:19 305:17 agreement 47:13 294:4 agreements 489:14 490:2
---	--	---	--

<p>agrees 136:5 243:18</p> <p>agribusiness 43:4 44:6,10</p> <p>agricultural 28:18 50:10 52:10 82:16 145:8 147:12 164:10 228:4,10 231:3 313:15,16 322:8,10 352:1 408:2,7 411:16 412:5</p> <p>agriculturally 411:15</p> <p>agriculture 4:20 9:16,18,21 10:3 11:11 18:10,22 42:14,15 43:8 47:15 161:11 166:8 227:10,12 367:21</p> <p>ah 169:5</p> <p>ahead 184:22 199:5 282:8 287:20 293:11 321:14 381:21 413:5</p> <p>ahold 423:9</p> <p>ahpa 111:11,12,14 111:19 112:1,16 113:9</p> <p>ahpa's 112:14</p> <p>aid 195:1 320:8</p> <p>aids 30:9</p> <p>ailments 261:7 262:1 341:8</p> <p>airborne 57:16</p> <p>airplanes 426:11</p> <p>airtight 491:2</p> <p>akin 416:11</p> <p>alabama 179:21 336:8</p> <p>alarmed 117:5</p>	<p>alarming 335:9</p> <p>alcohol 56:1 123:18 151:12 409:6,8,13 412:9 412:12 431:5 470:1,4</p> <p>alerts 77:3 439:4</p> <p>alex 242:18</p> <p>alexander 2:5 22:1,2</p> <p>alice 13:16 337:22 338:1</p> <p>aligned 238:21</p> <p>alike 54:6 100:20 163:8 340:1 417:8</p> <p>alive 245:2</p> <p>allen 66:18</p> <p>allergen 424:22</p> <p>allergies 491:7</p> <p>alley 431:15</p> <p>alleys 431:7</p> <p>alliance 5:15 8:20 56:16,18 142:16 143:5 144:9</p> <p>alliances 16:15 467:1</p> <p>allocated 98:15 168:10</p> <p>allotted 24:19 25:9</p> <p>allow 28:3 48:10 55:7 105:1 111:15 112:13 195:21 255:2,5,8 256:15 257:11,12 273:8 285:7 294:17 297:11 303:21 305:1 323:4 324:10 325:8 327:10 341:3 354:9 363:8 382:7 397:19 408:17 411:2 432:13,13 432:14,15 434:13</p>	<p>434:13 440:15</p> <p>allowable 211:2 464:18</p> <p>allowances 150:22</p> <p>alloway 180:15</p> <p>allowed 23:14 89:18 115:10 151:11 159:6 168:21 241:19 256:18 323:11 376:19 377:2,4,11 377:13 396:12 411:4 467:13</p> <p>allowing 28:4 42:12 60:19 72:17 73:19 79:16 104:16 120:7 159:19 160:22 181:19 273:14 274:12 298:2 322:2 326:14 346:11 371:9 400:8 411:16 413:8 433:12 435:13 466:2,22</p> <p>allows 82:21 167:14 267:7 285:12 290:13 374:14,19 433:9 436:21 446:19 477:15 488:5</p> <p>alluded 176:20</p> <p>allworth 12:6 258:22 259:2,3 263:15</p> <p>alter 153:20 178:7</p> <p>alternately 113:2</p> <p>alternative 261:9 375:9 385:21</p> <p>alternatively 408:10</p> <p>alternatives 101:16</p>	<p>alzheimer's 8:16 135:14,16 136:1,3 136:4,7,14,19,20 137:6,9 482:15</p> <p>amatucci 4:21 42:14,16,17</p> <p>amazon.com 237:2</p> <p>ambiguity 130:11 153:13 243:21</p> <p>ambitious 24:19</p> <p>amend 273:12</p> <p>amendment 412:22</p> <p>america 43:3 175:16 377:15 396:1 481:20</p> <p>america's 237:15</p> <p>american 6:3 7:19 8:18 30:17 43:6 45:1 46:6,15,19 47:14 63:16,19 72:18 78:9 82:18 83:5 111:7,10 125:12 126:16,19 132:14 137:17 138:2 166:11 195:14 216:18 297:14 347:22 354:19 433:21 463:8,9 483:8 484:13 497:15,17 497:18</p> <p>americans 16:13 31:7 45:2 46:21 108:17 118:4 125:19 127:17 145:14 154:9 247:15 248:5,11 348:21 400:19 462:9</p> <p>ames 271:3</p> <p>amino 234:8</p>
--	--	--	--

<p>amount 24:19 69:8 78:10 116:22 164:2 198:20 211:4 213:11,11 214:4 223:19 224:8 238:4 239:8 275:5 288:19 317:15 343:4 454:19 465:16 467:12 468:5,12 468:14</p> <p>amounts 39:6 157:1 174:6 175:11 224:9 308:8 341:1 455:6</p> <p>ample 209:9 439:14</p> <p>amy 2:2 21:7 61:11</p> <p>anab 442:13 443:1</p> <p>anaerobes 489:22</p> <p>analgesia 224:8</p> <p>analgesic 269:4</p> <p>analogs 306:18</p> <p>analyses 329:19 372:13 382:17 434:9 479:5</p> <p>analysis 63:2 189:13 194:22 196:14 204:8 205:2 206:20 207:4 237:7 238:12,15 293:1 325:14 363:21 370:16 372:9 391:20 392:2 393:2 428:2,12 479:13 493:9</p> <p>analytes 146:13 237:12,18</p> <p>analytical 99:5 109:15 133:7 134:12 135:4 144:22 145:1,4,18</p>	<p>220:1 236:9 237:9 303:13 304:11 305:19 306:7 311:16,17 312:1 370:17 378:19 391:1,12 394:14 462:20 463:22</p> <p>analytics 408:14</p> <p>analyze 175:18 439:14</p> <p>analyzed 189:18 380:8</p> <p>anatomy 259:11</p> <p>ancillary 107:10 235:1</p> <p>anderson 264:18</p> <p>andi 336:11</p> <p>andrew 7:16 107:2,4</p> <p>andy 8:6 56:20 57:10,13 58:9 125:7,8</p> <p>andy's 57:3,3,4,10</p> <p>anecdotal 54:8 80:3,8 127:20 360:20 381:13 459:8</p> <p>anecdotally 80:5</p> <p>anecdote 39:10</p> <p>anemia 141:21</p> <p>anesthesiologist 317:5</p> <p>animal 6:21 31:22 45:10,13,18 46:3 47:14 52:19 64:10 83:11 84:12 135:18 154:6 166:18 167:10,14 168:2,15,19,21 169:1 170:3,11,16 171:16,19 192:20 197:8 219:16 263:4 398:19,19 493:3</p>	<p>animals 46:20 54:6 64:5,10,21 66:2 84:9,22 86:16 169:15,22 170:18,21 171:7,9 357:8</p> <p>ann 12:6 258:22 259:3</p> <p>anna 8:11 132:12 132:13</p> <p>anne 5:18 59:2,4 62:11</p> <p>announced 31:11 283:20 357:21 368:6</p> <p>announcement 176:3</p> <p>announcements 22:16</p> <p>annual 289:15</p> <p>annually 43:12</p> <p>anorexia 30:9</p> <p>ansi 16:3 442:14</p> <p>answer 36:2 61:3 95:9 131:8 137:10 141:8 221:10 262:1,13 339:4,10 380:14 419:2 458:17</p> <p>answered 459:22 500:15</p> <p>answering 429:6</p> <p>answers 199:21 306:2 401:22 414:13,14 499:12</p> <p>anterior 474:10</p> <p>anti 143:9 178:11 179:13,14 269:4,4 280:17</p> <p>antibiotic 221:6</p> <p>antibiotics 202:6</p> <p>anticipate 101:5</p> <p>anticoagulation 180:2</p>	<p>antioxidant 122:22 126:7</p> <p>antioxidants 484:4 485:3</p> <p>antipsychotic 269:4</p> <p>antonio 294:11 457:2 459:2</p> <p>anxiety 71:11 80:18 96:13 174:13 223:10 248:17,22 249:20 271:13 274:4 275:16,17 276:8 276:19 318:2 344:21 374:22 387:4,17</p> <p>anxiolytic 80:18 269:3</p> <p>anxious 243:10</p> <p>anybody 55:14 97:8 241:10 475:8 484:7</p> <p>anyway 496:1</p> <p>aoac 14:21,21 145:3,17 390:20 390:21 391:14 394:12</p> <p>aoc 371:8</p> <p>aosc 379:6</p> <p>apap 203:2</p> <p>api 319:11</p> <p>aplastic 141:20</p> <p>apologize 25:13 334:19</p> <p>app 321:3,3</p> <p>apparent 143:21</p> <p>appeal 452:14</p> <p>appear 35:5 64:19 79:1 207:1 224:11 340:13,15 436:17</p> <p>appeared 57:7</p> <p>appears 78:16</p>
---	--	---	---

<p>appetite 251:8</p> <p>applaud 88:7 109:7 136:21 175:22 383:17</p> <p>applauds 322:4</p> <p>applause 26:12 36:20 58:16 209:16 220:6 227:8 232:6 240:9 245:11 250:21 252:6 257:17 263:14 273:16 281:14 326:7 341:18 378:1 419:5 450:21 462:1 471:6 475:19 486:18 500:18</p> <p>apples 334:1,1</p> <p>applicability 351:19</p> <p>applicable 113:1 113:11 354:11 363:1 414:10 415:6</p> <p>application 97:18 126:12 143:7 264:3,12 278:8 484:6,10</p> <p>applications 284:2 284:5 294:5 311:16 353:2 418:19 488:12</p> <p>applied 1:2 240:5 258:14 297:2 301:18 350:6 415:14 417:6 464:19 488:14</p> <p>applies 31:5 34:12 105:22</p> <p>apply 32:7 64:20 76:10 106:1 118:2 297:2 306:11 312:8 322:17</p>	<p>478:5</p> <p>applying 159:15 368:11,16 394:15 416:20</p> <p>appreciably 304:3</p> <p>appreciate 56:11 69:6 74:8 77:17 83:13 102:17 140:4 153:7 178:1 197:2 216:1 232:5 320:16</p> <p>appreciated 110:21 466:14</p> <p>appreciates 48:20</p> <p>approach 24:1 36:3,8 72:20 73:8 77:13 84:10 91:10 143:6 160:6 163:5 163:14 217:17 265:5 305:17,20 312:3 317:21 353:12 371:14 389:16 407:7,9,18 409:5,6 443:13 452:4 480:8</p> <p>approached 421:2</p> <p>approaches 5:13 265:8 456:5</p> <p>approaching 148:4 156:22</p> <p>appropriate 36:3 42:1 100:16 116:21 131:10 134:6 154:21 155:3 160:6 185:3 256:2 306:6 322:1 322:19 324:20 325:15 326:3 351:15 352:15 381:9 415:1 424:5 424:12 439:22 443:8 476:17 480:15,19,22</p>	<p>appropriately 155:1 307:4 323:8 325:4 435:20</p> <p>appropriateness 328:6</p> <p>approval 30:2 31:15 45:12 50:16 61:17 76:13 77:9 101:16 105:3,15 106:11 141:11 143:3 168:3 339:3 339:4 341:15 405:17 406:11,11 410:2</p> <p>approvals 35:14 140:16 148:5 150:19 491:16</p> <p>approve 221:6,7 392:1</p> <p>approved 30:3,22 31:1,19 32:1 35:18 38:22 51:6 64:2 81:18 84:1 94:9 101:9 102:8 105:13 106:2,5,7 106:8 129:21 130:20 139:1 140:9 142:5 144:5 166:22 174:16,17 177:22 221:2,3,5 222:3 241:11 260:15 284:21 321:21 325:2 329:4,20 333:16 338:11,14 341:10 341:16 344:13 360:17 369:5 370:1,19,21 371:1 385:13,18 387:1 402:11 405:21 422:4 428:8 448:11 453:10 457:4 459:20 461:6 464:20,21</p>	<p>482:11,18 485:20 490:7</p> <p>approves 33:1 185:8</p> <p>approving 273:1</p> <p>approximately 23:7 400:18 417:12</p> <p>apps 284:6</p> <p>april 433:8</p> <p>area 23:21,21 99:21 100:6 136:21 185:10 200:2 247:1 251:11 252:11 264:3 265:19 288:22 290:4 291:21 292:9 368:2 483:2</p> <p>areas 33:15 99:3 172:6 197:12 253:3 264:3 269:2 291:6 338:22 389:22</p> <p>argue 467:10</p> <p>arguments 328:12 345:4</p> <p>arising 476:15,19 480:12</p> <p>arizona 282:12</p> <p>arkansas 10:13,19 188:1 200:13 238:22</p> <p>arm 359:13</p> <p>armed 305:21</p> <p>army 57:14 67:2 96:5</p> <p>aroma 151:5 328:2</p> <p>arose 432:18</p> <p>arrangements 293:8 444:21</p> <p>array 42:8 76:20 76:21 138:11</p>
---	--	--	--

<p>270:7,9 324:3 337:15 arrested 82:9 arrives 383:16 arsenic 490:1 artemis 15:21 arthritis 186:3 209:1 276:8 article 324:5 360:7 435:14,22 436:4 articles 99:5 articulate 64:11 articulating 215:8 artificial 124:6 artisanal 261:18 asdm 379:6 ashley 6:2 63:16 63:19 aside 111:11 432:16 asked 57:7,9 98:5 118:11 248:15 249:2,10,17 250:14 251:6 269:7 386:4 417:10 448:17,19 481:7 485:22 496:1,4 asking 117:18,19 117:20 128:21 148:2 149:19 247:15 251:18 278:19 284:11 345:8,8 387:11 397:13 442:17 460:18 asks 269:16 asleep 495:22 aspect 201:11,21 332:1 357:6 410:16 aspects 146:17 187:1 259:10</p>	<p>386:22 387:10 427:13 442:20 476:9 aspergillus 393:18 aspirin 51:8 assault 376:18 assays 138:17 271:3 302:16,17 assemble 432:8 assembling 432:2 assess 278:22 494:8 assessed 298:21 299:5 300:14 444:18 assessing 454:20 assessment 61:12 134:1 175:10,14 199:7 313:20 442:15,18 443:7 443:14,17 444:11 444:16,18 445:19 446:3 assessments 175:18 200:17 389:12 443:13 444:8 assessor 378:21 assessors 49:17 134:10 assigned 484:1,2 assist 123:11 266:15 430:6 460:20 assistance 404:4 assistant 3:11 21:21 115:20 161:9 assisting 42:19 assists 410:4 associate 3:3,19 4:3 21:4 22:10 61:19 204:12</p>	<p>associated 33:8 68:3 93:3 143:3 157:20 173:21 271:11,16 379:15 453:3 489:4 associates 14:17 16:5 447:5 association 5:19 6:3,13 7:3,13,17 7:19 8:16 11:17 15:3 48:5 59:3 63:17,20 76:1,4 87:17 101:20 102:1,1 107:3,6 111:8,11 115:22 132:15 135:14 136:4,20 153:9 155:22 159:2 166:11 235:10 395:9,9 419:12,18 419:20 421:15 435:1 463:8 associations 241:13,13 assume 86:22 152:16 215:12 248:2 483:18 assuming 60:17 256:6 assurance 64:5 77:16 116:19 133:3,20 134:4,19 331:3 assurances 154:21 336:5 461:9 assure 123:4 138:14 303:8 305:10 316:3 437:21 assures 65:13 314:15 322:18 assuring 435:11 asthmatic 269:5</p>	<p>astm 15:19 425:11 425:18 426:1,3,6 426:14,19 427:6 427:21 428:17,21 astounding 349:6 349:17 ataxia 193:15 athens 311:2 atlantic 342:7 345:3,5 atmosphere 159:6 attacks 374:20 458:1 attained 371:18 attempt 141:22 175:4 333:2 attempted 373:18 attempting 119:19 attempts 57:19 attend 22:18 26:21 81:9 attendees 27:4 attention 24:22 60:16 185:13 192:1 201:3,22 203:1 204:3 302:21 497:13 attest 54:8 attestation 443:18 444:1 attestations 381:16 attitude 470:8 attorney 22:7 70:21 104:17 406:17 413:11 419:10,13,14 476:4 499:21 502:11 503:10 attorneys 420:6 attraction 75:3 attributable 28:14 330:11</p>
---	--	---	--

attributed 207:8 attributes 133:4 351:4 aubree 14:14 373:3,6 aubrey 7:4 91:20 373:2 audino 14:16,17 378:13,14,18 audio 503:3 auditable 305:11 audited 231:12,13 231:20 232:2 342:20 348:12 auditing 428:12 august 141:15 164:2 169:5 aureus 492:16 australia 94:1 213:1 authoritative 439:10 authorities 29:4 29:15,16 424:13 424:14 480:14 authority 29:6 38:12 62:6 77:8 112:18 113:12,15 116:4 118:7,9 153:21 159:9,14 162:18 329:7 342:21 345:5 354:8 355:8 371:11 460:19 481:18 authority's 49:11 authorized 105:14 284:19 380:19 autism 260:21 277:8 autoimmune 92:22 484:8 automatically 117:15	autonomic 385:19 autonomy 445:11 autosomal 473:3 availability 94:22 128:15 137:4 153:17 162:4,6 182:9 218:13 226:4 404:22 416:17 470:9 available 23:10 24:7 32:6 41:18 42:2,3,6,9 48:13 74:5 78:18 81:17 87:9 94:8 97:21 100:19 123:2 129:2 133:15 137:2 152:18 156:17 158:5 188:8 216:2 230:11 257:15 284:20 325:16 329:20 336:15 354:19 358:17,19 361:3 363:19 369:13 374:2 387:8 401:4 403:18 405:8 406:1 448:14 451:14 452:7 456:11 463:21 466:6 469:15 477:16 avenue 1:18 average 126:16,19 237:19 238:3,8 318:7,12 340:14 454:12 480:2 averaged 302:12 avma 65:7 avoid 93:13 144:1 285:14 avoiding 151:1 await 380:5	awaiting 60:8 107:22 awaits 168:5 awarded 79:3 aware 35:5 140:8 140:10 157:18 176:7 185:20 218:16 290:21 315:19 364:13 397:12 441:19 442:6 awed 54:10 <hr/> b <hr/> b 16:9 121:14 127:1 baby 96:4 248:22 375:21 back 20:17 23:18 92:10 114:20 120:2 127:21 175:7 178:4,21 180:7 247:9 275:10 279:11 281:8 283:21 289:1 291:19 312:11 334:6,20 372:18 373:20 407:20 420:22 422:3 431:7,15 486:12 496:6 500:6 background 216:10 367:11 379:9 391:14 399:7 background's 419:14 backup 220:2 bacteria 330:6 490:13 494:18 495:9 bacteriological 146:13	bad 206:19 208:5 208:8 221:10 255:8,17 257:9 270:6 414:3 449:18 461:4 477:15 badmouthing 498:11,11 bag 176:8 bailiwick 219:1 baker 6:9 70:19 70:22 balance 262:10 263:2 balanced 369:1 482:2 balancing 485:4 492:19 baltimore 70:21 ban 47:3 258:12 bank 147:17 banking 82:17 95:21 148:2 423:13 banks 108:8 148:4 175:5 banning 124:6 bapp 195:16 bar 304:10 419:18 419:19 422:4 428:18 479:2 barefoot 373:17 barely 42:7 130:1 barest 304:4 barley 147:12 barrels 59:19 barrier 316:7 478:1 barriers 41:16 139:18 182:14,14 barring 355:1 barry 10:7 176:12 176:16
---	--	--	---

bars 454:4	342:13 368:3	328:21 345:6	believers 173:18
base 54:16 116:17	444:10	400:18 419:11,11	believes 65:7
176:19 253:2	batch 153:6 319:8	425:11 476:5	136:20
290:9 423:1 499:4	319:9 372:5 479:4	484:13	benchmarking
499:11	479:7 489:19	behavior 261:16	195:1
based 32:6 33:22	batches 283:16	271:7 451:10	bene 312:22
36:3,8 42:11	314:17 315:1	behold 264:19	beneficial 54:5
52:15 61:17 72:20	480:11	bejesus 402:17	224:13,18 261:3
74:3 75:6 78:5,7	baxter 16:20	belief 78:14,16	408:1,7 461:11
78:15 81:16 84:10	487:1 489:7	139:7	benefit 68:8 79:2
88:3,22 95:20	492:13 494:7	believe 23:17	80:5 163:8 184:8
98:16 100:3,13	495:12	43:19 48:12,22	220:22 221:13
102:5 112:12	bcbc 407:20	63:20 72:1 73:4	223:21 224:10,16
115:21 118:16	bear 184:12 341:4	79:7,18,20 80:13	265:3 292:18
128:6,16 131:2	469:10	80:17,19 84:11,20	295:7 310:4 352:7
134:5 143:6 144:4	bears 341:5 469:9	85:9 100:22	358:18 369:20
156:21 183:6,12	beat 249:13	102:22 104:1,10	387:13 461:5
183:18 184:6	beaten 52:13	109:13 115:8	benefits 33:2
200:22 222:10	beautiful 431:7	117:10 122:17	46:17 49:6 71:17
226:8 237:19	beauty 72:15	126:13 143:14	73:16 79:19 86:5
238:20 240:4	74:13,18	149:8 150:14	123:2 126:20
271:2 322:20	beck 14:18 383:19	158:1 162:21	127:11 191:19
324:17 332:19	383:21 384:3,5,19	163:5,8 176:5	225:13 256:12,22
357:9 360:16	390:2,7	194:3 195:19	267:21 275:22
379:18 380:7	becoming 41:13	217:7 219:18	276:7 293:5 294:1
381:14,22 382:15	beds 374:2	253:18 259:6	379:15 380:10
383:12 384:14	beer 151:4 450:6	273:20 274:21	381:14 382:3
385:5 389:16	496:13	276:12 277:12	383:7 410:12
407:12 411:12	beg 175:22 485:20	297:19 306:17	445:18
413:11 416:8,9	began 121:3 160:8	313:11,17 314:4	benjamin 503:2
425:14 445:3	178:1 208:4	315:10 320:13	503:15
453:11 462:21	beginning 25:6	326:11,11 333:18	benzodiazepines
467:2 476:9	39:17 318:11	334:12 347:18	67:11
480:12 487:2	319:18 359:3	352:6 355:16	berenson 242:18
492:3	411:18 437:5	356:1,4 362:7	best 27:14 39:20
baseline 119:11	begins 73:12	378:22 379:17,19	49:13 73:8 125:18
146:5,12 350:4	begs 305:12	379:21 402:15	194:16 195:6
bases 113:6 208:3	begun 28:4 304:5	441:1,15 456:15	196:18 267:2
basic 219:13	behalf 40:5 76:3	457:12 476:17	353:13,17 396:17
basically 121:5	83:12 98:14 119:2	482:1 494:21	403:20 404:11
241:10 248:4	125:10,12 137:16	believed 59:16	446:11 448:7
344:1,18 423:17	138:2 144:8 153:8	208:12	460:10 463:9
basis 168:20	220:9 252:18	believer 59:5	485:16 486:10
248:10 269:14	298:17 317:6		490:4 496:5 499:2

499:2 502:6 503:6 bestseller's 237:2 bestselling 237:15 bet 243:3 betsy 7:2 87:14,15 better 45:3 71:10 71:20 80:1,7,20 90:17 97:15 162:5 162:14 165:4 213:21 214:12 245:18 411:21 458:4 459:9 464:12 476:12 498:13 beverage 34:13 88:6,14 227:18 289:22 306:18 342:11 beverages 154:4 304:15 beyond 23:21 41:12 71:3 72:6 77:3,5 110:6 178:11 179:13 182:5 442:6 443:15 472:13 474:21 bias 479:14 bibs 375:21 bifurcating 433:13 big 38:10 164:10 199:22 222:17 286:9 289:15 290:18 334:1 484:21 bigger 396:4 biggest 35:10 142:11 279:1 316:9,13 349:9 351:10 bilirubin 201:20 bill 10:12 13:6 28:19 29:6 33:22	48:15 54:19 81:13 82:8,17 111:14 147:11 150:17 153:20 160:17,19 185:7 187:9,21 226:6 295:18 310:19 313:15 329:6 341:2 414:2 414:5 423:16 469:2 bill's 111:18 billion 43:11 52:5 52:6 108:20 119:20 238:3,9 344:6 billionaire 287:21 billionaire's 174:12 billionaires 175:19 billions 54:17 bind 494:5 binding 488:14 493:20 bio 13:3 298:12,16 298:19 302:9 bioaccumulator 146:9 bioassay 398:15 bioassays 398:11 bioavailability 319:2 biochemical 270:22 biochemistry 419:14 biodistribution 264:13 biological 60:1 324:8 379:7 394:9 biologically 27:13 biologist 259:9 biology 274:14	biomass 288:18 362:13 424:16 biomedical 175:3 356:18 485:14 biopharmaceuti... 263:20 biopharmaceuti... 12:9 biosciences 5:7 13:17 17:3 50:6 50:10 456:21 495:20 496:3 498:3 499:8 biotechnology 361:20 biotek 9:4 144:21 biotransformation 176:22 bipartisan 284:10 biphasic 202:9 bird 9:3 144:18,20 144:21 birth 242:1 birthday 457:16 birthdays 496:13 bit 62:12 113:19 113:22 122:1 128:14 132:9,11 142:2 148:4,16 149:19 150:11 172:14 179:8 210:21 212:9 226:14 228:2 236:22 241:8 289:22 294:8 326:16 332:18 356:17 358:16 391:14 399:2 407:16 422:18 447:17 451:6 455:18 471:11 bits 417:4 bitter 328:8	black 54:16 253:17,20 272:14 346:15 blair 6:6 66:20,22 66:22 68:15,21 69:9,13,15,22 70:8,14 blanket 258:12 blehar 12:18 287:14,15,17,18 blessings 461:20 blind 299:4 461:13 493:5 blindness 472:3 blistering 119:9 block 267:7 blogs 237:3 blood 142:1 212:2 213:4,7 276:5,5 281:6,11 339:16 339:20 388:5 493:22 bloodstream 143:12 494:19 blue 205:17 385:4 387:12 bluetooth 471:21 blunt 234:16 board 16:3 53:15 95:16,19 317:4 379:1 429:13 442:14 boast 175:6 bob 425:11 bodies 134:16 380:2 381:6 429:1 443:11 444:16,18 444:19,20,22 445:1,11 body 49:5 71:7,9 78:13 132:18 135:5 149:2 258:6 259:10 261:4 262:2,3,9,9,17
---	--	--	--

263:2 340:13,16 442:15 443:12 445:10 469:6 474:13 478:14 487:21 body's 29:22 bog 304:2 bogus 62:4 boil 149:17 bold 429:18 boldly 437:21 bona 39:15 bones 401:1 bongs 375:10 bonn 211:7 bonni 261:15 bonus 376:13 book 242:18,22 275:9 bookout 6:20 83:8 83:10,11 85:15,18 85:21 86:4,10,13 86:15,21 87:3,5,8 boomers 248:22 boon 82:15 booren 7:2 87:14 87:15,15 89:20 90:14 boost 45:1 446:9 border 425:3 borrowed 495:8 botanical 78:5,14 79:11,15 99:5 188:4,17 195:11 195:14,15 216:12 216:17,18 218:9,9 285:5 297:4 323:1 323:20 327:5,6 botanically 315:18 botanicals 195:12 315:20 396:10 bother 227:3	bottle 70:4 120:1 279:3 459:13 461:1,3 469:8 bottles 450:6 469:11 bottom 109:8 283:9 304:6,8 387:5 453:15 469:18 bought 459:13 boulder 50:9 boutique 53:11 419:15 bovine 86:12 bowen 11:16 235:6,8,9 box 272:14 320:10 438:5 boy 96:4 461:15 bpm 300:18 bradykinesia 385:11 brain 56:20 80:8 93:14,16 94:16 126:9 139:15 221:15 260:7 382:7 458:18 468:17 brains 376:19 brand 17:2 238:12 279:16,21 321:19 343:16 357:4 452:13 495:19,21 496:2 500:14 branded 89:22 branding 255:2,12 256:19 brands 6:11 72:14 97:2 237:7,19 238:16 255:5,13 342:10 356:20 357:9 452:9 break 24:11 172:13,14,22	268:6 274:10 281:16 366:1 372:18 377:11 450:1 breakthrough 286:21 breast 259:11 brenda 9:17 158:9 158:21,22 brenda's 158:9 brethren 499:6 brfss 453:12 brian 15:14 413:3 419:6,9 brick 207:18 208:2 bridge 8:9 129:19 294:12 295:5,8 296:11 297:9 brief 120:6 176:3 458:19 briefly 91:15 110:18 434:2 brighter 362:20 brilliant 375:3 bring 76:15 77:6 145:9 161:12 166:2 168:7 279:10 289:16 345:12 391:17 460:3 497:20 bringing 50:21 100:5 235:20 287:19 352:4 386:9 427:15 441:17 brings 340:5,20 341:16 383:7 broad 84:3 89:15 111:15 263:8 269:1 279:5 289:2 292:14 303:6,17 305:15 306:14 307:12,19 308:4	308:20,21 324:12 358:13 417:14 418:7,7 424:7 430:5 432:11 437:2,4 broadened 179:22 broader 34:6 143:3 326:14 337:15 353:1 broadly 76:19 129:1 219:14 broke 248:12 brotherism 38:10 brought 54:11,12 57:22 58:5 78:6 291:20 292:10 338:15 357:11 389:17 brown 274:16 450:5 brownies 257:7 brumfield 12:20 293:16,17,19 298:5 bryant 12:8 263:17,18,19 268:4 bubb 10:2 166:7 166:10 169:16 170:1,19,22 171:17 172:7,10 buckle 275:15 budding 371:12 budtender 59:7 62:11 buffington 5:2 45:6,7,8 build 88:4 267:16 306:19 489:17 builders 391:17 building 1:17 47:22 500:4 builds 160:14
---	---	--	---

<p>built 339:12 348:6 378:19</p> <p>bulk 297:1 302:15 302:19</p> <p>bullshit 245:8</p> <p>bunch 238:15</p> <p>burchman 58:21</p> <p>bureau 189:14</p> <p>bureaucracy 445:22</p> <p>burgeoning 170:8</p> <p>burn 229:6 289:13</p> <p>burns 276:17</p> <p>business 47:20 53:12 96:14 107:10 319:17 336:14 342:11 445:10 446:9 463:10 491:11 497:7,7 498:12 499:20</p> <p>businesses 98:1 104:18 108:4 290:5,11 291:5 357:6 462:15 463:17 467:17 476:8 477:10 478:5,12</p> <p>businesswoman 429:14</p> <p>butane 465:2</p> <p>butchering 111:5</p> <p>button 295:14 496:18</p> <p>buy 147:14,15 226:17 236:6 247:8,17 249:11 350:1 459:2 482:20</p> <p>buying 73:14 174:22 207:15 237:4 249:16 290:6 337:1 431:18</p>	<p>bye 497:18,18</p> <p>byproduct 210:4 232:18</p> <p>byproducts 45:14 232:8</p> <hr/> <p style="text-align: center;">c</p> <hr/> <p>c 2:1 3:1 4:1 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:2 19:1 20:1 53:13 79:11 86:5 121:15 126:8,17,18 128:10 415:10</p> <p>cadfy 467:7</p> <p>caffeine 51:8 328:9 399:19</p> <p>cake 168:13 170:15</p> <p>calcium 415:9</p> <p>calculate 394:1</p> <p>calibrate 453:11</p> <p>california 10:11 122:12 123:21 146:2 181:22 182:2 187:4 242:10 261:15 274:15 292:1 293:21 294:1,2,10 297:16 336:18 432:17 467:3 480:1</p> <p>call 175:8 198:4 203:19 206:16 234:2 304:3 392:8 392:16</p> <p>called 62:13 93:2 180:8 202:9,22 221:2 227:10 230:2 236:14 242:9 374:5,6 401:9 402:3 447:22 497:12</p>	<p>calling 109:6</p> <p>calm 215:10</p> <p>caloric 224:4</p> <p>cameron 11:12 227:10,14</p> <p>camilla 457:14,16 457:17,18 458:12 459:1,13,19 460:6</p> <p>camilla's 458:2,9 459:5</p> <p>campaign 97:15 175:21 376:1</p> <p>campaigns 38:3</p> <p>campus 1:17</p> <p>canada 5:13 45:11 90:9 94:1 109:3 173:6 174:5,8 175:9 227:21 253:9 255:10 257:3 268:17 274:1 297:16 410:6</p> <p>canada's 196:9</p> <p>canadian 175:12 287:2</p> <p>canal 488:19 489:4 494:4</p> <p>cancellation 104:12</p> <p>cancer 26:6,9 35:14 62:4 67:8 96:13 174:11 259:12 260:7,22 264:4,18 286:20 398:11,15 482:16</p> <p>candida 489:22</p> <p>candispharma 59:1</p> <p>candy 34:13</p> <p>cane 11:12 227:10 227:13,14 232:10 233:6,11 234:3</p> <p>canine 96:11 358:2</p>	<p>canines 276:8</p> <p>cannabidiol 27:16 49:3 80:14 101:1 101:5 115:8,9 128:15,16 143:1 184:1 200:20 201:12,12,13 202:10,14,17 203:11,11 212:10 212:12 221:20 226:6 368:8 395:18 398:9 485:17 486:1</p> <p>cannabinoid 45:17 52:15 71:10 78:12,13 79:9,22 93:14,18,20 119:7 124:3 143:8,12 165:16 190:21 206:13 209:5 212:2 219:19 221:15 222:10 243:13 329:3,10 329:14 330:18 332:11 335:1 363:21 372:7 410:1 417:21 428:12 474:6 481:4 488:15</p> <p>cannabinoids 78:11 79:2,8 84:5 136:3 143:20 144:2 150:16 152:7 173:19 177:16 182:7 189:21 190:7 191:8,18 195:13 210:15,15,18 211:1 214:5 216:16 221:19 226:16 244:12 279:7,9 308:2 311:10,15 324:4 327:4 329:17</p>
--	--	---	---

331:7 350:14	143:7,15,16 144:4	363:18 365:20	canopy 230:18
362:14 392:10,14	145:4,6,7,19	367:2,14,17,17,18	capabilities 228:5
392:14,17 393:18	146:1,6,9 151:5	371:17,17 378:17	capable 202:19
393:20 410:11	151:15 157:20	379:5,8,17,17	487:8
417:15 418:2,7	171:15 173:11	380:17 381:4,14	capacity 231:15
442:21 466:3	181:21 182:3,11	381:14 382:5,13	472:4
476:18 477:5,19	182:12 192:21	385:22 386:4,12	capital 43:17
479:20 484:3	193:2,5,10 194:1	386:19,22 387:6	capitalize 131:20
487:8	194:2,2,15 195:22	387:11,19,20,22	304:14
cannabis 1:9,9	198:6 201:12	388:2,7 389:9	capsule 114:7
7:17 10:10 11:17	203:12 211:20	390:3,13 391:1	270:12
11:19 12:7 20:5,5	212:11 214:10	392:2,9,10,12	capsules 299:2
26:17,18 27:9,9	215:15,15 216:13	393:2,3,5,6,12,15	capture 39:19
27:12,13 28:8,17	216:16 217:1,18	393:17 394:16	296:13 297:22
28:20,20 29:7,7	220:16,18 221:10	398:9 406:17,18	451:18
29:12,13 30:4,13	222:17,20 224:2,6	407:8,19 408:16	captured 294:22
31:5,9,18 33:15	224:9 227:20	409:9,15 411:6	carbon 465:3
33:18 34:1 35:6,6	235:10 240:16	412:11 417:21	card 57:4,5
36:4,4,10,10 40:4	253:6,10,14	418:6 419:19,21	147:16
40:7,13,14,17,18	254:16,17 255:11	420:3,7,7,8,13,15	cardiac 300:14,21
40:22 41:2,4,5,14	257:4,6 259:8,17	420:18,19 421:8	302:3,5 376:11
41:15,17,22 42:2	259:20,21 260:1	422:1,5,8,16	472:15,16
42:9,10,22 46:10	260:14 261:18,21	423:10 425:1,17	cardiomyopathy
46:10 47:2 51:4,7	261:22 262:12	427:6,8,10,14	472:12
51:19 52:1 55:4	263:7,11 264:6,7	429:20,20,21	cardiovascular
57:18 62:8 63:21	264:10,21 265:1,6	430:9,13,15,19	193:16
63:22 64:2,12,12	265:15 267:11	431:2,6 433:13	care 13:15 59:16
64:17 66:2 71:1	268:16 282:15,20	434:1 442:14,19	62:15 88:6,15
76:15 81:11,11,15	283:4,12 284:3,19	451:10,13,15,18	138:3 194:16
83:14 84:3 88:16	285:11 286:5,19	452:1,3,7,20	199:14 261:9
88:16 93:10,11,12	295:3 296:4	453:7,12,14,21	277:17 332:18,19
94:22 95:5,18,21	297:12 298:22	454:3,8 455:1	334:6 472:8 488:9
96:3,9,12 98:6,17	299:2,6,21,21	456:1 457:8,9	career 26:5
98:17 104:17	300:8,10,13 301:3	462:11,15 463:4,5	366:20
107:2,6,10 109:10	301:10,17 302:8,8	463:10,16 464:2	careers 472:1
109:10,14 121:4,6	302:11,11 317:7	464:12,13,14	careful 344:12
121:7 122:10,12	319:5,20 322:4	465:4,13,13,17	carefully 33:1,16
122:18 123:7,12	324:13,15,16,20	466:5 476:5,7,8	219:17 339:15
123:20 124:7	329:17,19 330:5,9	477:3 478:11,12	caregiver 130:5
132:16 133:9,9	330:13 332:19,21	478:21 479:17	caregivers 131:16
135:15 136:6,13	333:14 336:15	480:6,16 481:2	carneal 359:3
136:18 137:4,4	338:5,12,14	482:12,18 483:6,7	carolina 9:21
138:7,8,19 139:5	341:10,11,14	483:14 484:21	161:10,14,17,20
139:11,19 140:2	357:11,15 361:13	485:17 486:3	161:21 162:15,16

207:22 228:16,17 229:4 233:2,5,9 carrier 308:17 carries 438:4 carry 443:20 485:11 cars 246:21 cartridges 124:8 carve 163:13 carving 258:13,13 cas 447:21 casa 345:6 case 32:11 81:19 122:17 183:18 191:4 201:15 207:17 229:4 258:10 403:20 417:15 444:16 455:7 484:11 cases 62:21 193:16 205:3 206:10 208:12 221:13 417:16 478:2 cash 46:7 cass 392:22 cass's 393:1 casual 173:16 casualties 433:21 catastrophic 388:9 catch 183:1 381:15 categories 64:15 68:22 113:11 192:20 453:16 categorized 93:17 category 37:9 42:14 53:6 58:20 66:17,18 83:7 99:8 120:18,19 135:9 144:17 147:4 153:3 187:9 200:20 220:8 235:5 236:11	238:5 248:19 253:6 258:21 264:15 287:11 323:12 350:17 358:22 373:1,2 439:1 456:18 462:3 497:12 cats 64:18 83:14 84:18 86:15 cause 57:9 175:16 177:16 201:14,18 202:10,11,12,19 203:12 267:19 339:20 340:2 375:13 387:14 403:2 487:17 489:3 caused 67:20 174:4 242:21 245:1 449:18 causes 210:11 257:22 339:14 468:13,15 475:6 causing 380:11 473:19 494:15 caustic 59:19 caution 431:9 468:1 470:18 cautionary 437:11 cautious 380:4 cautiously 379:22 cb1 94:16 262:7 269:22 cb2 262:7 269:22 cb3 262:8 cbc 150:16 275:5 cbd 8:5 17:5 21:6 21:9 27:16 28:3 30:5 31:18 32:8 32:11,13,19 33:7 33:19,21 34:3,11 34:12,13,14,17,19 35:1,9 36:1,5 37:20 38:2,8,13	39:3 45:15 47:11 48:9,10,16 49:4,7 49:20 54:4,5,7,9 54:11,14 62:9,13 62:16,17,21 63:2 65:3 67:1,5,7,19 67:22 68:2,4,6,18 70:2 71:2,4,6,9,15 71:17 72:2 73:2,6 73:10,19 74:1,4 74:13 75:9 76:11 76:18 77:7,9,13 78:5,7,10,15 79:5 79:8,12,15,19 81:19 82:6,7,18 82:21 83:4,4 84:4 84:6 94:22 102:6 102:18 103:2,6 104:19,22 105:2,3 105:17,18 106:5,6 106:19 107:9,11 107:21 108:10,18 109:5,22 111:17 111:21,21 112:3,6 112:8,14,20 113:7 113:13,18 114:8 114:13 116:2,5,7 116:7,9,13,14,15 116:19,22 117:1,9 117:17 118:8 119:11,16,18 120:7,11,17,22 121:13,15 122:2,9 122:11,18,21 123:11,12,21 124:2,4,6,10,21 125:17,20 126:5,7 126:14,15,20,21 127:2,7,13 128:2 128:8 130:8,12 131:2,2,7,15 137:4 139:2,3 140:8 142:10 148:13 149:4	150:14,18 151:1 153:18 154:5,10 154:18 156:9,12 156:15,17,21,22 157:5,7,9,11,21 159:3,7,12,19,21 159:22 160:19 162:1 163:14,18 164:14 165:16 168:17 170:4,18 170:21 171:3,8 173:21 174:16,21 174:22 176:1,21 177:4,6,15 178:5 178:10,18 179:10 179:22 180:3,22 181:7 182:6 188:7 188:9,12 189:4,7 189:10,11,11,20 190:2,3,9,12,13 190:15 191:5,9,12 191:13,17,18,20 193:7,11,14,17,20 194:5,17,17 195:19 196:1,8 201:22 203:2,21 203:21 204:8 205:3 206:16,18 207:3,4,10,13,20 208:1,6,10,13,20 208:21 210:3,7,13 211:1,7 212:14,19 212:22 213:3,5,6 213:19 214:5,15 214:19 215:4 216:19 217:3,9 218:2 227:20,22 228:18 230:1 233:3,10,14,15 234:6 236:11 237:4,15 238:1,19 239:3,8,10 243:8 245:21 246:14 247:16,20 248:2,5
--	---	--	---

249:5 250:8,15 251:2,14,21 252:12 253:7 254:9,18,19 255:3 256:9 257:11,14 268:19,21 269:1 269:13,22 270:5 270:10,11,20,21 271:2,3,5,10,12 271:15 272:2,11 272:14,20,21 273:14,18,22 274:20 275:5,19 276:10 277:5 279:2 280:9,22 288:3,19 292:11 292:11,12,18 293:6,12 299:13 301:6,11,12,13,15 303:10 304:13 305:3,7,12 306:1 306:8,13,22 307:21 309:3,8 311:19,21 312:9 312:13 313:6,11 315:5,13,17,20,22 316:4 317:9,12,19 318:21 319:3 320:2,13,16 321:19 323:22 324:6,10 326:22 327:1,11,14,16 328:8 329:4,7,20 330:2 334:12,15 335:4,11 336:4,10 336:20 337:1 338:7 339:8,13,14 339:18 340:1,6,13 340:16,17 341:1 343:3,6,17 345:10 345:12,16 347:12 347:13 348:4,18 348:21 350:6,8,10 350:12 351:6,16	351:18 353:11,19 353:21 354:9 355:2,7 356:3,7 356:19 357:12 360:2 361:21 363:1 364:6,18 365:1 369:17 372:14,14 378:16 381:22 382:8,13 390:6,9 393:20 397:1,1 401:14,18 402:9,21 403:10 403:14 404:4,5,16 410:18 417:14,19 422:16 424:6 431:13 432:19,20 433:2,2 435:5 436:11,17 437:6 438:1,15 439:1,10 439:17,19,21 440:16 441:2,9,15 441:17 447:19,21 447:22 448:3,5,15 448:16,19,20 449:9,11,12,19 450:13,15,17,19 452:15,22 453:3 455:4,5,6,19,21 457:4 459:1,2,9 459:17,20 461:1,6 467:11,13,18 468:4,7 469:9,11 469:11,19 470:21 473:11,12,16,18 473:22 474:1,5,12 474:13 475:5,14 476:21 477:2,22 478:16,18 479:2 485:2 486:1 487:3 487:6,16 488:12 488:14,14 489:1 489:15,19 490:9 490:11,12,17,19 491:6,9,14 492:1	492:9,15,18,21 493:7,8,12,20,22 494:2,10 495:1 497:12 498:11,21 cbd's 34:6 39:15 49:6 123:1 126:11 131:20 491:11 cbds 103:10 cbg 150:16 210:18 275:5 487:16 cbn 150:16 210:18 235:2 487:16 cdc 312:16 cdle 422:17 cdphe 368:22 370:1,22 cdphe's 368:9,14 368:20 369:3 cease 60:14 ceiling 437:3 celebrate 457:16 cell 135:18 259:9 264:20 271:5 cellphones 24:2 cells 174:2 203:4 259:11 263:1 264:22 270:2 494:5 celsius 315:6 449:22 450:3 celtic 66:19 center 1:2 2:20 3:16 4:10,16 10:10,18 11:5 12:3 17:5 21:2,17 22:14 26:9 37:10 37:18 59:14 167:7 173:15 181:20,22 183:4 188:3 189:9 192:10 195:9 197:9 198:4 200:1 200:14,15 201:8 216:10,12,21 252:19 257:16	263:21,22 264:1 264:18 265:18 266:1 379:2 centered 463:2 centers 182:3 386:2 central 270:1 380:19 centuries 71:5 381:12 century 145:10 ceo 50:9 53:11 95:16 101:22 117:10 129:19 142:15 268:9 293:19 342:4 467:1 471:14 500:1 ceos 430:16 certain 23:2 28:7 30:6 31:14 109:7 121:15 228:13,13 346:20,21 470:13 certainly 26:3 80:2,9 84:19 183:15 197:20 203:8 204:2,22 216:4 217:14 231:14 305:12 313:21 396:3 454:21 certainty 82:14 417:8 certificate 57:3 370:15 502:1 503:1 certificates 132:19 237:6 238:12,15 479:5 certification 49:11 235:15 289:17 462:9,13 463:13 certifications 290:14 305:9
--	--	--	---

363:11 certified 288:19 303:12 317:5 342:14,17,19,22 342:22 343:1 490:10 493:6 certifiers 133:1 certify 305:4 502:3 503:2 certifying 478:14 cetera 279:4 308:3 385:19 409:15 cfr 159:13 162:20 348:11 cfstan 216:11 269:18 399:20 cgmp 214:9 310:21 313:11 330:16 363:10 478:10,18 cgmps 310:14,15 313:1 372:3 425:1 478:13 chain 48:3 89:2 156:15 237:6 267:1,7 322:22 333:6 370:13 371:21 408:14 487:5,6 489:14 500:2 chains 305:6 322:16 chair 21:5,8,13,18 145:2 419:20,21 420:22 422:6 challenge 63:11 97:2 131:4 309:12 316:9,13 388:17 481:18 challenged 62:7 472:7 challenges 130:6 133:13 155:3 182:8 295:12	316:5 371:5 411:22 466:5 challenging 396:18 chamber 474:10 chamberlain 298:18 chamberland 13:2 298:7 chance 127:18 207:15 395:22 402:7 458:3 461:19 473:4 change 25:9 49:1 118:15 178:21 234:1 251:8 271:4 338:13 341:19 374:16 429:18 431:6 changed 28:2,2,7 28:18 29:4 175:5 175:6 373:8 changes 25:11 39:13 54:11 201:20 271:12 427:2 468:17 484:12 changing 293:13 322:6 386:5 430:7 430:8 channels 82:12 362:6 364:18 436:16 440:20 chaos 265:13 406:2 chapman 8:17 137:13,14,15,20 137:22,22 140:6 140:10,14 141:4 141:13 characteristics 69:11 455:2 characterization 195:12 438:19	characterize 169:20 315:22 351:2 characterized 311:22 360:3,10 385:9 characters 129:11 129:12 charged 126:13 399:12 429:17 charging 382:18 charles 6:8 70:18 70:20 chart 149:2 239:6 385:3 479:22 charting 77:1 cheaper 96:16 check 95:20 104:13 209:2 444:3 checked 23:16 37:4 446:7 checkpoint 231:13 chemical 27:14 106:7 135:15 218:10 230:8 366:13 379:7 394:10 447:21 chemicals 60:2 131:12 335:22 chemist 378:20 448:8 chemistry 50:8 236:9 237:10 324:17 447:6 449:19 chemo 67:8 chest 260:6 chief 3:3,4 4:3,4 22:8,10,10 77:21 150:10,10 357:3 384:5 400:10 child 129:22 130:3 130:5 336:21	359:16 457:5,21 472:21 child's 130:6 childhood 216:20 children 34:17 62:22 121:15 128:2,5 129:22 130:15,21 132:2 139:15 156:19 164:19 174:9 242:1,6 244:15,21 269:2 324:22 330:5 360:18 380:4 399:21 400:20 401:6,6 449:5,8 459:8 472:5,5,8 473:9 473:10 479:16,21 children's 377:5 426:13 childs 7:4,5 91:6 91:13,17,21,21 92:8 china 46:9 109:3 chips 147:15,15 chiropractors 62:18 chocolates 257:8 392:11 choice 12:3 88:4 252:19 253:1 257:15 304:12,20 445:2 choices 386:1 choir 337:5 choke 231:6,20 cholesterol 280:17 281:7 choose 104:3 355:12 390:8 446:6 chooses 239:19 347:1
---	---	---	---

<p>choosing 141:2 chose 239:16 492:3 chosen 112:10 chromatography 189:18 chronic 39:9 213:19 261:8,11 261:12 299:6 318:6 375:7 468:15 482:14 chronically 34:18 chronicling 358:11 cigarette 341:6 cigarettes 40:9,11 123:18 204:9,19 205:1 ciliary 474:13 cincinnati 180:16 circular 227:2 circulatory 262:20 circumstance 133:16 346:8 circumstances 71:12 194:19 403:17 436:2 circumvent 356:2 cite 418:18 475:2 cited 84:22 citing 369:15 citizen 73:18 75:11 civil 105:19 claim 74:15 96:17 186:2 188:7,21,22 189:6,17 190:4,12 190:14 191:3,4 192:2 239:5,16,19 268:14 351:11 436:5 449:7 484:3 484:3</p>	<p>claimed 190:16 320:6 486:12 claimer 343:17 claiming 35:12 484:13 claims 35:16 37:21 64:19,22 65:9 76:22 80:2 85:2 106:9 108:6 121:13,14 160:3,4 164:20 186:22 189:10,16 190:8 190:10 191:1,12 191:14 225:7 229:7 239:13 256:17 268:14,19 268:22 272:19 273:9,11 337:10 369:20 376:22 381:22 409:14 491:19 clarification 292:7 clarify 108:2 114:21 197:2 215:12 410:17 clarity 65:13 82:13,14 148:2,11 148:17 149:19 154:16 155:7 254:19 class 28:10 152:1 429:4 classic 71:12 385:15 classical 203:2 classifications 414:9 classified 301:19 classify 139:20 classifying 138:13 clause 272:21 clauses 407:16 clean 235:9,11,13 235:18 244:14</p>	<p>270:5 488:11 490:10 cleaning 428:1 clear 44:20 53:21 74:6 75:18 83:21 88:21 90:3 97:10 97:22 100:16 101:15 108:7 117:18 125:15 129:6,7 139:5 160:2,3 163:12 243:20 254:5 256:6 265:9 268:20 269:19 271:18 272:1 303:16 304:20 321:13 323:10,15 323:18,21 328:12 338:9 343:17 379:19 382:2 408:3 418:22 424:10 436:22 439:5 457:12 461:12 476:21 491:4 clearance 491:20 clearing 129:12 clearly 25:5 48:12 64:11,18 83:20 84:6 85:9 159:8 173:12 191:18 201:4 203:19 214:4 225:13 261:21 369:19 383:3 388:18 395:14 417:4 428:17 452:14 click 489:11 clicker 240:14 487:10 489:8 clicking 340:21 client 419:12 423:1</p>	<p>clients 54:12 70:10 71:1 231:8 268:13 343:4,7 418:16 420:15,19 421:8 422:13 clinic 7:5 clinical 32:2 42:7 50:15 51:17 73:4 75:5 93:22 94:17 96:10 106:12 123:6 125:22 136:10,17 142:21 143:7,18 177:21 177:22 178:2,15 179:4 180:9,14 192:8 193:13 194:7 195:21 196:5 197:16,19 201:1,2 218:14 219:6,7,11 225:19 268:13 270:11 271:10 284:4 286:18 298:19,21 311:15 316:1 317:14,22,22 318:19 326:15 334:7 339:9 354:17 358:1 360:16,17 381:9 460:2 461:17 491:17 clinically 318:9 clinicaltrials.gov 128:18 clinician 472:3 clinicians 472:13 clinics 209:9 clobazam 143:10 178:16,18,20 180:7,7,10 359:21 360:1,2 405:22 clogging 205:7 close 43:10 174:4 250:11 315:4</p>
--	--	---	---

<p>383:5 430:14 495:19 closed 362:16 closely 87:12 94:18 130:18 145:21 195:8 322:13 475:14 closer 94:7,8 137:21 298:14 356:21 closing 19:9 123:17 152:9 153:6 306:22 315:8 325:22 341:7 399:4 500:19 clothing 375:10 cloud 205:11 cmax 299:11,15 299:16,17,19 301:1 cmcr 183:4,16 coa 345:22 coal 52:8 coalition 4:22 5:3 42:18 45:6,9 53:16 107:11,14 376:2 476:8 coated 487:3 490:11,12 492:21 coates 14:20 390:18,19,20 394:21 coating 490:9 494:10 cocaine 271:8 code 159:17 397:12 codes 479:2 codified 313:1 codify 121:20 coexist 320:14 323:4 326:11</p>	<p>coexists 263:1 coffee 50:12 coffeemakers 247:11 cofounder 53:12 96:1 cognition 301:21 385:18 cognitive 67:12 86:6 211:13 212:18 213:2 cold 289:20 450:2 cole 121:5,11 coli 372:11 489:22 492:16,16 coliform 372:11 collaborate 73:21 198:8 322:13 collaborated 195:9 collaborating 157:14 160:20 collaboration 197:21 264:17 364:4 425:20 collaborative 426:21 collaborators 451:11 colleague 211:6 475:3 colleagues 180:15 192:14 218:21 361:9 collect 90:11 collected 68:12 266:17 269:8 410:5 453:6,9 collecting 75:11 90:6 158:2 197:16 412:10 collection 74:15 157:19 410:4</p>	<p>collects 197:7 college 11:8 57:14 188:1 220:10 334:16 483:8 colonel 67:2 colonic 389:3 colorado 50:9 67:2 121:3 137:16 138:1 141:16 142:4 146:2 242:11 347:16 357:10,14,14 361:21 365:3 366:5,8 367:2,19 367:20 368:5 370:18,18 371:13 373:6 375:1,14,16 375:20,22 376:5 376:19 377:2,3,8 377:21 386:8 415:18 459:2 480:1 496:3,3 498:4,4,5 499:5 colorado's 499:2 colored 25:7 385:5 columbia 13:15 332:18,18 334:6 408:19 column 190:1,2,3 190:4,6 249:21 250:1 combative 243:11 combatting 269:5 combination 194:17 458:4 combine 350:16 combined 224:9 433:21 come 31:10 35:4 64:5 127:8 131:3 149:15 167:15 171:2 210:16 213:13 214:3 222:20 232:8</p>	<p>233:22 241:5 242:14 243:11,12 244:4 245:22 274:22 291:10 296:12 297:18 325:1 375:12 395:13 400:13 421:9 435:14 470:7 485:6 498:2 499:1,7 comes 43:10 50:21 131:6 148:6,8,9 148:22 174:4 232:2,9 253:19 255:22 266:7 304:13 391:5 396:21 424:15 437:19 441:11,11 471:16 481:19 490:16 491:3 comet 271:3 comfort 236:1 238:17 439:9 coming 30:22 71:17 235:13 236:16 238:10,15 256:4 276:14 278:18,18 289:7 307:1 343:4 384:8 420:17 421:20 423:22 447:8 command 239:9 commend 140:2 352:4 383:4 comment 20:13 36:22 37:1 65:21 83:13 85:13 89:5 115:5 120:5 152:16 153:7 164:1,5 173:1 193:4 197:12 226:3,5 313:4,14 433:12 440:15 447:9 448:12</p>
--	---	---	--

500:21 commentary 413:19 416:16 commented 415:16 comments 4:13 18:8,18 25:16 27:5,7 36:6,14 37:15 58:19 66:9 68:9 69:5 79:17 80:10 81:1,10 83:16 89:14 91:14 98:15 107:13 111:13 114:21 115:3,13 116:2 117:6,10 118:18 118:19 122:6 123:17 124:12 144:7,11 147:8 153:6 155:19 158:3,3,17 161:12 163:21 169:5 192:13,14 204:10 215:22 252:1 274:8 309:18 325:7 326:6 328:1 337:19 357:7 372:17 412:18 425:13 429:6 446:22 462:21 501:2 commerce 27:20 31:22 53:12 71:18 82:11 133:3 159:8 407:14,15,16 411:8 423:20 424:18 491:10 commercial 76:18 107:9 137:3 153:17 293:8 314:18 315:1 435:10,17 436:13 commercially 42:5 188:7 316:8	329:20 330:18 commissioner 2:3 3:11,19 4:7 20:11 21:5,8,21 22:5 25:22 36:15 46:22 61:19 97:9 117:7 161:9 433:7 commissioner's 21:13 commitment 47:13 136:22 329:2 348:10 428:18 committed 47:21 73:1 100:5 245:2 347:19 366:11 484:19 committee 67:21 123:10 313:21 406:16 407:1 408:7 419:20 420:3,4 422:4,5,9 427:7,8 428:21 committee's 123:13 committing 368:21 commodity 46:8 82:5 269:10 322:8 322:10 369:6 471:2 common 70:9 88:11 126:17 139:7 215:9 238:7 277:11 300:2,6,10 312:6 330:5 339:20 349:3 371:15 486:16 commonly 45:15 143:9 261:7 306:15 447:22 commonsense 129:13	commonwealth 10:21 204:14 communicate 130:3 communication 44:21 communities 52:12 community 16:15 38:8 66:12 82:16 100:11 122:12 131:9 142:20 144:9 228:4,10 231:3 375:1 384:9 384:21 385:20 387:16 388:16 389:6,15 401:15 401:20 403:6 440:9 467:1 companies 35:5,8 47:8 64:16 84:21 85:2 87:19 89:22 95:21 96:2 108:10 112:7 116:1 119:7 148:12 149:11 153:14 154:15 193:2 194:16,19 195:5,6 196:17 197:10 198:19 199:5 200:5 206:3 255:5 256:15 265:2 267:18 273:8 279:2 289:19 291:9 305:3 322:3 323:15,19 324:10 326:1,18 339:1 342:9 346:20 353:18 354:6,13 355:9,12,17 356:10 366:7 395:11 405:12 411:11 416:18 423:17 441:3,12	441:16,18 476:10 498:6 company 12:19 50:10 73:1 95:20 147:9 199:15 227:16 230:11 255:17 264:5 287:18,22 293:21 303:6 317:7 319:4 328:14 332:19 347:12 348:3 355:1 361:21 436:4 440:1 441:21 448:16 460:2,12 487:2 company's 354:20 comparable 183:14 211:22 comparative 306:20 compare 131:17 189:10 197:12 299:15 compared 41:2 51:5 83:1 102:11 103:12 206:9 211:21 286:20 315:17 453:3 454:17 455:11 467:20 comparing 455:3 comparison 186:11 comparisons 434:9 compel 413:19 compelling 127:20 compendia 99:1 competence 133:20 134:2,20 443:3,9,12,19,20 444:3,7,18 445:5 445:6
---	--	---	---

competent 133:6 444:9 446:8	445:4,21 462:14 462:16 463:14 477:10 479:10	compounds 1:9 20:6 26:18 27:10 27:14,15,17 29:8 30:4 31:18 32:2 35:7 36:10 63:22 81:11 83:22 84:1 84:20 93:12 94:15 98:18 106:4 109:10 133:9 138:14,15 139:6 139:11,14,19,21 141:18 151:8 165:17 168:20 193:21 222:8 225:9 229:19 230:1,4 234:6,7 234:17,21,21 306:13 308:2 350:13,21 361:14 365:20 371:18 417:21 418:6 450:2 485:17	concentrating 152:17 concentration 152:18 181:7 212:3,12 229:15 229:21 301:7 338:10 340:19 361:1 402:22 453:1 489:21 concentrations 271:19 401:18 concern 35:10 59:22 67:18 99:14 168:4 175:17 202:2,8,15 205:7 209:12 235:21 270:18 336:11 346:10 391:21 465:12 concerned 60:7 246:8 251:21 278:21 290:1 334:17 353:9 359:19 387:21 389:6 447:11 449:1 467:12 475:12 concerning 425:14 concerns 65:7 66:4 102:17 103:2 109:11,13 117:8 126:22 138:6 139:2,13,16 142:11 193:6 223:5 251:19 269:21 340:9 367:16 386:15 391:5 462:21 463:4 464:13 465:11 468:6 concertation 212:13
competition 253:16 497:10	compliant 228:6 231:9 232:3 325:19 330:16 333:12 342:18,18 342:21,21,22 343:2 344:3 369:9	comprehensive 26:8 49:18 85:10 120:4 166:21 196:13 265:5,8 267:17 329:5 338:3 339:13 434:14 478:22 comprised 48:1 compromise 411:10 compromised 143:19 398:20 computers 250:12 concentrate 114:12 229:12,13 229:16 240:7 294:8 308:13 392:10 concentrated 248:13 367:15 concentrates 84:6 371:3	
competitive 47:15 82:20 445:2	complicate 452:4 complicated 149:1 176:21,22 177:4 179:16 405:15 409:4 423:15 458:18		
competitors 96:16	complications 67:8 complies 344:9 345:19 478:3		
compilations 434:9	comply 31:15 94:6 412:5 415:12 437:22 438:11 440:18 480:6		
complaint 241:2 480:10	component 269:17 307:22 348:9		
complaints 124:22 277:15 278:1,6,6	components 135:15 194:3 196:8 205:10 262:6 263:5 266:21 306:8,9 323:16 348:14 427:13		
complete 25:18 83:16 139:21 145:5 168:11 169:2 302:22 319:18 326:15 363:8 370:9 440:2	composite 260:18 composition 99:12 163:10 222:2 324:14 438:18		
completed 31:12 168:12 183:5 282:19 285:10 323:13 492:17	compound 71:2 119:15 127:11 230:7 232:21 245:21 270:6 389:3		
completely 396:5 396:21	compounded 388:22		
completes 168:16			
completing 94:7			
complex 105:4 139:14 140:3 142:17 221:11 472:6			
complexities 34:8 477:9			
compliance 3:15 22:13 95:21 112:22 113:10 123:8 154:19 165:2 228:4,7,18 228:20 229:3 231:7,8,13 235:15 238:18 348:10,13 348:16 363:11,16 364:5 365:7 428:12 443:6			

<p>conciierge 274:17 concise 97:22 conclude 33:4 175:21 272:18 concluded 25:12 32:7,10 320:1 501:6 concludes 102:6 500:20 501:4 conclusion 155:9 493:10 conclusions 104:2 136:2 360:15 concrete 426:12 concurrent 452:1 452:3 concussion 277:6 concussions 276:3 condition 87:8 149:4 401:9 459:16 conditional 196:16 218:5 conditioning 113:9 488:22 conditions 94:10 96:13 138:21 183:22 221:2 260:16,19,20 261:4 262:4 263:5 280:20 319:8 332:1 355:22 400:2,2 415:5 conduct 41:22 49:10 134:10 219:13 372:5,5 418:15 conducted 87:10 94:2 135:17 159:10 169:17 189:8 211:6,18 298:19 339:9 418:13 490:17</p>	<p>conducting 40:8 41:17 192:20 195:2 198:8 268:12 381:17 440:14 493:21 conference 331:10 confidence 43:22 49:14 304:21 349:21 417:7 431:16,17 443:18 446:5 479:12 confident 132:2 148:4 251:13 317:9 407:3 confidential 303:1 confidentially 324:11 confines 408:9 confirm 126:4 345:14,22 445:21 479:9 confirmation 196:18 confirmed 57:12 183:9 confiscating 205:5 conflict 358:16 conflicting 371:7 conflicts 247:2 432:9 445:15 conform 133:4 conformance 444:15 conformity 442:18 443:6,14 443:17 444:3,11 444:16,17 445:19 490:2 497:4 confound 285:20 confounding 123:18 confronted 156:8 confused 35:20 150:1 205:4</p>	<p>confusing 130:8 210:6 398:1 confusion 48:17 82:6 88:20 108:4 112:7 129:6 153:22 329:14 395:14 410:17 432:19 436:22 congo 1:21 502:2 502:15 congress 29:9 48:7 48:12 111:15 151:17 155:12 284:5 297:3 435:21 congressional 112:13 congruent 146:4 conjunction 230:17 conmen 290:4 connecticut 95:20 connection 43:2 connotation 270:7 consecutive 301:13 consensus 109:21 279:6 292:18 391:16 392:2 425:14,21 426:19 427:22 428:19 429:2 consequence 62:1 355:10 consequences 139:11 176:18 449:18 consequential 182:20 conservatively 259:22 consider 24:10 27:7 65:8 98:6 110:13 169:13</p>	<p>184:15 212:19 214:8 271:21 306:17 331:16 383:12 388:14 433:7 436:22 442:17 443:4 446:20 480:22 considerable 70:3 consideration 25:20 118:19 212:5 259:18 281:2 320:18 332:4 408:22 436:21 447:1 considerations 118:2 184:13 331:20 339:6 considered 45:22 84:1 115:8 118:2 151:9,14 160:18 185:12 194:4 196:10 217:5 270:10 272:9 300:5 343:20 369:22 395:18 408:1 423:4 437:14 454:19 458:2,18 considering 42:8 47:1 160:1 249:7 279:7 320:16 417:19 422:15 436:19 456:3 459:6 considers 44:9 48:9 83:3 435:5 consistency 138:14 159:4 168:2 303:9 350:20 371:16 372:4 404:18,19 408:11 464:10 consistent 64:7 84:9 86:4 88:21</p>
---	--	--	---

94:12 136:17 163:5 165:22 221:4 265:10 267:2 349:20 350:5,22 381:10 393:12 407:9 464:3,11 477:5 489:16 consistently 65:17 179:2 362:1 381:10 consroe 359:7 constantly 281:7 448:15 483:20 constituent 99:11 105:18 106:19,21 211:2 constituents 71:4 84:4 100:1 165:18 221:12 225:4 324:4 327:4 409:1 constitution 481:19 constraints 325:8 construct 101:12 construction 428:16 constructive 291:18 consultative 467:8 consulting 6:11 9:4 61:12 72:12 144:21 379:6 447:6 consumables 393:19 consume 34:11 139:17 145:14 184:10 257:6 303:12 consumed 109:17 342:12 465:16 468:13	consumer 6:13 9:18,22 11:21 12:3 33:11 44:19 53:6 56:18 62:2 75:6,22 76:3,17 77:3 87:18 88:4 89:1,16 90:16 107:21 116:12,17 120:17 124:22 131:19 149:17 153:15 154:8,12 161:10,11 163:6 173:2 194:7 207:13 208:12 227:5 235:16,19 235:20 236:5 237:3,5,9 238:4 245:16,19 246:3 246:19 247:1,3,6 247:7,13 252:19 252:19,22 253:5 254:13 256:20 257:15 278:12 304:7,20 312:18 314:20 315:13 321:18 338:7,11 344:16,17 346:2 347:4 349:2,12,21 352:20 361:2 362:17 363:5 364:11 365:16 396:2 409:14 425:22 437:15 466:2 468:4 470:21 479:11 480:7,10 481:5 487:14 490:22 consumer.org. 252:4 consumers 5:9 11:15 18:11,22 30:16,17 33:17 35:11,18 42:9 46:16 48:13,17	49:14 50:19 53:8 54:15 76:9 88:12 88:14,20 90:18,22 97:4,12,15,21 99:16 102:4 109:8 110:8 116:18,20 133:3 146:20 147:20 148:20 163:7,16 174:22 191:20 195:7 208:5,10 235:5,7 237:4 238:17 242:7 246:13,18 248:1,4 254:1,8 254:21 255:6,13 256:11,16 257:12 267:14,20 291:5 303:10,20 304:2 305:21 306:11,20 307:3 322:2 325:10 326:2 342:12 349:21 352:7 362:9 363:3 364:13,21 365:9 365:19 383:2 410:22 415:2,13 417:8 425:19 438:7 446:4,5 452:21 455:13 456:2 477:9 490:14 consumes 34:13 34:14 consuming 60:14 123:5 131:17 132:1 173:10 182:11 279:20 466:4 consumption 146:14 174:7 278:5 306:3 369:7 416:6 465:16 contact 23:15 132:14 287:8	contacted 101:10 contain 29:12 30:4 30:5,7 47:11 73:15 78:10 112:14 116:22 193:20 206:4 222:12 329:21 350:13 459:15 469:11,12 contained 120:5 190:12 191:13,15 191:17 207:11 209:4 211:8 container 120:13 188:16 189:17 containing 1:9 20:5 26:17 27:9 27:12 29:7 33:21 35:6 73:6 77:7 78:5 79:8,12 81:11,15 83:14 84:3 88:15 98:17 111:17 112:2,8 113:7,14 133:8 138:19 143:16 153:15 154:18 189:4,7,11 190:7 190:18 193:7,11 195:22 203:21 212:11 272:19 324:3 329:4,14 351:17 355:7 362:14 371:17 437:6 438:2,15 461:1 465:18 468:4 470:21 476:18 477:5,18 contains 27:13 105:17 106:3 207:15 318:22 320:11 438:3 469:5,6 contaminant 133:11 363:19
---	--	--	--

<p>contaminants 99:14 100:1,3 109:16 146:11 213:16 315:19 330:5,11 335:19 362:2 364:1 394:10,10 417:1 449:15,16 480:5</p> <p>contaminated 99:17</p> <p>contamination 102:20 237:18 242:8 302:9 330:8 330:12 352:3 490:13</p> <p>contemplating 165:10</p> <p>content 28:21 99:22 138:12,18 188:6,7,16,22 189:5,10,20 190:5 190:9,15,17 191:12 214:7 228:15 229:10 238:19 273:10 306:5 309:9 335:1 351:16 442:21 479:7</p> <p>contents 188:20 364:13</p> <p>context 89:19 117:22 201:17 407:18 408:2</p> <p>continue 30:11 48:16 65:18 134:14 146:15 153:16 157:8 167:13 185:2 203:8 330:15 331:5 335:15 355:14 362:20 382:11 408:19 418:18</p>	<p>continued 36:9 401:8,11 458:8</p> <p>continues 125:17 223:14 413:21 460:9</p> <p>continuing 100:12 187:8 282:5 365:17</p> <p>continuously 490:4</p> <p>contract 268:10 349:14,16 351:20</p> <p>contractor 216:14 218:18</p> <p>contradictory 135:20 356:9</p> <p>contraindications 124:1</p> <p>contrary 67:7 431:1</p> <p>contrast 197:12</p> <p>contravention 146:8</p> <p>contributes 426:18</p> <p>contributing 198:1</p> <p>contributions 36:17 446:13</p> <p>control 55:14 81:14 117:3 143:19 146:19 166:12 197:9 213:16 214:8 236:15 294:16 296:17,20 314:2 314:14 319:19 331:16 333:2 342:17 345:11 346:16 350:19 351:1 362:12 363:13 365:7 366:12 367:17 370:5,9 379:1</p>	<p>382:17 383:14 385:21 401:5 402:7 428:3 431:8 446:12</p> <p>controlled 28:9,9 29:3 34:4 73:4 81:22 82:3 93:21 136:10 210:18 211:19 219:8 222:1 241:16 296:2 299:4 322:9 322:11 332:1 351:4 401:17 459:17 477:3</p> <p>controlling 314:11</p> <p>controls 60:22 296:22 316:12 330:22 331:14 332:8 349:10 363:12</p> <p>controversial 411:1</p> <p>controversy 150:16</p> <p>convene 392:1</p> <p>convenience 38:21 156:11 453:11</p> <p>conventional 111:22 188:14 260:5 263:6 272:15 323:5,13 328:4,6 415:5</p> <p>conventions 414:20</p> <p>conversation 24:5 74:10 175:5,7 291:8 365:6,12</p> <p>conversations 131:3 460:15</p> <p>conversion 213:6</p> <p>convey 153:12</p> <p>convinced 208:21</p> <p>convincing 208:17 220:21</p>	<p>convo 291:2</p> <p>convulsions 402:12</p> <p>coo 342:5</p> <p>cookies 96:20</p> <p>cooperation 134:18</p> <p>coordinated 219:3</p> <p>coordinating 124:20</p> <p>cope 71:10</p> <p>copies 20:17 23:6 225:20 242:18,22</p> <p>copy 23:9</p> <p>corbus 7:7 92:19</p> <p>cord 202:20</p> <p>core 122:19 407:10 478:20</p> <p>corey 58:21</p> <p>corn 44:2 147:12</p> <p>corner 288:21</p> <p>corporate 38:21 127:16 298:17 485:10,11</p> <p>correct 55:10 114:4 134:4 183:2 197:4 279:22 308:8 391:18</p> <p>corrective 478:16</p> <p>correctly 335:5</p> <p>correlate 267:10</p> <p>correlates 212:3</p> <p>correspond 325:5</p> <p>corresponded 359:15</p> <p>corresponding 322:14</p> <p>cosmetic 27:18 73:7,11,20 105:5 114:10,15 117:21 185:19 241:17 289:21 419:22 421:1 436:17</p>
--	--	---	--

cosmetics 31:21 33:12 52:19 143:13 156:9 159:7,21 227:19 352:12 414:21 416:7 447:7 450:8 450:9,15	377:7,9 500:1 country's 458:13 couple 182:4 199:21 209:20 252:10 288:1,12 307:8,12 452:12	113:13 116:4 130:11 138:17 150:22 152:10 205:11 206:6 228:6 332:13 362:20 364:19 378:16 404:19 414:4 421:22 422:4 431:22 446:4 470:10 482:7	cristinzio 2:10 18:5 20:3,7 22:15 36:21 39:22 42:13 45:5 47:16 50:4 52:20 53:5 56:14 58:19 61:9 63:15 66:16 70:13,16 72:10 75:21 77:18 81:4 83:6 87:13 91:5,10,16,18 92:12,15 95:13 98:8 101:18 104:10 107:1 110:4,6 111:3 115:16 118:21 122:5 125:6 129:15 132:8 135:7 137:12,18 137:21 142:12 144:16 147:3 149:21 150:2,5 153:2 155:14 158:20 161:5 166:4 172:11,19 176:2 181:12,15 187:6,8,13 192:5 200:8 204:4 209:17 210:20 216:5 220:7 226:1 227:7,9 235:4 240:10,13 245:12 252:14 258:20 263:16 268:3,5 274:9 281:13,15 281:21 282:2 287:10,15 293:15 298:4,6,13 303:2 310:18 316:19,22 321:8 328:16 332:15 337:21 341:19 347:5,7 353:3 356:14,21 357:2 361:6 365:22 372:16,21
cost 140:20 254:15 433:20	course 62:3 77:1 110:7 112:22 184:16 186:14 202:2,15 212:1 278:8 284:16 379:12 405:19 409:5,16 417:20 418:9 449:17 485:16	created 51:16 105:4 130:12 230:12 243:4 383:6 427:15 433:19,20 434:1 463:13 467:3 477:14 500:8	
costing 54:16 290:17	couriers 82:10		
costs 446:1,12	court 57:19 244:17	creates 136:15 440:6	
cottonization 487:22	courts 98:4	creating 43:18 152:7 159:5 163:14 230:16 309:13 357:12 365:18 371:18 442:1	
cottonized 487:20 488:4 489:15	cousin 149:16	creation 122:2	
cough 207:12	coverage 22:22	credibility 443:13	
coumadin 277:21	covered 140:20 224:15 312:10,22 349:5	credible 54:7 200:17 336:16	
council 6:21 7:21 15:17 83:12 115:17,20 195:14 216:18 432:2,9 434:22	covering 245:17 389:13	credit 147:15	
counsel 2:19 3:3,4 4:3,4 22:8,10,11 115:20 240:16 430:3 496:2 502:8 502:11 503:7,10	coveted 373:1	creep 38:9	
count 39:14 153:18 372:11 469:8	cow 430:4,5	creeps 474:4	
counter 51:5 96:21 207:12 245:17 320:12 500:9	cpg 87:20 231:4 343:15	crime 205:1,6	
countless 381:13	crack 374:5	criminal 204:20 205:2 241:16 244:15 376:20 377:9 439:5	
countries 94:2 166:15 311:6 427:13	crafting 42:19 83:3	criminals 241:14 241:18	
country 48:2 54:19 71:7 90:10 153:11 160:18 241:22 253:13 267:15 369:6,10	craig 17:2 495:19 496:2	crisis 51:17 260:10 374:7 447:8,10 449:1 484:17 485:12	
	cramp 491:15		
	craves 440:8		
	craving 223:11		
	craze 62:16		
	crazy 374:3 459:4		
	cream 276:10,13		
	creams 154:5		
	create 32:16 45:2 46:20 52:3 60:21		

<p>378:2,5,8,10,12 383:18 384:1,16 390:17 394:19,22 400:5 406:13 412:13,17,20 413:2,5 419:4,6 425:7 429:8 434:2 434:5,19 442:10 446:15,21 450:22 451:5 455:15 456:17 462:2 466:19 471:7 475:15,20 476:1 481:6,13 486:7,17 486:19 492:7 495:11,14,18 500:13,20 criteria 99:6 133:22 346:21 368:4 critical 30:11 33:9 49:3 88:18 108:12 163:6 173:20 259:12 266:16 269:17 297:11 332:8 351:3 394:17 428:2 450:11 critically 142:20 155:4 262:2 378:15 criticism 51:1 crn 115:21 116:1 117:5,7,9,10,18 117:20 118:17 435:1 440:13 cro 273:17 cromer 5:10 53:6 53:9,10 55:5,7,10 55:16,20,22 56:4 56:13 crop 46:7 147:12 161:22 164:11 229:7 302:14</p>	<p>crops 44:1 46:5 50:11 66:19 82:22 229:6 289:13 cross 296:5,7,11 330:12 crossed 171:8 398:3,22 crossing 411:16 crossroads 125:14 crucial 97:10 408:15 crystal 9:7 147:5,7 crystalline 315:5 327:11 crystallization 229:22 232:15 crystallized 234:11 csa 28:10,13,22 119:18 121:6 210:9 cto 347:10 cultivar 325:11 cultivars 115:1 185:8 322:19 411:20 cultivated 368:1 cultivation 59:14 330:13 367:22 370:10 393:14 427:17 463:11 464:15 cultivator 427:6 culture 135:18 cumulative 89:17 cure 35:13 62:4 105:9 130:10 cures 260:4 curiosity 249:11 320:20 curious 69:17,19 128:13 440:22 current 32:12 38:17 49:8 52:4</p>	<p>90:17 95:16 108:16,19,20 116:6,14 118:7 120:17 138:7,10 140:16 154:17 161:22 216:19 287:1 320:15 323:3 327:6 329:13 353:9,12 353:16 354:5,8 362:13 363:1,7 368:11,16 371:8 383:8 384:15 385:14,17 387:1 412:4 420:8 432:10 454:2 463:3 471:15 477:13 currently 28:16 41:20 43:3 44:1,7 45:22 46:9 53:20 64:9 66:12 84:15 97:4 103:19 108:9 112:9 120:11 136:17 138:20 156:16 159:2 168:20 170:1 183:16 188:12 195:4 196:4 210:8 229:7 230:15 273:19 284:21 286:13 294:3 297:1 318:18 364:1 393:16 394:4 396:8 397:9 402:15 408:18 417:11 419:16 435:5 451:14,17 485:19 491:13 493:2,5,21 494:7 curve 182:21 185:1 199:5 curves 184:3</p>	<p>custody 237:6 333:6 custom 366:8 customer 120:12 customers 54:12 74:18 153:14 154:14 266:9 347:13 363:2 444:6 customized 348:6 cutting 92:3 cv 13:11 321:12 321:17 323:9 324:8 325:6 cvm 85:12 87:9,11 167:17 168:10,15 cvm's 168:4 cycle 319:14 444:8 cyp2b10 202:2 cyp2b6 202:3 cyp2e1 202:5 cystic 93:5 cytochrome 177:2 178:19 179:11 180:8 202:5 271:17 359:20 cytotoxicity 264:22</p>
d			
<p>d 20:1 490:10 d37 427:7,12 428:21 dabs 374:3,4,5 dad 457:10 daily 270:17 298:22 301:13 340:19 342:12 397:1 dale 495:21 damage 174:1,1,4 174:14 241:21 242:6 243:19 359:22</p>			

damaging 244:10 244:15	318:9 319:21 320:8,20 324:12	176:12 245:10 267:19 270:16	291:11 351:6 387:18 420:18
damn 187:17	327:18 352:18	272:7 277:3,7,8	431:15
dana 17:4 481:14	359:10 360:12,20	278:7 301:3,5,15	deals 421:18 447:6
dangerous 33:6 59:11 60:20 109:16 206:13 207:16 209:5 242:17 336:10 376:18	360:21 399:5 408:14 410:4,5 439:15 440:3,12 451:9 453:6,9 455:22 456:11 466:12 470:16 475:22 476:14,19	334:19 340:14 345:1 359:8,14,15 359:16 377:12 379:13 383:16 397:2 453:7,12,14 458:1,7,7 471:10 496:9,10	dearth 292:22 358:4
dangers 56:20 191:21 243:6	480:5,20,21	daye 16:21 17:7 487:1	death 57:3,9 375:13 376:11 401:9 404:7 472:16
daniel 15:2 395:1	491:11,17 493:17	daye 2:10 18:5 20:7 26:14	deaths 207:8 244:22 484:18
daresay 54:22	493:18,19	days 23:8 209:1,3 212:7 273:6 301:14,19,22 373:22 402:12 453:21 454:12,16 454:17,17	deb 13:8 316:20
dark 127:18 148:21 450:5	database 79:5 84:11 86:19 267:6 339:13	dc 115:21 253:2	debatale 243:20
dartmouth 274:16	datavive 61:10	de 98:6 259:20 263:12	debate 39:16 71:3 117:11 364:16 484:16
data 1:8 20:4 26:16 35:2 39:11 45:19 47:1,6 50:15 51:17 52:22 63:13 65:9 66:5 68:9,12 76:14 80:11 84:13,20 85:19,22 86:11 90:6,11 103:16,19 104:6 110:19 128:1 134:12 136:18 152:17,22 165:7 179:20 180:20 185:17,21 186:18 187:1 189:22 194:22 195:21 196:3,13 196:13 197:3,13 198:1,18 201:1 203:6 211:14 213:21 216:1 218:4 219:2 220:13 222:18 236:2 261:17 294:22,22 296:14 301:10 302:22 317:14,17,22	datasets 186:21	dea 95:6 98:5 185:8 225:16 226:15,20 283:20 284:2,4,6,11 286:10 296:12 297:11 311:1 316:11,16 333:10 414:17 418:18 477:1	debilitating 457:21
	date 1:14 37:20 66:9 68:2 101:1,4 112:20 135:19 136:12 298:18 414:15 427:21 450:19	dead 244:21	deborah 317:4
	dates 133:14	deadline 204:11	decade 51:15 193:10 476:13
	daughter 128:7,10 457:4,14	deadly 374:16 401:12	decades 127:18 145:7 381:12 416:20 432:1
	daunting 119:19	deal 48:17 89:17 227:19 242:20 289:15 343:9 418:11	deceitful 175:21
	dave 119:1	dealers 377:11	deceive 173:11
	david 6:12 8:2 9:9 11:18 16:4 70:17 70:17 75:22 76:2 91:21 92:8,11 118:22 150:6,9 240:11 447:1,4	dealing 242:13 244:12 290:3	deceives 173:9
	decisions 122:19 456:8		deceiving 384:7
			december 31:11 92:8 316:18 453:9
			decent 454:18
			deception 382:14
			deceptive 373:12
			decide 55:12 344:2 391:18 482:4
			decided 343:16 392:22
			decision 122:19 456:8
			decisions 102:2 126:15 289:13,14 380:16 461:10

<p>decisively 440:13</p> <p>deck 4:13 10:5 18:8,18,20 37:15 155:19 176:12,14</p> <p>declaration 443:15</p> <p>decrease 261:10 261:20</p> <p>decreases 223:11 260:9</p> <p>decriminalize 429:20</p> <p>decriminalized 28:5</p> <p>dedicated 53:13 95:18</p> <p>dedication 378:22</p> <p>deemed 54:7 151:21 396:17</p> <p>deep 50:16 205:6 385:4</p> <p>deeper 246:15 364:20 387:9</p> <p>defects 242:2</p> <p>defense 342:18</p> <p>deficiency 243:13</p> <p>deficient 78:12</p> <p>deficits 223:3</p> <p>define 84:6 100:8 285:17</p> <p>defined 83:20 85:9 119:13 144:5 211:3 219:7 303:18 307:15 330:20 365:2</p> <p>defining 327:2,13</p> <p>definite 261:12</p> <p>definitely 66:4 115:12 141:17 278:11 475:5</p> <p>definition 29:1 32:4 71:12 77:10 102:5 167:3,15 279:5 305:16</p>	<p>definitional 436:20 440:14</p> <p>definitions 75:5 83:22 148:19 166:20 169:9,11 295:18 307:20 371:20 424:6</p> <p>definitive 413:15 418:22 448:1</p> <p>degradants 350:14</p> <p>degradation 450:9</p> <p>degrade 262:11</p> <p>degree 274:14 276:17 357:20 360:11 361:1 451:15 453:19</p> <p>degrees 57:16 76:21 315:5 449:22,22 450:3,3</p> <p>delaware 311:2</p> <p>delay 284:7</p> <p>delayed 41:8 93:22 186:16 388:22 389:2</p> <p>delays 94:5 267:20 458:9</p> <p>delete 229:19 230:8</p> <p>deleterious 431:4</p> <p>deliberately 114:12</p> <p>deliberations 320:9</p> <p>delighted 247:19 487:2</p> <p>delineating 83:22</p> <p>deliver 265:3 341:5 366:13 388:19</p> <p>delivered 389:5</p> <p>delivering 87:21</p> <p>delivers 75:2 321:18</p>	<p>delivery 40:12 313:8 437:10</p> <p>delta 291:20 292:2 292:8</p> <p>delusional 374:17</p> <p>delusions 390:14</p> <p>demand 54:22 97:19 107:22 116:13 146:21 153:15 154:5 191:22 209:7 243:2,5 436:10 440:17 482:4 485:9</p> <p>demanding 291:5 439:12</p> <p>demands 471:5 483:5</p> <p>dementia 135:17 136:8,14,19</p> <p>demise 377:5</p> <p>democracies 265:20</p> <p>demographic 455:2</p> <p>demonizing 54:20</p> <p>demonstrable 73:3</p> <p>demonstrate 134:13 305:8 315:4 317:17 329:19 351:18 355:21 428:18 461:18 478:15</p> <p>demonstrated 102:15 103:14 152:1 191:11 381:2 445:14 460:12 479:21 492:15</p> <p>demonstrates 49:5 123:20 283:2 318:9 480:5</p>	<p>demonstrating 263:11 445:4 474:1 477:4</p> <p>denise 16:16 471:8 471:13</p> <p>denver 173:14 357:9 366:21 367:6 413:11</p> <p>deny 436:3</p> <p>denying 173:11</p> <p>department 9:16 9:18,21 10:3 121:4 161:10 166:8 198:7 204:13 244:9 344:9,11 365:3 366:21 367:21 368:5 374:8 415:18 429:15 483:22</p> <p>departments 236:1 410:21 412:5</p> <p>depend 30:18 114:17</p> <p>dependence 11:9 67:22 220:10,13 313:21 482:15</p> <p>dependency 318:2 468:13</p> <p>dependent 277:12 474:16</p> <p>dependently 224:6</p> <p>depending 29:17 40:19 327:17 390:12</p> <p>depends 134:2 308:15 309:6 314:21</p> <p>depicting 384:13</p> <p>depicts 190:22</p> <p>deployment 365:3</p>
--	--	--	---

deployments 288:2	409:10,15 417:16 420:3 440:16	desperation 458:22 459:3 473:6	deutsche 11:13 227:14
deposit 147:16	457:9 463:5	despite 51:1 60:9 61:16 67:18 116:6	devastating 94:10
depression 374:18 374:22	464:14 465:13	284:5 401:3	devastation 57:21
deputy 2:3 4:9 21:8,16	deriving 69:1	despres 16:12 462:4,6,8 466:16	develop 30:12 39:18,19 74:10
derivative 69:2 114:18 130:9	dermatology 7:5	466:18	76:14 94:11
derivatives 28:20 36:5 82:3 88:16	dermatomyositis 93:5	destruction 203:3 377:16	100:18 101:17
94:22 103:7,10	describe 212:9 215:5 317:20	detail 114:21 312:11 313:5	117:16 130:19
137:5 143:8	448:6,8 458:19	392:13 456:12	133:17 144:22
153:16 367:17	described 62:11 311:18,19 312:2	463:1	195:18 201:2
derived 1:9 20:5 26:18 27:9 29:8	316:1 353:13	detailed 20:17 111:12 123:13	230:19 264:17
29:13 31:5,9 35:7	374:4 443:22	185:7 325:7	295:4 296:5
36:10 42:22 47:9	472:6	details 196:21 237:21 481:9	323:17,19 362:4
48:13,19 49:7,20	descriptions 130:9 206:5	detect 363:3	364:5 386:18
51:4 62:8 63:21	deserve 31:7 54:21 118:4	detectable 214:5	392:22 393:3,5
64:12,17 67:4,19	315:13 461:11	detected 190:3 191:6 302:10	405:13 425:15
68:6,18 71:2	471:5 498:7	detection 145:1 189:19 196:14	466:7 474:9
76:10,15,18 81:11	deserves 461:19 492:2	198:9 238:14	developed 89:12 134:1 267:6
84:2,14 93:11,12	designated 68:22	314:19	293:22 302:13,15
95:5 98:17 103:8	designation 44:13 47:10	detects 238:16	374:10 380:18
107:21 109:10	designations 93:7	determination 54:1 136:4 436:11	426:2,8,20 427:21
111:16 112:2,14	designed 93:13,13 140:1 266:14	determinations 407:13	437:4 475:17,18
116:9,13 119:18	348:6	determine 69:7 444:15 460:15	developer 94:4 296:17
133:9 139:5,19	designer 205:18	264:22 280:11	developers 93:19
143:16 145:16	designing 268:12	444:7 445:6,9	developing 50:14 92:20 100:6 101:8
146:14 155:4	desirable 75:4	460:12 472:13	139:15 145:15
168:6 170:2,10,14	desire 64:4 154:13 371:15 477:19	determining 480:22	223:17 265:5
210:8,10,14	desired 306:7,11	detrimental 82:8	322:7 383:11,14
218:13 272:20	desk 20:18 384:17		392:7 425:5
273:14 302:8	desmethyloba... 179:1		468:17
315:18 322:4	despair 482:14		development 63:21 65:11 89:6
323:4,7,14 324:15	desperate 97:7		89:7,10 92:19
338:5,12,12,14	desperately 41:22		94:13,17 95:2
353:10,19,21			98:21 99:4 143:7
354:9 355:2,7			177:21,22 178:15
356:4,6 361:14,22			179:14 180:9
362:16,21 364:14			196:11 218:9
365:20 371:17			235:15 266:7
380:17 407:8			268:14 270:21

282:17 283:5 294:13 295:5 297:4,13 330:19 331:1,2 334:5 338:5 356:19 362:8 363:5 381:8 381:10 394:14 425:21 426:16 427:2,9 429:2 435:11 458:9 460:9 491:12 developmental 174:1 242:2 device 72:2 483:1 devices 24:3 265:16 426:17 devoid 228:19 devon 328:20 devoted 96:1 98:20 366:16 dextromethorphan 207:11 336:2 diabetic 276:4,15 diagnose 35:12 105:9 diagnosed 92:5 402:2 447:13 472:11,17,21 diagnoses 458:15 diagnosis 135:22 diagnostic 264:2 264:12 diagnostics 50:14 dialog 365:17 dialogue 100:12 dialysis 277:21 diarrhea 492:12 dichotomies 432:12 dichotomy 432:17 dictated 175:20 died 245:3 431:14 472:22	diego 10:11 diet 259:13 dietary 10:18 30:14 32:5,9,14 33:10 34:7 44:12 44:15 47:10 48:10 48:14 52:18 71:2 71:5,13,13,15 72:2 73:6,11,20 76:5 77:6,10 79:4 79:5 98:12,22 101:14 102:7 111:21 115:22 116:8 117:14 120:8,20 128:16 143:20 154:4 159:15 162:2 188:4,17,18,19 189:1 200:14,18 205:17 268:15 269:9,13 272:15 272:19,22 273:3 295:21 323:5,22 327:7 337:8,14 350:7,8 352:11 353:8 354:10 355:2,19 356:7 364:18 365:10 395:10,19 396:9 396:13 398:17,18 399:15 403:19 406:1 407:12 410:15 415:21 416:19 433:10 435:2,6,14 436:11 438:2,3,8,16 439:2 440:5,16,18 440:22 441:12,21 442:6 450:16 477:7 496:20 497:22 diets 78:9 differ 188:20 337:18 455:18	difference 54:14 65:3 83:2 120:14 126:18 213:6 236:8 272:7 288:5 291:21 293:12 300:17 433:2 differences 186:7 186:9 255:13 292:10 299:10 329:15 437:12 455:14 different 40:19 101:15 103:7 114:22 115:1 120:18 131:17 146:4 149:1,2 172:1,2 177:18 184:18 186:8,15 212:1 215:9,9 221:3 224:15 227:17 230:6 235:14 237:3,20 244:5,6 252:20 257:21 258:1,7,8 258:9 266:10,19 266:20,21 282:20 285:5 288:1,9 289:4 292:12 293:9 294:18 299:14 307:12,17 307:18 310:6 323:6,8,20 324:5 324:21 326:9 338:22 374:1 388:16 405:16 415:14,22 417:12 417:13 418:2 420:10 421:15,16 421:16,19 426:2 448:17 454:21 458:15,16 464:6,7 464:9,19 470:5 differential 120:16 202:10,13	differentiate 97:1 255:7 322:15 differentiates 324:9 differentiation 266:13 338:10 differently 30:15 126:16 147:2 266:22 416:11 differing 477:11 difficult 40:12,15 41:9 157:7 179:8 208:18 215:7 350:19 389:19 396:18 423:8 448:9 difficulties 152:8 172:12 388:20 495:15 digestion 71:9 digestive 262:19 digital 253:4 452:9 503:3 dilated 472:11 diluted 308:17 diminished 435:13 ding 291:1 dioxide 465:3 direct 12:15 24:16 108:21 400:22 419:18 497:13 directed 272:8 direction 187:3 502:5 directions 183:17 directly 58:2 96:21 137:8 206:21 208:11 director 2:6,11,15 3:15 4:9 20:7 21:16 22:2,13 26:6,8 45:8 122:9 135:13 158:16 181:20 200:2,13
---	--	---	--

235:9 298:12,16 356:18 366:3 390:20 462:8 dirty 270:5 disagreed 111:20 disappeared 260:7 disappointed 85:4 disappointing 287:3 discern 433:1 discharged 92:6 288:2 373:19 disciplines 421:17 421:19 disclose 214:4 237:19 disclosed 237:7 448:22 discomfort 86:6 disconcerting 190:19 disconnect 238:11 disconnected 260:21 discontinued 67:13 discontinuing 51:12 discordia 7:6 92:16,17,18 95:3 95:12 discount 452:18 discover 285:13 discovered 221:17 294:15 295:7 388:13 485:5 488:18 discovery 54:4 143:6 discrepancies 188:22 189:5 discretion 35:22 113:5,10 353:14	379:20 435:21 discriminable 212:17 214:20 discuss 49:21 176:18 362:15 467:10 496:19 discussed 292:18 393:3 497:21 discussion 72:9 85:12 103:21 115:15 220:19 294:21,21 295:14 295:17 350:11 399:10 discussions 47:22 88:10 90:5 disease 29:21 102:9 105:10 130:13 132:5 136:7 243:1 268:21 272:17 337:10 338:22 339:5 359:8 374:10 384:10,14 385:8,9 386:10,13 387:7,18 388:1,6 388:8 389:1,13,21 401:2 457:6 458:10 472:14 473:1 474:3 475:18 diseases 35:13,19 93:4 323:20 389:21 457:13 473:22 474:17,20 484:6,9 disguise 373:13 376:21 disincentivizes 95:2 327:12 disincentivizing 326:13,14 disneyworld 82:9	disorder 57:18 130:1 222:21 336:22 disorders 92:22 130:2 222:6 264:4 300:3,4 301:20 385:19 disparate 130:5 dispensaries 59:15 193:2 222:9 381:5 431:7 dispensary 57:4,6 59:8,15 62:13 140:22 249:13 390:11 459:3 496:21 498:1 displayed 380:22 disrupt 173:17 disrupted 262:4 263:9 disruptions 263:4 disseminate 100:10 415:1,13 dissolved 270:12 distance 408:17 distillate 69:2 292:15 distillation 152:5 distinct 321:17 distinction 80:20 112:5 192:16 258:1 distinguish 195:5 distinguished 20:21 25:22 26:4 361:9 distress 224:4 distributed 24:12 330:18 362:6 distribution 82:11 157:6 166:17 329:15 463:11 distributors 9:6 16:19 18:17 19:8	38:15 147:4,6 481:15 district 408:18 disturbing 335:4 dive 246:15 diverse 123:7 261:22 270:9 318:1 321:15 diversion 497:2 499:16 500:7 diving 90:1 387:9 division 87:11 98:13 235:11 321:18,20 367:1 370:19 390:21 398:16 divisions 78:6 321:17 dixie 356:19 357:9 dizziness 300:20 388:5 dmf 311:10,11 312:2 314:10 315:3 316:1 dmfs 311:4 dna 174:1,4 docket 23:7 25:17 25:19 27:5,6 36:7 36:15 52:22 86:1 91:9,14 110:15 111:13 122:6 124:17 125:2 152:20 157:19 161:2 165:7 196:22 204:10 216:2 309:20 325:17 412:18 446:22 456:11 481:10 500:22 501:2 docs 260:3 doctor 39:1 457:7 doctor's 251:4
---	---	---	---

doctorate 356:17 doctors 259:6 260:1 430:15 458:17 460:15 485:6 documentation 194:22 369:13 documented 123:21 143:10 157:4 193:9 196:6 224:22 331:19 documenting 197:18 242:9 documents 60:9 392:13 dod 296:10 dogs 64:18 83:14 84:18 86:15 doing 29:9 32:19 140:13 162:14 182:16 186:10 188:4 210:11 227:13 231:11 236:13 240:19 241:15 244:7 289:4 293:8 318:20 334:7,14 344:2 360:14 382:22 394:5,12 394:13,15 416:20 421:16 423:10 424:5 456:7 472:2 474:6 498:18 doj 121:5 doj's 121:10 dollar 119:20 290:19 dollars 49:10 52:6 54:17 161:22 290:17 291:16 347:21 348:1 435:12 domestic 110:18 287:4,5	domestically 227:22 dominant 473:3 donelson 6:9 70:19,22 donors 247:7 don't 25:18 30:21 33:21 41:8 55:10 55:11 56:7 73:15 74:14 80:2 86:13 90:3 95:3 97:8 108:4,9 115:1 128:6 137:7 148:9 149:5 150:17 158:8,10 178:8,20 181:6,9 183:11 186:4,18 187:5 208:6 212:15 213:18 215:3 224:7 225:4 231:21,22 232:1 234:11 241:20 243:16,22 251:9 254:11 255:14,18 256:9 280:14 284:14 296:20 297:7 304:8 308:11 313:17 346:10 349:10,13 349:19,21,22 375:22 382:16 391:6,9,10 395:5 403:16,22 412:17 417:2 432:13,15 448:4 455:6,7,12 461:14 470:15 474:5 475:2,10 478:15 482:7 484:7 491:8 497:17 498:21 door 354:15 355:6 375:9 428:15 477:15	doors 149:18 dopamine 385:10 dormant 407:16 dosable 334:3,8 dosage 33:2 40:12 40:14 41:10 105:14 118:1 130:9 359:5 397:7 409:13 410:12 424:21 437:3,10 437:11 dosages 118:12,15 120:16 319:22 358:13 359:13 dose 40:17,17,18 40:22 51:22 115:7 120:7,10 141:3 201:16,17,18 202:11,12 211:15 212:22 213:3,10 222:15 224:6 277:2,12 278:5 279:4 280:11,19 281:3 285:14 300:1,3,4,15 301:3,22 302:4 334:15 339:3 359:14,16 361:3 454:20 459:19 474:15,21 492:3 dosed 93:9 doses 51:9 124:4 181:1 184:7,9 202:9,17 211:12 212:22 217:12 270:15 271:1,4,5 298:22 302:5 410:1 433:14 474:16,19 dosing 38:21 39:1 69:7 70:1 131:10 148:22 177:5,6 211:22 264:12 272:5,6 276:21	277:14 278:3,4 293:1 300:18 301:17,19 319:10 338:10 388:20 492:1 dossier 272:1 double 299:3 493:5 doug 21:15 douglas 4:8 13:10 321:9,10 dovetail 192:13 downregulation 202:11 downside 127:13 downward 44:3 57:17 dozen 284:10 333:16 391:4 dozens 106:3 207:22 265:13 428:9 dr 20:10,22 21:7 21:15 22:12 25:22 26:2,11,14 36:21 40:3 50:7 53:2 61:15,19 63:6,18 63:19 66:4,14,22 66:22 68:15,21 69:9,13,15,22 70:8,14 77:20 79:20 80:15 81:2 87:15 89:20 90:14 91:13,17,21 92:17 92:17 95:3,12 98:10 101:3,7 117:7 135:12 137:7,14,15,20,22 137:22 140:6,10 140:14 141:4,13 162:9 174:5 175:8 176:16 181:14,17 185:20 186:10 187:2,7,10,15
--	---	--	---

192:7 193:6 197:4 198:2,15,22 199:4 199:20 200:10 204:6 209:19 210:22 214:18 215:7,14,19 216:4 216:7,21 217:20 220:9 226:7,10,12 226:15 242:4 259:2,3 261:8,14 263:15 274:12,13 279:18,21 280:2,4 280:6,13 281:1 282:1,10 298:18 316:21 317:2,4 321:1,10 332:17 337:17 356:16,16 357:1,3 361:8,15 378:14,18 383:21 384:3,19 390:2,7 395:2 396:5 398:14 399:18 400:7,8 405:14 451:2,7 455:16 456:14,20 471:9 471:13 475:16 487:1 489:7 492:13 494:7 495:12 draft 135:22 drafting 48:7 dragged 458:21 dramatic 181:1 260:9 dramatically 180:3 dravet 140:16 338:17 341:9 dravet's 174:17 draw 136:2 dreams 57:13 241:5 dressings 151:3	dried 302:11 392:11,18 drink 162:2 249:5 257:8 291:14 467:21 drinks 151:12 152:3 432:14,15 drip 275:19 drive 39:20 54:15 107:19 108:14 109:4,20 292:1 346:13 364:20 365:5 431:10 459:2 driven 425:14 driver 233:12 drivers 376:7 drives 399:10 driving 116:12 174:18 184:13 243:14 340:4 375:17 428:9 454:7 471:15 dronabinol 30:7 186:12 drop 279:4 dropped 275:8 318:13 drops 249:6 drowsiness 320:5 drs 192:14 drug 1:1,16 2:4,9 2:13,17,21 3:5,9 3:13,17,21 4:5,10 4:11 11:9 16:15 20:3 21:17 27:18 28:10 29:2,20 30:1 31:20 32:10 33:1 35:15 41:1,5 41:7 47:4 50:16 57:8 58:5 61:21 63:12 67:18,22 76:13,22 77:9 81:19,22 89:19	93:2,18 94:4,9 95:2 101:16 102:5 102:10,12 105:3,5 105:8,13,15,21 106:2,5,7,8,9,11 106:12,13 107:13 114:10,14 117:20 124:1,3,14 131:7 136:7,8,12 141:12 141:20 143:1,8,11 143:11,14 144:12 150:19 156:1,2,21 159:2 174:3 175:14 177:8,17 177:18 178:2,7,16 179:10,15 180:2,3 180:12 181:2,6,11 201:22 202:16 203:13,20 205:14 208:4 209:10 211:13,20 212:1,3 212:16,17 213:9 213:10 214:15,15 214:20,20,21 215:6 216:15 217:13 218:10 220:10,12 241:17 242:5 265:1 268:22 271:14,16 282:16 283:5,8 284:17,17 285:21 286:14,14 287:1,2 292:2 294:13 295:1,22 296:16 296:21 297:4 300:5,12 306:3 311:7,20 313:7,21 315:12 320:14 321:21 323:18 324:22 326:19 331:12 334:5 339:5,7,14,18,18 343:21 353:1 359:18 360:17	361:11 375:14 377:10 387:20,21 389:18 395:19 401:15,16,16 403:17 404:10,13 405:2,7 410:18,19 419:13,21 420:2 421:1,17 426:14 429:17 433:13,18 435:11,13,15 436:4,5,18 449:6 458:2 460:16 467:1,5,6,9 470:13 471:1 475:9 483:10 500:7 drugs 4:7 30:4,10 30:12 31:19,21 32:1,22 34:15 50:17 51:6 57:11 64:10 67:13 84:1 93:20 94:13,19 130:22 138:8,14 139:21 140:2 144:5 168:18 175:18 178:6,10 178:11 180:18 183:14,21 204:19 205:15,18,19,21 206:4 207:16 209:10 214:9 218:9 245:17 271:8,9 290:14 313:2 314:21 323:5,19,20 325:2 329:4 339:21 374:14,14 377:13 377:14 398:4 405:18,21 447:7 450:15 461:16 470:4 drugstore 126:17 drugstores 62:18
--	--	--	--

<p>dry 28:22 240:4 278:8 368:3 394:1 469:3 488:9 489:3 494:14</p> <p>dryers 246:21</p> <p>dshea 38:20 64:20 435:9 439:3,13 476:19 480:6,17</p> <p>dsm 173:12</p> <p>dual 409:5 434:1</p> <p>duality 407:11</p> <p>due 28:13 51:12 82:12 96:8 119:11 130:3 143:12 151:13 162:4 271:8 326:18 436:15 439:13 458:10</p> <p>dunking 59:19</p> <p>dupont 2:14</p> <p>durable 89:12</p> <p>duration 301:7</p> <p>dustin 261:14</p> <p>duty 371:15</p> <p>dvm 6:2</p> <p>dwel 184:4</p> <p>dwindling 46:8</p> <p>dying 327:20</p> <p>dynamic 307:5</p> <p>dysfunction 385:19</p>	<p>eager 428:21 476:14</p> <p>eagerly 107:22</p> <p>earlier 31:17 96:18 162:10 210:13 360:4 386:8 424:8 474:15</p> <p>early 96:2 104:12 141:17 160:10 183:4 184:6 333:3 388:9 433:8 439:21 467:4</p> <p>earned 57:16</p> <p>ears 54:11</p> <p>earth 151:7</p> <p>ease 452:9 458:2</p> <p>easier 150:20</p> <p>easily 53:19 124:2 131:16 382:9 427:1</p> <p>easy 51:2 152:10 218:19 231:15 278:12</p> <p>eat 30:18 249:5</p> <p>eating 224:2</p> <p>echo 193:5</p> <p>echoing 408:15</p> <p>ecodrop 275:4,19 275:20 276:7 277:9</p> <p>economic 43:11 44:5,9 46:17 52:1 52:12 65:14 108:15,20 233:12</p> <p>economically 52:13</p> <p>economy 45:2 54:16 83:5</p> <p>ecs 262:7,12,22 263:4</p> <p>edge 209:8</p> <p>edible 185:17 279:4,16 280:6</p>	<p>454:1 469:6</p> <p>edibles 34:18 222:9 256:3 276:11,18 373:9</p> <p>edict 432:18</p> <p>educate 139:6 149:6 297:3</p> <p>educated 148:20</p> <p>educating 11:19 170:12 240:17</p> <p>education 8:9 12:7 53:14 129:20 149:9,18 188:19 240:17 273:4,5 278:17 364:16 393:7 396:2 418:17 455:10 463:18</p> <p>educational 97:14 98:1 122:10 130:17 400:21 484:15</p> <p>effect 29:21 41:7 70:10 95:4 118:16 129:2 173:19 178:10 179:9 211:21 212:17 214:15,15,20,21 215:6 254:22 258:5 270:20,21 278:2 300:11,16 301:12,14 306:15 318:16 328:3 330:4 358:11 388:22 407:2 449:8 493:8</p> <p>effective 45:3 53:18 72:7 74:18 74:22 76:16 89:11 112:20 126:8 132:6 142:19 232:16 236:1 247:22 249:22 250:2,9 261:6,21</p>	<p>263:6 265:9 266:8 276:21 317:12 320:2 354:18 389:5 403:14 479:22 481:4 492:15</p> <p>effectively 60:5 97:13 159:21 229:18 230:8 355:9 495:3</p> <p>effectiveness 39:19 295:15</p> <p>effects 28:15 40:19 41:1,5,7,9 54:9 67:6,20 68:1 69:19,20 70:1,6 80:18 82:8 139:3 139:7,14,16 141:20 143:21 179:3 193:12,13 193:16 194:22 200:5 209:13 211:13 212:1,4,16 213:17,19 214:20 214:22 217:13 222:15 224:12 251:6 256:12,21 261:3 271:18 277:11 306:15 318:16 320:3 328:11 339:21 340:2,12,15 358:12 359:9 360:21 376:4,9 380:11 386:15 387:21,22 388:12 388:12,15 389:8 405:2 430:22 431:4 451:20 452:2 454:20 468:7,16 473:14 474:12 487:16 492:11,11</p>
<p>e</p>			
<p>e 2:1,1 3:1,1 4:1,1 5:1,1 6:1,1 7:1,1 8:1,1 9:1,1 10:1,1 11:1,1 12:1,1 13:1 13:1 14:1,1 15:1,1 16:1,1,9 17:1,1 18:2 19:1 20:1,1 40:11 53:12 126:8 205:1,1,9 206:4,8 206:9,21 372:11 491:10 492:16,16</p>			

efficacious 64:7	elbow 186:3	182:5 368:18	107:16 110:14
efficacy 65:6,8	elderly 214:1	371:5 382:10	120:2 138:16
93:3 125:16 126:5	271:21	429:4	139:20 175:8
131:6 136:2,11	elect 159:1	emphasis 357:19	197:14 214:2,6
140:2 142:22	election 482:10	357:19	354:13 358:17
167:20 183:13	electric 488:2	emphasize 177:13	414:15 419:1
186:8 222:4	electronic 22:22	177:20 178:12	465:7,19
264:21 282:14	23:1 24:3 40:9	261:2 325:22	encouraged 63:14
283:4 285:20	186:22 204:9,19	emphasizing	353:17 414:3
286:7 299:6	element 115:14	25:15	encourages
317:18 320:13	elemental 100:3	empire 111:6	322:12 338:4
329:11 333:18	elements 478:3	empirical 220:13	341:14 355:9
357:20 358:1	elevated 201:3,19	259:18 260:14	364:16 443:1
369:19 379:12,14	238:14 300:18	262:14 360:20,20	encouraging
460:13 461:19	elevates 474:2	employ 347:20	304:11
492:5	elevation 202:20	446:3 478:13	endanger 163:16
efficiency 50:19	475:6,9	491:9	ended 482:3
232:17 446:10	eleven 248:17	employed 357:17	endless 127:11
efficient 48:9,15	eligibility 272:22	502:8,11 503:8,11	endocannabinoid
efficiently 322:15	eligible 336:22	employee 59:6	54:5 78:18,20
426:20	eliminate 333:20	502:10 503:10	92:21 94:14 259:7
effort 49:16 88:7	eliminating	employees 59:22	262:1,16 263:9
383:17 426:21	445:22 479:13	247:9	482:2 485:4,8
efforts 72:18	elise 11:7 220:8	empower 304:20	488:17 493:20
109:7 124:21,21	elixinol 6:7 66:20	307:3	494:6
145:19 170:13	67:1 69:4	empowering	endocannabinoids
195:13 369:1	ema 493:6	380:15	262:8
381:1 425:15	email 169:10	empty 177:8	endocrine 262:20
428:4,17	225:21	enable 362:8	endogenous 78:13
egregious 85:2	emails 208:9	365:8 425:19	79:9,21
eight 56:16 108:22	embarrassed	enables 71:9	endostatins 202:4
121:8 127:18	208:7,16	285:13 363:2	endothelial 203:4
160:1 318:11	embolden 287:7	enabling 364:17	endpoint 398:12
338:22 402:5	embrace 285:7	365:12	ends 146:4 234:1
eighth 373:10	embraces 321:21	enact 120:21	enforce 121:6
either 78:2 86:12	embracing 267:5	160:18	244:6 273:3
104:1 159:18	embryonic 270:20	enacted 221:1	330:15 354:5
189:16 191:3	emergency 207:8	352:7	412:6 438:22
270:12 284:6	208:1 484:17	enactment 111:18	enforceable
316:6 349:14	emerges 223:13	enantioomer	303:14
354:5 370:16	437:9	179:17	enforced 119:14
482:18	emerging 41:19	encounter 316:6	377:22 432:22
elaborate 68:19	46:18 65:6 130:14	encourage 27:3	enforcement
214:16 226:13	154:13 163:7	73:20 98:1 104:5	35:22 49:14 65:16

72:6 77:2,4,6 102:17 113:5,10 120:22 121:1,9,12 160:2 189:14 192:3 205:3 235:16 353:13 367:6 370:19 410:21 471:18 482:7 enforcing 57:1 353:16 429:17 442:2 engage 200:5 214:2 engaged 78:1 303:21 engagement 2:11 20:8 88:9 89:5 365:12 engaging 199:6 engineer 96:5 235:13 engineering 348:5 enhance 89:1 319:2 enhanced 446:5 enhancement 189:2,3 enjoy 82:4 127:6 enrolled 196:4 ensure 36:2 46:17 49:19 50:18 60:5 66:5 74:4 89:8 99:6,11 109:15 117:14 121:16 146:20 154:20 163:3,9 167:18 269:8 285:17 304:20 305:5 322:13 325:9 330:17 331:3,14 331:21 332:9 343:10 354:18,22 355:18 356:5	359:2 369:7,11 371:15 372:3 380:21 425:21 428:19 462:11,15 463:14,20 466:1 479:10,11 481:4 487:17 488:10 489:13 490:19,21 492:14 495:9 ensures 52:15 319:18 338:7 489:16 ensuring 50:21 112:15 145:13 329:5 393:12 426:10 428:6 464:1 490:3,13 493:11 enter 151:18 163:19 173:14 175:3 321:4 354:15 356:11 423:18,19 494:19 495:9 entering 313:4 389:2 enterprises 14:11 366:4,6,11,15 368:19 370:3 371:22 enters 143:12 entire 50:2 120:13 152:1 168:11 256:4 267:1 282:16 284:22 309:8 319:11 328:21 341:6 418:6 457:22 499:9 entirely 119:13 120:18 247:6 entities 9:14 18:19 155:17,20 443:10	entitled 188:6 entity 218:10 entourage 306:15 entrance 494:16 entrepreneurs 107:12 entry 316:7 environment 108:3 130:11 322:6 357:14 365:4 366:22 368:6 396:16,17 426:1 environmental 146:10 366:18 367:4 379:2 environments 60:1 490:22 envisioned 185:6 enzyme 177:14,17 178:6 179:10 180:8 enzymes 177:2,19 201:3,19 202:20 262:10,11 271:17 epa 464:21 epidemic 39:12 epidiolex 30:5 51:9,17 67:17 102:10 120:9 139:1 140:9,14 141:12 142:22 174:16 177:21 178:15 180:10,22 181:1 201:2,4 210:9 270:17 272:5,8 334:13 337:1 338:13,19 339:17 359:11 401:18 402:10,10 403:7 405:7 410:19 433:15 459:19 485:20	epilepsy 8:18 15:5 137:16 138:2,4,22 140:18 142:19 143:3 178:17 216:20 221:8 261:7,16,17,19 269:2 324:22 338:17 400:6,10 400:12,13,16,19 401:1,4,9,15 402:3,3,11 403:16 404:2,15 405:16 458:16 459:8 epilepticus 401:11 epileptologists 386:11 458:14 episodic 468:15 epithelium 488:15 492:19 493:21 494:5 epstein 13:4 303:3 303:4,5 307:7,10 307:18 308:8,15 309:1,5,15,17 310:8,10,12,17 equal 355:4 426:9 455:5 equine 96:11 equipment 127:5 134:4 227:15 348:1,7 445:8 465:4,9 equipped 441:14 equivalent 102:12 122:17 er 173:15 278:19 373:20 eradicate 253:17 eras 407:20 erik 3:10 21:20 erin 10:2 166:7,8 172:11 eroding 304:6
---	--	---	--

<p>errors 446:12 ers 242:16 escalation 224:21 escherichia 489:22 esoteric 407:4,20 especially 61:1 102:21 113:2 130:18 132:1 141:16 153:17 170:5 188:17 189:1 200:5,21 217:13 254:1 291:19 396:15 452:21 455:19 468:2 470:19 493:12 essence 107:21 397:18 essential 79:10 99:15 108:11 404:18 essentially 136:6 230:7 232:21 422:10 establish 50:1 120:9 151:17 155:8 163:18 214:7 255:15 305:18 325:12 332:8 393:6 396:20 397:18 450:13 established 121:1 121:8 132:17 181:22 269:20 329:2,12,18 330:14 331:1 332:5 369:5 396:10 425:18 440:19 445:2 establishes 173:12 338:9</p>	<p>establishing 73:9 146:11 194:6 266:15 291:4 327:2 393:8 estate 421:18 estimate 198:12 estimated 108:19 259:22 348:20 estimates 430:14 442:4 et 279:4 308:3 385:19 409:15 ethanol 202:7 ethical 366:12 ethics 421:7,9 eu 491:22 euphoria 300:4 euphoric 293:22 300:10 330:4 europe 207:9 332:20 333:17 european 253:13 491:21 evaluate 33:1,16 34:22 138:18 141:19 225:7 266:1 269:20 282:14 306:12 350:15 413:21 439:7,15 443:11 evaluated 134:17 167:20 205:16 269:18 324:19 334:22 369:18 380:9 444:20 446:7 evaluation 4:10 21:17 31:12 36:9 134:11 168:6 169:13 212:5 213:18 330:19 446:18 evaluations 169:17</p>	<p>evans 11:18 240:11,12,15 eve 459:18 event 84:17 194:8 196:13,13 218:3 219:21 325:20 441:20 480:9,13 events 51:13 124:22 141:10 157:20 194:13 197:17 198:3 199:11,16,18 269:8,12 285:15 299:20,22 300:2,6 300:7,9,19,22,22 301:2,9,19 302:3 302:5,6 358:15 438:14 493:1,4 eventually 285:7 345:4 evergreen 366:5 everybody 149:1 250:11 403:21 408:15 451:12 496:14 evidence 34:6 39:20 41:18 42:11 51:18 54:8 61:21 68:2 72:20 73:5 74:3,15 75:11 80:3,8,21 90:3 109:9 125:16 127:20 136:2,11 136:15 137:1 143:6 205:2 257:21 258:6 259:19 260:14 263:11 381:15 389:15 431:2 436:10 454:5 476:21 477:4 evident 201:19 301:21</p>	<p>evolve 285:17 evolving 39:20 exacerbate 203:14 exact 105:12 254:11 271:7 345:22 416:21 exactly 75:12 103:4 131:22 185:21 191:4 215:8 238:10 239:1,13,20 254:14,21 255:15 396:7 466:2 475:10 exaggeration 94:5 examine 145:21 436:8 455:1 examined 224:17 examining 436:15 example 29:19 30:9,21 34:11 114:5 127:3 202:11 221:5 267:6 284:9 290:15 305:18 339:8 341:3 365:9 380:7 402:19 432:17 452:12 454:15 455:3 465:1 478:12 examples 86:7 260:6 283:7 323:6 385:16 exceeded 190:5,13 190:17 191:16 240:1 331:22 exceeding 464:18 exceeds 484:18 excellence 216:12 386:2 excellent 141:13 exception 32:8 33:7 77:10 105:16</p>
--	---	--	---

<p>exceptions 32:16 163:14 258:12</p> <p>excepts 106:10</p> <p>excessive 283:3 286:5</p> <p>excessively 283:16</p> <p>excited 276:3</p> <p>exciting 74:11 471:10</p> <p>excludes 32:4</p> <p>exclusion 435:8 436:7</p> <p>exclusionary 435:7</p> <p>exclusive 453:17</p> <p>exclusively 272:8 413:12</p> <p>excuse 73:18 112:4 135:3 150:10 196:20 215:11 327:6 368:13 415:21 432:21</p> <p>execution 166:16</p> <p>executive 77:21 158:16 235:9</p> <p>exempt 77:8 411:9 411:15</p> <p>exemption 106:20</p> <p>exemptions 185:6</p> <p>exercise 77:8 113:5,9 189:2 265:21 354:8 392:19 460:19</p> <p>exercising 355:8</p> <p>exhaustive 96:17</p> <p>exhibits 67:22</p> <p>exist 159:3 182:12 255:6 313:1 317:17 360:19 409:11 441:3 463:7 476:18</p> <p>existence 311:9</p>	<p>existing 76:13 214:9 217:20,21 331:1,6 332:6 348:22 350:10 360:1 414:1,8,18 414:19 416:3,14 441:5,12 442:6 480:17</p> <p>exists 331:7</p> <p>expand 117:9</p> <p>expanded 216:19</p> <p>expanding 128:14 183:21 382:1 491:14</p> <p>expansion 119:10</p> <p>expect 26:21 90:18 141:18 146:21 193:14 303:10,15,17,21 346:8 394:5 417:2 452:6</p> <p>expectations 74:6 97:11 269:15 306:21 380:22</p> <p>expected 116:10 168:14 251:1 260:8 300:11 371:5 440:19</p> <p>expecting 22:17</p> <p>expedite 122:2</p> <p>expedited 108:13</p> <p>expeditious 98:7</p> <p>expeditiously 49:1</p> <p>expensive 123:5 206:9 251:22</p> <p>experience 63:7 126:19 127:2 142:19 195:22 196:22 197:16,19 199:8,22 223:17 236:5 304:14 325:7 326:4 367:12 412:4 445:6 465:17</p>	<p>483:2</p> <p>experienced 67:6 70:10 251:8 260:11 299:22 300:9 301:4</p> <p>experiences 94:4 194:7 196:5 198:14 376:13 412:2</p> <p>experiencing 260:11</p> <p>experiment 174:12</p> <p>experimental 93:20</p> <p>expert 67:21 96:22 97:6 134:10 151:15 313:20 379:4</p> <p>expertise 99:3 100:6 204:15 348:5 378:19 426:18</p> <p>experts 39:4 45:10 85:9 197:7 200:17 324:2 392:1 432:2 433:18 444:9</p> <p>explain 103:4 113:21 284:7 328:2 447:10</p> <p>explaining 361:17</p> <p>explanation 284:12</p> <p>explicitly 29:6 329:6 452:17</p> <p>exploded 441:10</p> <p>exploding 116:8 348:18</p> <p>exploration 100:13</p> <p>explore 355:15</p> <p>explored 184:12</p> <p>explosion 33:20</p>	<p>exponential 119:12</p> <p>exponentially 40:15 74:1 307:1</p> <p>export 425:3</p> <p>exposed 60:1 143:17 375:16</p> <p>exposition 120:4</p> <p>exposure 60:10,16 63:5 89:17 99:18 144:1 177:6 178:7 181:7 269:9,16,17 306:7 332:3 337:15 397:1 399:9,11</p> <p>exposures 193:10 193:12,17,19 197:3,3 454:20</p> <p>express 338:2</p> <p>expressed 131:10</p> <p>expression 202:10 270:2</p> <p>extend 164:1,5 219:15</p> <p>extended 72:6 217:7 359:11,13</p> <p>extends 480:11</p> <p>extension 169:5 299:5 369:21</p> <p>extensive 124:3 267:8 492:4,20</p> <p>extensively 179:18 413:14</p> <p>extent 62:16 170:17,20 336:12</p> <p>external 2:12 20:8</p> <p>extra 64:3</p> <p>extract 102:8,10 103:4,9,14 105:7 105:16 106:3 201:13 203:12 216:19 217:9 229:13 303:7 305:12 308:4</p>
--	---	---	--

309:5 316:10 324:3,9 327:2,3 327:14 335:11 372:14,14 398:9 417:14,14 424:6,9 487:13,18 extracted 45:17 84:2 210:16 308:11 313:6 336:4 487:7 extracting 314:13 362:13 extraction 165:15 288:19 327:17 335:13 347:11 348:7 367:14 370:6,11 465:4 497:8 extractions 370:20 extractors 312:8 extracts 73:6 102:12,14 114:12 207:3 272:20 304:1 327:2 328:3 335:4 340:2 361:22 371:2 extraneous 285:19 extrapolated 414:11 extreme 174:13 468:1 470:18 extremely 79:12 249:22 250:9,13 251:13 271:1 339:12 405:4 exuberance 286:5 eye 473:15,17 474:2,7,12 eyes 127:19 459:22	f fabricant 15:2 395:1,2 399:18 408:20 face 65:19 93:18 148:1,1 150:18 202:13 484:17 490:5 faced 119:19 382:20 477:9 facilitate 42:5 65:11 99:17 393:1 facilities 134:9 231:14,21 232:2 289:3,5,20 311:1 316:15,16 342:16 347:15 349:7 441:6 442:5,7 478:7 499:9,10 facility 61:6 99:16 229:11 325:19 345:2 438:10 441:5 478:6 493:6 facing 43:7 153:13 182:8 466:5 fact 60:9 69:3 85:3 87:10 117:5,21 126:3 142:21 151:20 154:8 179:3 180:2,20 181:8 182:5,18 187:2 190:19 193:17 194:10 217:18 255:5 263:12 277:22 284:14 303:20 318:16 320:3 326:10 336:9 340:9 360:2,10 361:3 382:16 388:22 430:17 434:12 496:16 factor 397:6 437:13 463:22	factors 134:3 185:11 399:16 408:22 465:14 facts 79:14 382:12 438:5 faculty 26:9 200:12 fahrenheit 450:1,3 fail 437:8 failed 402:5 failures 65:20 fainting 300:20 fair 94:12 239:8 345:9 369:2 fairly 140:17 217:12 fake 131:21 fall 64:13 93:20 264:15 377:15 388:7 falls 27:20 200:20 296:1 431:19 false 37:21 149:11 238:17 376:22 famers 43:4 familial 410:14 472:11,12 familiar 128:1 172:7 179:15 326:10 378:22 441:14 477:8 families 30:19 58:4,8,14 125:11 130:16 136:16 140:22 142:3 217:11 338:15 460:4,14,20 461:5 family 12:15 46:18 57:22 92:6 125:12 208:20 275:21 374:7 403:13 457:4,22 461:20 472:10,21	fans 334:1 fantastic 276:6 336:17 466:17 far 43:9 70:4 178:12 183:4,12 190:13 191:3 217:10 221:3 228:11 232:16 276:3,18 293:5 296:9 322:5 381:21 402:17 416:16 422:17 431:1 432:22 488:13,21 492:9 492:22 fargo 8:15 135:10 135:12,13 137:7 farm 28:19 29:5 33:22 46:18 48:15 54:18 81:13 82:8 82:16 111:14,18 147:10 150:17 153:20 160:17 226:6 291:22 295:18 313:15 329:6 341:2 363:8 408:13 414:2,5 423:16 farmer 43:7 farmers 43:15 44:1,6,9 45:9 46:2 46:6,13 47:14 50:11 82:18,22 127:5 156:10 161:21 229:5 233:8 288:14,14 288:15 289:12 347:22 410:10 411:4,17,19,19 farming 52:12 233:8,9 288:13 497:6 farms 288:10,13 291:20
---	--	---	--

fasciitis 276:15	114:9 116:3,16,18	323:2,3,9,10,12	468:4 470:17,21
fashion 64:4	117:1,6,7,16,18	323:13,21 324:8	471:3 476:14
108:13 185:4	117:19,20 118:6	324:12,19 325:1	478:2,3,17 481:3
fast 93:6 430:8	119:3,18 120:2,21	326:1 328:22	483:5 486:14,15
fatal 35:19	121:10 122:18	329:2,3,12,18,20	490:7 493:11
father 457:5	123:14 129:21	330:15,20 331:5,7	496:9 497:13
fathom 430:7	138:9,14,16 139:1	332:5 337:5	fda's 20:11 21:6
fatigue 70:11	139:20,22 140:2	338:11,15 339:2,3	21:11 22:7 27:11
251:9,9 300:21	142:5 143:3 144:3	339:4 340:10	27:20 29:4,6,9,16
fats 234:7	144:4 145:8,12,16	341:15,16 342:14	38:19 48:20 50:20
fatty 45:21 486:2	145:21 146:15,17	343:18,19 344:10	62:6 105:3 107:15
favor 218:11	146:22 148:3	344:12,15,18	107:22 109:7
favorite 151:4	149:19 150:22	345:1,4,7 346:13	112:6,12,15 116:6
fd&c 111:20	151:10,13,17	347:1 350:3,9,15	117:8 135:1
112:18 113:6	152:10 153:21	352:4 353:12	136:22 153:20
120:22 121:12	155:7,12 157:10	354:4,22 355:6,14	154:20 159:9
144:6 410:18	157:14 160:8,9,21	356:5 358:21	162:10,20 163:12
433:9	161:12 163:17	360:16 369:18	164:4 167:7
fda 21:5,14,17	165:21 167:5,13	380:1,19 381:11	244:11 313:19
22:21 23:3,13	167:14 174:11,16	383:6,8,15 391:16	329:7,22 354:20
26:4,15 27:7,19	175:6,22 177:21	396:19 405:17	412:3 435:3 480:8
27:22 29:13 30:2	185:9 188:15,18	406:10 407:7,10	fear 291:7
30:3,16,18,22	194:5 195:18	408:5,12 410:13	feasible 404:1
31:2,11 32:7,15	197:14 205:20	411:4,6,21 413:20	features 452:16
32:17,20,22 33:15	214:2,6 219:1,12	414:8,22 415:12	february 110:9
34:6 35:1,5,7 36:2	222:3 225:16	416:12 419:1,15	236:20 373:14
36:10,15 38:4,5,9	226:21 236:12	420:6,6,6,14,15	federal 28:7,9,17
38:11,22 42:21	239:15 241:12	420:20 421:4,5	29:3 31:20 56:22
44:8,14,20 46:22	246:9 252:17	422:1,15,19	57:1 81:12 88:11
48:9,22 49:4,22	266:4,15 268:1,20	423:21 424:2,20	98:4 113:1 125:17
50:16,17 51:6	269:7,16,18,19	424:21 425:4,12	138:10 145:5,20
54:2 58:11 60:21	279:10 282:16,19	426:17 428:22	146:8,18 156:3
61:17,19 64:2,11	284:15,16,20,22	429:22 430:1,4,17	160:7,13 165:3
65:7,12 71:19,21	285:3 290:1 291:7	431:8 432:3,18	166:14 182:18
72:6 73:10 74:4	294:21 295:6,20	433:3,3,4,11,15	195:4 218:17
75:12 76:6 77:1,8	296:10,12 297:3,6	435:5,21 436:7,14	228:12 229:7
81:10,13,18 83:3	297:11,18,19	436:21 437:15,20	231:13,16 241:15
83:21 85:12 88:7	302:22 303:21,21	438:6,10,22 439:6	241:18 265:4,7,13
88:10 89:2 93:1	304:4,14 305:2,18	439:9,13 440:2,6	267:19 283:21
94:11 102:5 106:4	305:22 306:6,17	440:13 442:17	292:2 294:11
107:13 108:2,12	307:2 311:1 312:2	443:4 450:12	312:18 329:16
109:13 111:18	316:15 317:18	457:3,3,12 459:20	354:12 356:5
112:3,9,17,18	320:14,16 321:20	460:1,12,18 461:6	362:19 363:14
113:2,3,6,12	321:22 322:4,7,13	461:16 467:22	364:4,5 369:16

377:11,21 407:14 409:18 410:21 412:7 413:17 414:4,16 421:10 421:10 428:22 429:16 432:16 476:16 477:20 486:13 federally 229:17 286:14 federation 476:6,7 481:3 feed 5:3 45:6,8,9 45:13,18 46:3 52:19 64:10,11 66:2 166:12,18,18 166:22 167:10,14 168:2,15,19,21 169:1,13 170:3,11 170:16,18,21 171:16,19 392:3 497:22 feedback 164:4 feeding 132:1 feeds 46:19,20 feel 41:4,7 132:2 148:3 215:1,1,8 231:11 286:4 310:4 314:6 334:2 341:9 374:3 394:17 457:2 feeling 214:21 300:21 321:5,6 feelings 246:3 473:6 feet 161:18 feinstein 185:7 felberbaum 23:15 feline 96:11 fell 495:22 fellow 24:18 73:20 275:20 felt 54:14 142:3 250:6	female 487:2 feminine 487:3 fentanyl 286:20 fertilizer 330:11 fetal 340:9,11 fetus 123:20 173:22 fewer 315:18 ff 272:21 fi 496:11 498:15 fiber 83:1 171:19 233:15 322:19,22 325:11 487:22 fibers 487:21 488:3,5 fibrosis 93:5 fides 39:16 field 94:5 194:21 203:9 229:10 316:17 345:9 471:20 fielding 154:15 194:12 fifth 190:4 fighter 457:18 fighting 433:18 491:15 figure 75:17 243:15 245:20 255:15,16 280:16 498:1 figures 212:8 file 72:1 77:12 173:6 311:20 312:2 324:11 files 355:15 filled 125:5 filling 24:10 film 23:2 final 112:19 153:3 285:3 286:18 351:3 finally 77:5 85:6 110:7 220:3	239:12 243:16 283:22 286:8,12 315:8 331:12 332:1 338:9 365:5 452:6 455:17 491:15 492:12,13 492:20 493:8 financial 95:22 108:11 financially 502:12 503:11 find 58:4 110:10 130:7 141:8 209:10 295:8 296:11 345:18 346:19 347:3 374:9 439:9 finding 190:19 206:15 238:19 findings 135:19 183:8 204:7 217:9 237:16 359:17 477:1 480:12 481:9 fine 423:20 finish 20:15 491:1 finished 158:5,6,7 302:18 348:14 351:5 362:5,8 363:20 369:11 370:12 372:7,15 416:19 490:18 finishing 220:7 fired 175:11 firm 70:22 119:6 379:7 381:3 413:11 419:12 420:8 447:6 firms 48:2 419:15 420:10,17 435:11 500:1 first 28:2 37:8,9 37:10,11 38:2 51:3 78:7 83:18	88:8 105:7 107:20 145:21 153:6,12 155:17 166:8 177:12 182:2 183:17 189:22 193:4 201:11 204:6 217:7 234:4 237:17 243:14 247:20 248:3 250:14 257:5 274:20 275:6,7 276:22 278:2 283:11 287:13 297:8 301:14 305:2 306:4 307:11 319:5,19 324:14 334:21 338:4,14 364:12 367:3,7,8 368:10 368:15 373:2 393:16 394:7 413:19 422:7 423:1,18 433:10 435:15 436:20 437:17 452:19 459:5,19 468:15 471:17 486:9 489:14 491:8 495:1 496:4,8 499:4,11 firsthand 500:4 fish 46:3 365:1 fit 33:17 239:5 262:22 fits 68:21 350:10 416:13 437:2 fitted 437:5 five 47:17 67:5 68:7 107:19 108:21 117:3 119:7 141:15 166:9 250:17 288:14 290:19 297:10,10 300:16
---	---	--	--

314:17 355:11 367:12 447:13 460:8 495:20,22 fix 261:22 fixes 263:8 fixing 297:15 flags 149:14 flame 189:19 flavonoids 486:1 flavor 124:7 205:13 flavored 151:3 flaws 38:19 flea 62:20 flexibility 437:8 flexible 304:21 flight 472:18 flooded 246:6 florida 9:18 333:11 478:12 flour 45:15 flourish 376:20 flout 355:10 flow 20:19 flower 257:5 282:15,16 284:15 284:22 285:1,11 285:13,15,22 286:4,6,7,12,19 334:2 411:14 432:13,14 flowering 285:18 flowing 327:11 fluoro 207:5,7 flying 461:13 fmi 155:2 focus 52:14 86:15 99:4 138:3 173:17 183:22 184:1 205:18 218:1,2 253:3,6 264:4 350:11 357:5 379:10,14 383:15 387:15 393:19	467:5 focused 34:1 60:15 78:4 122:10 130:21 183:5 220:12 235:20 264:2 303:6 309:2 348:3 362:22 408:10 412:3 462:9,13 463:13 focuses 93:15 160:11 205:15 467:3 focusing 45:13 150:14 393:17 467:5 fog 80:8 folium 17:3 495:19 496:2 498:3 499:8 folks 126:13 169:7 243:4 245:2 275:15 276:13 398:22 470:1 follow 75:7 77:3 80:12 95:7 121:1 141:7 152:15 196:20 233:19 251:5 257:15 309:11 313:1 314:1 316:8 318:19 339:2 352:9 354:14 355:12 372:2 480:8 followed 299:4 362:16 438:20 following 47:5 53:19 112:17 173:7 226:20,21 300:14 301:13 310:15 314:13 344:4 433:22 498:22 499:15	food 1:1,2,16 2:4,9 2:13,17,21 3:5,9 3:13,17,21 4:5,7 4:11 9:12 20:3 21:12 27:18 30:14 30:18 31:1,2,8,20 31:22 32:9,13,22 33:12 34:7 44:11 44:15 48:10 52:18 64:10,10 66:3,7 81:20 88:6,14 89:16 97:17 105:5 105:8,10,14,16,21 105:22 106:1,11 106:14,15,18,20 106:21 107:13 114:10,14 116:1,5 116:7 117:15,17 117:20 118:3,5,6 120:8 128:22 143:13 145:7,10 145:20 146:18 147:1 151:12,19 152:11 153:4,8 155:22 156:2,3,9 157:1,4,9 159:2 159:17,21 160:11 160:12 162:2 167:2,11 168:19 168:21 169:14 170:18,21 171:7,9 177:8 223:11 227:17 235:12,16 238:5 241:11,17 257:8 269:10 271:14 272:15,15 273:1 289:21,22 305:9 306:10,18 313:7 322:19,22 323:15,16,22 325:2,11 326:21 327:11 328:4,6,12 328:13 337:7,13 342:6,9,11,18	361:11 363:16 364:19 367:7,16 368:8,12,14,17 369:4 370:21 371:1 391:15 392:3 394:16 395:19 398:2,6,17 415:21 416:18 417:3 419:13,21 420:2 421:1,17 426:14 428:16 432:20,21,21 435:2,13,22 436:17 440:16,18 478:13 486:9,9 496:21 foodborne 366:20 367:8 foods 3:8 30:22 31:14 33:10 47:10 48:14 53:21 98:22 111:22 112:8,16 112:21 113:7,14 116:3 128:15 150:21 152:3 154:3 159:7 164:17,17 268:21 272:11 304:15 313:1 315:12 323:5,13 342:5 352:11 370:1 414:21 416:7 433:10 435:6 450:15 497:12 forage 45:15 171:18 forbes 46:12 forbid 291:13 force 120:1 234:16 forced 127:17 229:6 287:2 foregoing 172:17 281:19 372:19 501:6 502:3 503:4
--	---	---	---

foreign 285:1	formulary 331:11	found 30:4 31:18	fox 15:15 419:7,16
foreigners 297:11	formulate 350:21	44:7 49:4 92:2	framework 33:13
foremost 153:12	formulated	104:19 107:17	48:16 52:15 89:10
234:5 338:4 345:5	333:21 334:8	109:19 126:6	90:17 91:3 94:12
forensic 204:13,15	337:18	140:7 151:8	108:1 117:13
335:17	formulation 33:2	152:19 154:9	145:15 154:17
foresaw 436:2	143:1 319:1	171:4,4 174:3	162:3 163:2,8
foresight 119:4	334:15	175:10 186:9,20	165:5,15 194:4
forever 374:17	forth 149:7 184:19	194:1 206:12	196:7,10 304:10
460:1	186:17 241:3	207:4,5 209:2	306:19 322:2
forget 251:9	268:20 368:4	211:7 212:2,14	324:20 331:6
412:17	forthcoming	213:4 237:16,21	332:10 338:4
forgive 377:12	413:22	247:22 260:4	341:14 371:19
form 24:10 33:2	forthwith 68:10	278:11 296:12	438:8 445:10
62:8 118:1 203:11	fortunate 60:13	306:8,13 386:3	476:19 480:17
249:2 320:2 330:6	fortunately 105:6	439:10,21 471:10	493:11
387:19 403:9	fortune 342:9	474:15,21 475:5	frameworks 88:3
426:8 450:2	430:16	483:16	88:17 478:9
471:16	forty 335:6	foundation 8:10	frank 127:1,1
formal 10:5 18:18	forum 393:1	14:19 15:5 129:20	328:12
18:20 20:16	forward 74:9 77:1	162:21 383:20	frankly 206:14
107:14 113:5	80:10 100:12,15	384:6,9,20 386:7	307:21 312:19
155:19 176:11,14	101:14,15 105:7	400:6,11,16	316:9
214:2 337:19	152:10 155:8,12	404:15 449:3	fraud 191:21
386:17 443:19	155:13 157:14	foundations 96:2	fraudulent 76:22
500:21	160:20 161:13	founded 42:17	188:11
formally 128:17	166:3 184:15	77:22 78:16	free 16:15 62:20
formation 58:13	195:18 203:22	founder 50:9	131:12 239:13,14
85:8 123:9	217:16 219:4	53:11 81:8 125:9	239:16,17,19
formed 35:1	267:22 282:8	293:19 347:10	286:1,2 305:13,19
107:11 427:7	291:16 293:2,12	447:5	309:22 327:11
former 95:16	295:13 320:19	founders 361:16	361:21 362:1
117:7 373:6	325:6 326:5 337:4	four 39:13 76:6	366:13,13,14,15
429:14,16 432:3	356:6 365:17	77:5 78:6 96:4	375:12 424:11
forming 44:10	386:19 428:21	191:4,5 248:4	467:1
122:22	429:6 433:17	249:15 250:5	freedom 252:22
forms 42:2 77:8	456:7 466:8	279:8 282:19	287:7
208:4 317:14	473:21 490:6	297:6 298:19	freely 379:20
338:17 371:3	493:10 498:18	318:14 352:10	french 15:4 400:6
373:13 388:21	500:10,10	402:12 413:19	400:7,9 405:14
403:15 405:10,12	foster 400:19	417:12,12 464:19	frenzy 381:22
405:16 424:22	fostering 47:21	fourth 92:7	frequencies
437:10 488:13	fought 458:3	109:20 190:3	198:14
		414:13	

frequency 198:21 198:22 199:18 454:11	fulfillment 497:8 full 12:21 67:19 68:5,17,19 69:2 96:11 108:21 113:10 148:9,13 148:18,19 154:19 228:17 229:12 233:20 234:2,3 242:8 275:4 276:9 277:4,10 279:5 292:12 293:19 294:3 303:18 305:15 306:14 307:13 308:1,4,6 310:1,5 324:3 366:9 370:12 371:20 376:20 417:13 418:4,5,8 424:7 427:21 485:22	485:10,15 funding 393:13 397:13 451:11 471:16 475:4 funds 147:17 fungi 330:6 fungicides 331:18 further 65:16 85:12 112:14 117:9 131:5,7 137:9 152:4 157:3 157:6 184:12 203:4,14,19,20 204:2 217:15 338:4 360:19 363:12 371:2 386:17 389:3 475:5,7 487:20 489:11 492:2 493:2 502:10 503:9	gamma 488:11 490:12 495:7 gap 8:9 129:20 272:1 295:9 gaps 34:20 35:2 65:5 176:19 269:19 386:14 455:9 garcia 7:8 95:14 95:15,16 garrett 15:8 413:4 413:6,10 gas 62:19 189:18 gastaut 140:17 338:17 447:15 449:3 gastric 389:2 gastroparesis 389:2 gateway 374:13 gather 90:16 195:18 218:4 220:4 386:7 gathering 219:2 geffrey 360:3 gel 327:21 genco 12:19 287:18 gene 202:10 general 22:16 115:20 169:10 197:8 198:16 199:1 227:20 228:3,5 238:11 258:14 300:4 360:22 438:12 439:19 443:3 496:2 generalinquiries 169:8 generally 30:1,21 31:3 32:21 51:19 120:13 133:5 145:6 151:9 167:3
fresh 279:20 280:5 freshleaf 276:11 279:16 friction 494:17 495:4 frictions 89:2 friday 1:14 friend 211:6 238:22 friendly 423:19 friends 39:4 125:12 127:5 275:20 frightening 382:4 front 5:7 23:22 50:6,9,13 354:15 fronts 376:21 fruit 150:22 frustrate 304:1 frustrated 96:16 frustrating 423:13 frustration 423:7 458:21 frye 261:8 fsma 146:18 342:22 363:16 372:3 fsvp 146:19 ftc 268:20 fubinaca 206:13 fuchsia 342:5 343:15 fuel 426:11 fulfill 146:15 fulfilling 500:15	fully 36:18 78:14 84:7 112:12 319:12 321:21 487:9,12,17 fun 248:18 250:6 function 29:22 67:17 71:14 86:6 86:7 121:14 174:19 177:10 270:3 273:10 281:10,11 300:14 339:16 391:19 functional 74:13 116:1 435:2 functioning 223:1 fund 214:10 412:11 fundamental 259:18 262:14 263:11 482:2 fundamentally 72:22 funded 204:17 451:9 483:17,22	furthurance 329:8 furthermore 135:19 202:8 397:10 451:22 future 135:2 152:14 160:10 162:16 219:4 272:3 355:10 362:20 375:4,22 377:6 383:15 408:4 493:13 500:10	g
	g 20:1 86:5 120:10 302:12 469:9 gabriel 7:10 98:9 98:11 gain 317:18 483:3 483:4 gained 275:11 galvanizing 307:3 gambling 381:20 412:9,12		

205:4 206:8 217:10 399:22 422:1 479:18 486:4,13 generated 50:15 230:1 439:17 generating 52:5 generation 472:20 473:2 475:13 generations 248:14 generic 351:13,21 448:19,22 generics 449:7 genetic 92:22 130:1 497:7 genie 119:22 genotype 267:9 gentleman 210:12 233:13 gentlemen 119:22 127:10 200:10 293:18 georgia 311:2 geriatric 138:5 getting 58:3 62:20 63:4 74:2 75:13 128:21 142:3 148:9,10 168:22 182:21 238:17 249:14 285:18 336:10 395:21 396:1 398:22 402:7 459:9 484:8 gfsi 363:16 gi 224:4 270:3 giancaspro 7:10 98:9,10,11 101:3 101:7 gidal 10:7 176:13 176:16,16 gifts 127:14 gill 11:20 245:13 245:14,14 250:22	252:9 girl 457:18 458:7 459:7 461:15 gitto 15:6 406:14 406:15,16 412:15 412:19,21 give 44:12 45:2 74:15 128:7,9 148:3 162:13,18 181:15 224:2 225:10 240:22 242:14,15 259:17 281:21 363:2 364:10 392:13 393:21 402:1 424:2 430:5 432:17 433:22 439:13 443:18 447:9 458:3 498:5 given 33:14 37:5 39:1,5 41:16 46:6 51:15 65:4 71:6 79:14 89:15 123:1 141:8 155:5 160:6 198:5 242:17 252:7 270:19 318:21 358:20 407:18 440:21 481:19 496:15,16 gives 287:8 421:9 432:12 giving 49:13 344:21 422:18 425:13 459:6 461:14 462:7 glass 450:5 glaucoma 473:21 474:3,3 glimpse 365:15 global 268:10 305:8 467:9 497:10 globally 73:13 233:16 334:15	427:3 glorifying 375:11 glucosamine 65:3 gluten 239:15,17 glycerin 205:12 glycol 205:11 gma 87:17 88:2 90:15 gmp 196:10 222:14 285:17 286:1 315:14 319:8 325:18 333:12 343:1 348:11 349:11 351:9 416:2 438:11 478:13 gmpe 159:17 194:6 218:3 337:6 348:13 349:8 416:6 gnatt 2:18 go 22:16 24:18 36:12 57:14 66:7 104:3 126:21 135:8 140:22 141:4,6 149:12 178:11 179:2,13 183:11 223:3 226:22 227:1 229:11,20 236:4,5 241:19 244:14 254:3 259:3 265:12 275:16 282:8 284:18 287:20 291:22 293:11 295:6 297:7,9,14 308:18 309:7 312:11 317:2 344:18 345:21 352:14 358:3 375:17 379:12 390:11 400:16 402:19 407:5,6 433:17	446:19 454:13 455:16 468:6 473:7,11 475:8 497:18 499:17 goal 45:12 88:11 112:15 123:6 253:14 317:21 326:1 386:9 423:18 462:14 goals 30:16 118:7 146:4 god 288:22 291:13 god's 127:14 goes 58:3 232:4 347:13 443:15 499:19 goggle 471:20 going 36:22 66:7,8 102:19 118:10 122:3 123:5 127:9 130:15 132:10 135:8 150:6 158:3 158:9 163:4 166:6 167:12 172:13 185:1 209:14 213:12 219:4 222:16 231:16 241:6 242:16 243:13,14 244:1,5 244:5 245:6,7 253:15,16,17 254:3,5 255:7,21 256:10,11,21,22 258:15 259:19 273:21 281:15,17 282:7 288:17,17 288:18 289:7,9,11 289:12,12 290:1 291:9,12,15,19 294:20 296:14 316:2 321:14 333:20 334:19,20 343:10,11,12,12 343:14,16 344:6
---	--	--	---

344:14,17 345:10	282:3 284:9	241:18 242:12	80:8 98:8 115:16
345:10,13,15	286:10 293:17	244:8,11 265:4,7	125:6 137:7
346:6,13,13,14,17	303:12 305:7	267:19 283:3	142:12 144:16
357:5 358:3	310:20 319:12	294:4 312:16	153:2 161:5 165:6
361:17 364:10	321:16 328:18	345:6 346:2	165:8 172:11
372:17 379:9	331:9 332:17	368:22 386:17	175:17 187:6
392:15,22 395:7	335:10 338:1	440:9	220:7 236:12
402:1 405:16	350:2 353:5	governments 52:6	242:20 246:4
406:20 407:5	356:16 361:8	157:17	254:18,19 274:9
417:22 420:12	366:2 368:11,17	grade 151:21	383:22 384:3
422:14 423:2	369:8 378:14	373:10 403:21	388:21 392:13
430:4 434:12	383:5 390:19	490:8,10	414:5 415:8,17
440:11 451:8	395:2,4 400:7	graff 15:8 413:4,6	418:11 432:8
470:5 475:12	406:15,19 413:7	413:7,10	481:13 488:9
498:4 499:10,11	414:3 419:8,9	graham 503:2,15	495:11
500:10	421:12 422:11	grains 171:16	greater 41:1 65:19
goldberg 3:2 22:6	425:10 429:10	grandchildren	190:16 211:21
22:7 174:22	434:21 456:20	208:22	318:20 334:21
goldilocks 304:19	461:4,17 466:21	grandmothers	339:1 456:11
goldstein 261:15	471:9 475:16	82:9	greatest 127:14
good 21:3,7,10,20	476:3 486:21	grandparents	131:4 383:2
22:1,6,9 26:14	498:19	483:6	greatly 110:20
37:17 42:16 45:7	goods 87:18 253:5	grant 10:9 181:13	466:14
47:19 53:22 56:10	255:3 338:11	181:14,17,18	greed 127:16
59:16 61:15 63:18	362:5 468:5	185:20 186:10	485:11
64:6 70:20 74:6	470:21	187:2,7	green 13:9 25:9
77:20 81:2,7	gotten 243:7 284:7	granted 93:6	95:19 317:6,11
87:15 95:15 98:10	326:19 336:4	319:5	319:4,19 385:15
101:21 104:15	gottlieb 97:9	grants 481:20	green's 317:10
107:4 111:9 119:1	117:7 162:9	graph 179:7	greenhouses
122:8 125:8	gottlieb's 433:8	gras 31:4,11,12	161:19
129:11 135:12	gourmet 53:11	44:12 102:16	greenwich 13:17
137:10,14,14	governance	103:15,22 104:4	456:21
144:20 147:7	486:16	152:2,22 167:4	grew 333:5 458:8
150:9 153:5	governing 306:10	217:20 273:7	grocery 7:3 87:17
155:21 166:10	332:7 369:9	323:14 356:2	96:18 153:10
173:4 176:16	government 4:20	grasp 267:22	groom 375:4
187:19 192:3,7	9:14 11:11 18:10	grassroots 48:4	gross 43:14
195:20 204:6	18:19,22 42:15	grateful 259:4	259:11
209:19 221:10	56:22 63:10 80:16	460:1	grossly 242:12
223:8 234:15,22	109:6 133:2	gray 228:21 290:4	ground 312:6
244:13 246:10	155:16,20 160:15	291:6,21	grounded 435:17
252:17 254:1	165:4 166:14,15	great 24:8,14 44:5	grounds 75:18
255:7 268:8 277:8	175:12,13 227:12	48:17 60:20 68:14	

<p>group 8:3 14:3 15:9 20:14 21:6,9 21:14,19 35:2,4 45:9 47:8 60:7 70:17 111:6 119:3 124:20 145:3 179:21 252:20,21 268:16 294:1 353:7,9 354:14 360:5 385:6 387:15 394:2 413:11 420:9 421:4</p> <p>groups 62:2 145:17 410:14 420:18 452:11 453:1</p> <p>grow 7:9 44:1 74:5 91:1 95:17 116:10 119:8 153:16 229:1 290:10 307:1 316:10</p> <p>grower 369:8 486:9</p> <p>growers 49:18 161:16 233:3 283:22 284:3 286:11</p> <p>growing 38:2 49:5 116:17 154:7 160:19 161:15 170:8 252:11 297:17 302:14</p> <p>grown 40:13 45:15 46:19 146:7 161:18,19 403:10 427:12</p> <p>growth 43:22 119:12,21 163:15 230:18 233:4 304:22 307:4 492:16</p>	<p>grubb 13:6 310:19 310:20 315:21 316:9</p> <p>gruesome 458:19</p> <p>guarantee 312:18</p> <p>guaranteeing 319:9</p> <p>guess 9:7 55:12 147:5,7,8 149:22 150:4 199:10,14 326:12 340:21 400:15 405:11 447:3</p> <p>guests 361:9</p> <p>guidance 49:18 74:3 83:21 104:22 108:7 113:4 121:11 130:17 163:12 165:20 239:15 323:10 324:9 331:8 337:5 363:15 371:10 381:4 386:17 413:16,20 418:22 420:19 423:3,21 424:2 427:10</p> <p>guide 25:8 145:19 241:1 386:16 411:2</p> <p>guided 486:13</p> <p>guideline 56:4,7 315:2</p> <p>guidelines 39:5 53:19 95:7 120:9 218:17 265:9 266:6 272:5 314:1 314:13 330:21 331:11 349:11 350:9,10 351:9 352:21 363:5 364:6 366:12 369:16 370:4 372:3 394:11 411:7 425:1</p>	<p>guiding 222:5 307:4 327:19</p> <p>gulf 67:3</p> <p>gummies 96:20 164:18</p> <p>gummy 34:18 341:4,5 469:9,10</p> <p>gurley 10:12 187:9,10,15,21 192:14 193:6</p> <p>guthrie 12:10 268:6,8,9 273:20 274:7</p> <p>guy 13:2 127:4 298:6,18</p> <p>guys 56:10 187:15 214:13 243:21 249:10 287:17 290:21,21 291:10 291:20 292:16 308:18 321:14 346:6 409:4,21 486:14 498:12</p> <p>gw 338:2,21 340:1 340:1 358:14</p> <p style="text-align: center;">h</p> <p>h 16:9</p> <p>habit 122:22</p> <p>haccp 146:19 342:21</p> <p>halal 342:19</p> <p>haley's 403:9</p> <p>half 59:8 116:15 159:13 246:5 250:7,8 251:12 260:9 274:19 281:3</p> <p>halfway 282:4</p> <p>hallucinating 209:3</p> <p>hallucinations 206:6 209:13 374:17</p>	<p>hammer 14:11 366:4,6,11,15 368:19 370:3 371:22</p> <p>hampshire 1:18</p> <p>hand 23:18 38:19 92:3 361:17 379:13,13 433:5,5 475:3</p> <p>handicapped 295:10 472:4</p> <p>handle 150:8 289:6 418:2 448:9</p> <p>handling 427:18</p> <p>hands 127:22 147:21 296:18</p> <p>haney 220:14 223:20</p> <p>hang 245:19</p> <p>hanging 150:22</p> <p>happen 39:7 377:13 383:10 397:19 405:21</p> <p>happened 62:13 136:13 149:16 336:6 422:21 423:16 500:5</p> <p>happening 182:22 246:17,18 255:4 397:9 420:9,14 422:22 441:15 475:11 495:4</p> <p>happens 34:18 160:12 234:12 238:14 292:5 402:19 494:20</p> <p>happiness 481:22</p> <p>happy 217:11 399:13 434:16</p> <p>harbor 396:20</p> <p>hard 57:15 74:15 121:20 127:4 206:17 212:9 321:15 334:2</p>
--	--	---	---

360:6 430:7 harken 178:4 harm 39:8 99:16 100:14 123:20 160:11 173:16 257:2,10 276:22 387:14 harmed 374:21 harmful 46:14 59:12 60:1 99:20 257:13 374:16 410:7 468:7 490:13 harming 42:10 373:11 harmonization 331:10 harmony 497:20 harms 58:5 60:13 harness 127:21 harpc 342:21 harry 487:1 harsh 131:12 harvard 17:5 26:10 173:18 harvest 229:3 harvested 43:16 harvesting 497:7 hassan 59:1 hassel 5:18 59:2,4 59:4 61:7 hauser 15:10 476:2,3 481:11 hazard 428:2 hazards 60:6 head 92:11 282:12 355:11 375:8 headache 70:9 138:22 headaches 261:12 275:14 300:20 headlines 207:21 headquarters 347:15	health 5:17 7:13 12:5 14:3 17:5,5 18:12 19:3 26:4 29:10 30:17 35:11 38:11 42:10 49:2 51:16 54:6 58:18 58:20 59:9,12,17 60:6,6,21 61:3 62:3 65:4 68:3 71:16,20 72:22 78:16 79:1,10,19 80:1 88:18 90:7 94:3 98:20,20 99:10 100:6 101:20,22 104:20 108:6 110:2 122:15,19 123:22 124:10 126:12 127:15,21 136:22 138:3 145:13 146:16 156:18 157:12 160:3,3 164:20 173:15 174:5,8 175:9 180:4 186:22 188:19 191:21 196:9,9 198:7 213:19 221:17 223:4 225:2,7 244:9 245:15 247:1 253:5 256:17 258:21 259:1,14 260:10 265:18,19 268:10 273:4,9 282:5 295:19 313:20 329:9 332:6,13 344:8,10 353:7,9 353:15 354:14 358:2 361:4 365:3 366:17,22,22 367:4 368:6 369:19 381:20 386:15 393:13	397:15 399:12 400:17 407:9,18 408:6 409:15 415:18 433:16 439:20 451:16,20 454:20 455:19 456:3,4,4,6 460:21 461:13 468:3,16 470:20 471:2 472:15 473:8 477:1 483:22 487:2 493:12 healthcare 6:13 57:20 76:1,3 135:21 181:10 192:18 461:8 499:21,22 healthier 46:19,20 46:21 healthy 215:13,14 272:11 325:3 359:4 364:15 388:13 398:7 399:1 hear 20:10 91:10 96:7,14 102:22 129:8 181:17 187:18 246:12 252:2 298:10,14 383:21 398:4,4 435:3 448:15 473:16,18 474:17 496:18,19 497:1,4 heard 58:10 128:7 129:10 166:1 171:14 233:20 274:20 278:14 326:15 334:18 358:4 396:5 397:17 401:21 405:22 408:15 409:19 447:16,20 447:20 448:10,17	468:8 470:9 472:6 488:20 492:2 497:6,10 498:10 498:11 hearing 1:11 20:6 20:9,13 22:18 23:5,8,9 24:1 26:16 35:3 36:8 42:21 72:19 119:3 148:7 150:13 156:6 163:22 165:22 187:12 209:1 290:12 329:1 361:13 379:13 381:17 383:4,15 405:10 457:8 501:4 hearings 22:20 heart 150:12 300:15 351:1 472:18 heartrate 271:12 heat 491:2 heated 124:9 heather 16:12 462:4,8 heavily 303:8 343:2,2 412:8 heavy 60:10,11 70:1 72:4 102:22 234:10 237:13 278:14 306:9 312:4 319:15 330:6,10 335:20 345:14 352:2 357:19 362:2 363:22 372:8 417:1 428:11 442:21 480:4 heightened 489:5 heinous 260:10 held 132:3 147:21 329:10 438:7
---	---	---	--

<p>heldreth 9:9 150:6 150:8,9 152:21</p> <p>hello 66:22 72:13 245:14 259:3 274:12 303:4 317:2 406:15</p> <p>help 24:11,16 25:4 27:7 30:18 33:5 34:22 36:7 39:8 47:14 49:19 50:1 97:8,15 99:6,9,13 99:15,18 100:14 100:14 110:2 128:18,22 130:15 139:7 151:16 197:2 208:6 214:12 248:20,22 252:13 266:5 286:9 288:4 294:18 297:3,18 317:18 355:16 386:22 387:2 391:13 426:19 432:6 446:11 466:9</p> <p>helped 250:3,7 276:20 431:22</p> <p>helpful 69:12 87:7 104:22 219:3 243:10 246:14 249:18 256:10 352:16 387:3 420:20 424:1,21 486:6</p> <p>helping 67:4 260:9 384:17 413:15 495:17</p> <p>helpline 193:9 197:7</p> <p>helps 79:22 186:3 479:11</p> <p>hemonc 334:4</p> <p>hemorrhage 203:4</p>	<p>hemp 4:22 5:3,5 28:19,22 29:2 31:13 34:4 42:18 42:20 43:2,13,16 43:16,19 44:2,4 44:11,16 45:1,6,8 45:12 46:5,18 47:9,17,19,20 48:3,4,13,18 49:7 49:11,14,19,20 50:11 53:13,15 54:18 67:1,4,19 68:6,18,21 71:3 76:10,18 78:5,7 78:14 79:8,11,19 81:12 82:2,14,15 82:19,21 83:1 84:14 96:9,12 102:8,9,12,14 103:4,8,9,10,10 103:13 105:7,16 105:18 106:3 107:21 111:16,16 112:2,14 116:9,13 119:17 132:16 145:6,16 146:6,14 147:1,11 150:21 151:2,3,4,11,18 152:11,19 153:15 153:15 155:4,4 160:16,19 161:15 165:18 168:6,13 168:13,14,19,22 170:2,8,10,13,14 170:14 171:15 210:4,8,14 211:2 211:3 213:19 226:8 233:3,3,4,9 233:10 240:4 272:20 273:13 295:18 303:7 304:1 307:22 316:10 321:18 322:15,17,19,20</p>	<p>322:22 323:2,11 323:14,16 324:3,9 324:16 325:8,10 325:11,12 326:1,3 327:1,2,3,14 334:12,12 347:11 347:22 351:16 352:2 353:10,10 353:19,21 354:9 355:2,6 356:3,6 356:19 357:12,15 361:22 362:10,13 362:16,21 364:14 366:7 367:13,20 367:22 368:7,8,9 368:15,21 369:3,5 369:12,16 370:2 370:22 371:14 392:2 393:4,5,6,9 393:15,20 394:16 395:18 411:19,20 413:13 414:11,19 415:7,15,19 416:6 416:11,22 417:6 417:13,14,16,17 418:9 424:9,9 427:14 428:14,15 432:19 433:3 440:15,15 469:2 479:2 485:22 487:21 488:4 489:15</p> <p>hempseeds 45:13</p> <p>hepatic 270:18 272:6,13</p> <p>hepato 359:22</p> <p>hepatocellular 174:19 201:5,6</p> <p>hepatotoxic 139:3 141:20</p> <p>hepatotoxicity 203:15 360:5 397:3 398:9</p>	<p>herbal 7:19 98:12 111:7,11 123:10 205:16 463:8,9</p> <p>herbicides 331:17</p> <p>hereto 502:12 503:11</p> <p>heroin 174:3 374:12</p> <p>hey 248:15 250:15 252:16 276:14 292:20</p> <p>hhe 396:11,19 397:19</p> <p>hi 40:3 129:18 135:12 157:16 173:4 235:8 287:17 298:8,11 321:10 383:21 399:14 451:2 476:3 481:7</p> <p>hia 49:16</p> <p>high 13:21 45:20 46:2 49:12 50:11 51:9 61:1 68:5 82:21 107:21 124:4 175:2 184:11 201:15,22 202:11 206:2,6,17 207:2 208:17 209:7 212:12 215:1 230:2 242:21 271:1 276:5 283:16 304:10 317:16 325:10 333:13 334:15 347:10,10 362:7 365:7 366:12 375:2,6,9 376:14,15 390:9 390:13 395:22 401:18 406:20 423:10 429:2 453:3,4,19 455:4 455:5,11,19 465:5</p>
---	--	---	--

474:18 483:15 487:18 488:1 492:14 higher 75:2 109:5 115:9 152:18 200:6 212:22 213:3 251:1 271:5 299:16,18 301:6 363:13 365:8 371:10 390:5,6 410:1 418:17 455:20 470:14 highest 132:3 238:4 364:9 365:19 366:16 377:3 highlight 208:19 209:20 212:6 379:15 highlighting 83:15 highlights 201:9 highly 38:14 73:3 173:13 237:17 323:21 324:5 hinder 43:21 128:19 163:15 hip 38:7 hippocampal 485:18 hire 382:21 hired 463:19 histomorphologi... 201:20 historian 173:5 historic 72:17 124:11 history 43:8 54:20 72:18 246:22 332:6 391:15 407:19,21 426:15 500:3 hit 44:3 52:5 102:18 288:11 295:13 297:10	390:12 hits 238:7 hiv 223:22 hmm 280:4 hoban 15:9 413:11 hold 38:4 149:10 149:13 267:13 295:13 354:5 holding 42:21 88:7 457:15 holdings 15:21 holds 408:5 467:7 holistic 73:2 holistically 324:19 hollister 359:6 holmes 70:17 holyoke 5:19 59:2 home 43:8 92:9 107:19 108:14 109:4,20 243:14 373:8,21 389:10 486:8 499:4 homeland 342:18 homeostasis 485:5 homes 375:18 377:14 467:17 hometown 467:16 homogeneity 465:19 honest 72:19 199:2 honor 81:9 200:11 361:10 honorably 288:2 honored 429:11 honors 429:15 hope 36:6 44:6,7 143:2 152:9 178:12 196:21 285:3,7,16 338:15 365:13 377:17,17 403:9 471:12 hoped 63:9	hopeful 157:10 hopefully 37:4 172:22 228:6 251:5 hoping 124:16 293:11 hopkins 4:18 11:3 11:8 40:1,5,6 209:22 211:11 hops 151:6,8 horizon 63:8 horrible 260:11 404:21 448:5 horribly 406:7 horror 473:1 horses 64:18 83:15 84:18 86:16 171:6 hospital 92:3 hospitalized 373:19,22 hosting 119:3 160:8 361:13 hot 417:20 hotel 417:3 hour 306:1 318:15 hours 20:16 41:8 173:17 223:13 275:12 297:21 298:1 299:12 318:15 house 92:9,10 254:9 348:16 349:14 370:16 377:17 housed 490:9 household 88:6,15 152:3 252:13 houser 476:4 houston 263:21 373:7 howard 7:12 16:20 101:19,21 101:22 103:6,18	104:8 242:4 hpp 342:20 345:2 345:3,5 huge 52:10 71:17 156:8 hugely 122:13 hugh 174:5 175:8 human 31:14,21 50:14 64:3 66:3 71:5,14 126:9,12 136:9,12 146:14 154:6 174:2,6 192:19 197:3,5 202:6 259:10,13 259:14 271:10 357:5 360:8 369:7 370:21 389:19 397:7 474:14 482:3 484:1 488:21 humans 54:6 67:22 145:9 202:3 210:19 358:12 475:11 humble 326:22 humectants 205:10 humidity 315:6 hundred 27:1 74:20 107:11 161:22 221:18 289:7 299:21 300:8 417:21 453:17 hundreds 22:17 54:13 290:17 431:13 hung 375:21 hunter 5:2 45:6,7 huntington 359:8 hurdles 94:19 150:18 283:1 hurry 297:6
---	--	---	---

hurt 375:22	identified 37:7,8	366:20 367:9	imparted 400:3
hurts 58:7	141:11 143:14	459:5	impartial 443:10
husband 96:4	236:15 321:4	illnesses 338:6,21	impartiality 444:3
374:19 457:5	439:8	imagine 51:2	444:12 445:5,14
hydrocarbons	identify 25:4 47:9	129:20 151:2	impede 117:11
465:2	106:7 306:5 393:4	334:2 395:6,7	imperative 65:12
hydrogen 59:19	444:6 474:8	458:15	296:21
hydrogenate	identifying 352:14	imitations 449:17	implement 47:3
232:11	369:16 387:16	immad 16:17	97:22 112:12
hydrogenated	463:6 472:7	471:14,14	290:8 466:8,9
230:17 234:21	identity 99:7,11	immeasurable	implementation
hydrogenating	163:9 167:19	68:8	53:22 368:20
234:17	273:13 315:14	immediate 407:2	445:20 478:10
hydrogenation	324:7 325:13	immediately	implemented
230:6,13,14	331:15 353:20	121:22 214:7	117:16 145:22
232:20 234:1,13	355:19 368:2	immune 86:6	362:11 408:21
234:14,16	369:12 438:4,17	93:15 262:21	415:19
hygiene 487:3	438:18	270:2	implementing
hyperemesis	idiopathic 472:11	immunocompro...	123:11 194:7
173:11	ids 479:4	380:4	367:7 487:5
hypertensive	ignore 293:6	immunosuppres...	implications 180:5
280:17	ignored 244:3	180:18	425:3
hypotension 388:6	igor 10:9,17	impact 43:11 52:1	implicitly 312:3
hypoxic 269:5	181:13,18 200:9	52:10 66:3 108:15	438:6
i	200:12	128:14 204:20	implied 65:9
ian 129:16,16	ii 93:4 282:19	226:6,12 266:1	import 287:2
iceberg 203:18	298:20 299:3	288:7 290:11	297:12,16 425:3
ich 314:1,13 315:1	301:10 484:19	293:13 301:21	439:4
idea 56:10 123:16	iii 93:7 142:21	332:2 428:4,10	importance 44:16
158:4 184:11,20	284:15,17 286:13	467:14 491:11	88:18 143:5
207:14 225:5	286:15 360:17	impacted 82:7	important 27:8,11
253:15 254:21	ilac 445:1 446:20	impacting 71:13	29:10 30:10 31:20
257:2 266:3 285:8	illegal 226:19	impacts 156:18	32:21 34:20 36:9
285:22 286:3	243:22 344:1,20	157:12 173:10	36:17 38:10 49:22
288:3 352:13	344:20 354:7	178:6 219:14	52:2,14 53:10
355:15 386:16	421:11 423:5	468:9	72:8 77:4 97:12
448:16 467:18,19	431:10 432:16,19	impair 211:13	107:19 110:8
468:12,14	433:19 500:7	impaired 215:1	112:4 115:14
ideal 341:12 405:6	illegally 355:2,5	376:7 473:10	119:5 142:20
ideally 258:15,16	430:20,20	impairment 41:1	155:5 157:15
ideas 309:16	illinois 146:2	174:18 211:16,21	160:21 177:18
ideation 174:18	377:18 430:10	212:4,16,19 213:2	178:16,22 179:13
identical 106:2	illness 57:18	270:18 272:6,13	179:20 180:17
151:10	242:20 243:1	471:14	181:4 209:21

211:2,18 212:4 213:12 220:18 223:15 240:3 247:18 249:4,7 250:13 251:1,3,12 254:4,7,15,20 255:20 256:20 257:1 261:16 262:2,14 268:1 288:17 302:6 303:17 306:4 313:12 314:12,14 331:16,20 334:13 339:5 352:22 356:5 365:13 378:15 388:14 391:19 397:17 398:21 404:9 405:1,4 408:6 435:16 448:12 457:2 460:21 480:21 486:3 488:19 490:16 491:19 importantly 40:18 178:9 417:18 487:9,12,18 impose 409:12 impossibilities 477:22 impossible 120:1 333:4 356:10 398:1 impressed 276:4 483:20 impression 112:9 125:19 improper 330:9 497:3 500:12 improperly 500:14 improve 132:6 352:7 473:8	improved 182:17 326:20 473:11 488:6 improvement 28:18 93:3 261:13 313:15 improvements 43:17 67:16 improves 224:3 improving 98:20 impurities 138:13 312:5 314:2,19 331:17 487:19 impurity 459:14 inability 130:3 223:2 inadequately 459:17 inappropriate 212:20 incapable 60:4 incentive 137:8 incentives 128:20 137:5 339:1 410:3 incentivizations 409:20,21 incentivize 95:1 435:11 incentivized 490:4 incident 200:3 incidents 193:18 220:1,2 430:21 431:12 incisions 494:15 494:18 include 30:5 38:17 47:6 68:11 74:19 99:22 120:6 121:13 135:2 144:11 167:6 174:18 183:17 194:6 196:10,16 239:4 256:18 262:7,18 269:15	273:12 308:7 330:5 357:7 385:11 442:20 445:18 450:10 476:10 479:2 included 25:17 28:12 34:1 64:14 316:1 435:9 455:6 492:12 includes 31:22 173:21 182:18 192:20 195:13 250:19 372:10 432:3 443:8 including 23:3 27:14 29:11 30:14 34:7,9 36:5 38:14 41:14 45:21 49:2 49:20 67:13 69:12 71:4 84:4 89:5 99:5 107:9 111:16 117:6 118:14 134:3 143:10 145:6 153:9 154:3 156:18 157:12 165:17 173:22 174:3 180:19 182:8 183:3 184:17 192:22 194:12,21 195:12 196:1,12 224:22 293:1 305:22 318:2 368:8 369:17 376:10 379:6,8 397:6 414:17 430:9 463:10 465:15 478:18 479:10 482:6 488:18 492:18 inclusion 143:13 144:3 272:20 income 289:15	incoming 220:16 348:14 incomplete 160:13 inconclusive 135:20 inconsistencies 265:7 inconsistency 349:15 incorporate 146:17 incorporated 59:1 293:20 incorrectly 47:3 335:6 increase 67:11 74:1 77:2 181:1 204:22 223:10 224:4,20 404:22 470:8 473:19 increased 143:21 364:12 374:18 458:1 473:15 increasing 75:4 160:19 182:10 224:21 410:3 420:5 423:1 increasingly 452:10 478:9 incredible 51:4 259:4 321:6 incredibly 397:16 ind 77:9 93:1 216:19 217:7 226:22 418:19 435:8 436:6 indefinite 436:3 independence 445:5,9 independent 63:1 98:19 283:12 295:2 319:9,16 329:22 436:20 443:8 446:7,18
--	---	---	---

451:4 462:14 479:6,8 489:20 indeterminate 190:11 191:2 index 180:1 indiana 479:1 indicate 272:5 397:5 453:18 indicated 90:4 454:4 indicates 108:16 109:9 190:5,6 indicating 479:19 indication 382:3 397:3 indications 90:21 93:19 274:2,3,4 328:8 491:4 indicative 68:1 91:1 indicators 67:14 indicted 454:11 individual 147:10 152:19 163:13 243:11 246:13 311:14 437:1 451:16 456:4 461:12 488:2 individually 437:13 individuals 136:16 137:1 149:11 224:1 384:11 388:2 401:7 404:6 452:16 inds 225:18,18 induced 202:16 242:19 339:14 376:5,6,11 inducing 178:6 203:14 industrial 4:22 42:17 53:15 82:2	161:15 227:15 361:22 362:10 366:7 367:13,20 367:22 368:7,8,9 368:14,20 369:3 369:12 370:2,22 371:14 395:18 428:14 487:20 industries 48:4 110:2 133:19 227:18 306:19 322:21 412:8 413:13 415:9 427:14 industry 7:17 11:19 38:2 42:20 43:9,20,22 44:16 45:1 46:18 48:1 50:3 52:4,17 53:14 59:7,20,21 60:3,14,19 65:15 73:12 74:5,11 83:19 85:8 87:20 95:18 96:6,22 97:11 103:21 107:2,6,22 108:16 109:21 110:18,20 119:8,20 121:18 121:21 145:17 147:18 151:14 153:9 155:9 161:15 162:8,22 163:1,7,7,16 165:20 166:1 168:1,16 169:2 170:9 174:14 175:19 200:16 204:1 209:6 228:8 230:9 231:9 232:4 240:16,19,22 241:5,7,9,13 242:1 243:4 244:15 254:16 256:4 266:5	290:20 291:2 294:14 296:22 297:2,14 307:5,15 321:21 322:4,12 323:10 344:4,6,7 346:5 347:19 348:8 351:12,20 352:8 357:11 361:9 362:21 364:4 365:2,15 366:17 367:7,13 367:13 368:18 369:2 370:3,22 371:6 373:12 375:4 376:12 377:4,5,19 379:5 410:13 411:20 420:9,18 425:19 426:3 427:6,15,20 428:19 432:4 433:20 435:2 437:15 440:22 463:6,17,21 466:6 478:1 485:15 497:15,16,17,18 498:12 499:3 industry's 47:20 49:12 168:5 ineffective 382:22 inevitable 307:4 infantile 447:14 infection 221:7 infections 330:10 inflammation 71:11 inflammatory 269:4 484:8 inflicted 174:14 influence 175:18 183:20 482:21 influenced 35:18 175:20 influx 141:16	inform 27:7 40:9 41:18,21 42:1 135:2 214:13 221:9 426:19 456:5 information 1:8 20:4,19 25:19 26:17 32:6 61:3 65:5 69:7 71:8 73:16 75:8,13 77:15 81:17 86:20 87:6,9 90:12,16 97:16,18 98:2 100:4,7 101:10,12 103:16 115:3 118:12,14 135:1 144:8,11 151:22 152:12,14 158:2 158:14 162:9 165:3 169:18 172:3 183:3 185:3 185:4 193:22 195:19 197:1,8,11 197:15 198:5 200:17 225:21 228:11 256:14 266:17,22 267:3,8 267:15 279:11 287:8 296:15 297:22 305:22 313:5 361:19 390:10 405:1 415:1,13 454:10 456:12 461:9 462:18 479:3,10 483:17 informational 491:5 informed 36:3 76:9 88:3,22 110:8 123:16 162:13 173:20 175:1 369:1 380:16 383:11
--	---	---	--

461:10 informing 162:8 infrastructure 348:2 363:13 364:11 426:12 infused 72:15 156:15 168:17 170:4 171:3 257:11 258:2 303:10 367:8,15 367:18 432:14,15 495:1 ingest 257:12 340:17 ingested 41:6 75:14 306:1 469:6 ingestible 154:3 ingesting 382:2 ingestion 41:8 156:18 366:10 371:4 ingram 216:21 ingredient 45:13 71:13 74:19 77:16 81:18,21,22 105:13 112:21 153:18 167:1,8,15 167:18,19 168:2,5 169:9 171:19 207:12 268:15 269:13 303:7 310:22 311:7 314:21 324:15,16 324:17 325:16 350:5,7 352:19 355:19,21 364:19 365:5 368:9,12,14 368:17 369:17 436:9,12 440:4,5 441:11 496:21 497:22 ingredients 29:12 31:6,13 51:4 53:20 73:15 112:2	121:17 153:21 157:1 166:18,22 167:10,14 168:7 169:13 188:16 216:12 272:22 306:10,11 323:3,4 323:6,11,14,17 325:13 348:4 353:21,21 354:1 354:10 355:7 356:4,7,8 362:4 365:1 372:6 380:9 380:11 396:8 416:19 431:13 438:16 459:14 479:4 inhalation 299:1,1 302:2 366:10 371:4 388:18 inhaled 41:2,4 124:9 185:16 299:21 313:10 inherent 91:2 105:18 106:19 inherently 411:21 inhibited 178:17 inhibition 177:17 180:12 271:16 359:20 initial 393:19 422:21 436:11 initiated 85:8 initiating 196:2 initiative 49:12,22 305:9 367:3 injuries 67:20 401:8 injury 174:19 201:5,6,14,19 202:16,21 203:12 339:14 404:6,13 innate 259:12 innovation 90:22 252:22 266:2	304:12 407:10 innovators 295:9 innumerable 152:2 input 162:22 inquirer 336:8 inr 180:3 insert 130:8 insertion 488:8 494:17 495:5 inside 120:2 236:10 276:6 insight 317:18 insights 89:9 insist 439:14 insomnia 318:2 inspected 441:7 inspecting 463:17 inspection 331:8 346:2 438:11 478:13 inspections 171:2 366:22 367:5 478:8 inspectors 463:20 inspects 369:6 inspired 237:1 instability 450:18 instance 77:2 87:2 190:15 206:12 instances 190:8,17 191:5,5 312:22 353:20 481:8 institute 9:12 12:13 14:21 26:6 153:4,8 204:17 242:5 282:7,13 295:1 390:21 420:2 451:4 instituted 32:3 106:13 141:19 institutes 78:22 institutions 95:22 187:4 264:1	418:17 instructed 339:15 instructions 479:20 instructor 378:21 insufficient 125:20 136:1 159:20 160:13 insurance 229:6,8 410:12 intake 143:20 223:12 224:4 301:14 integrate 264:5 266:5 integrated 160:11 197:18 264:7 317:21 332:22 333:1 366:4,7 370:8 integration 319:17 integrity 38:6 131:7 193:7 341:15 366:13 380:21 408:18 intellectual 264:16 intelligence 259:12 intend 223:3 345:9 intended 29:20 48:12 64:9,20 65:4 86:3,4 102:9 105:9 117:21,22 118:16 120:13 167:20 204:8 272:3 313:7 315:11 324:15,18 324:21,21 339:22 436:5 471:18 480:18
---	--	---	---

intending 118:17	interested 71:1	internationally	invariably 65:19
intense 76:17	100:17 107:16	253:8 293:7	invention 294:14
116:12	123:15 169:9	443:10	inverse 410:13
intensity 275:17	170:10 252:12	internet 39:4 92:1	invested 161:21
intent 111:15	334:7 502:12	207:18 211:8	347:19 460:2
112:13 113:4	503:12	237:2 243:7 346:1	investigate 435:20
intentionally	interesting 184:5	interplay 421:9	436:1 475:5,7
65:17 382:21	238:21 239:14	422:19 423:11	investigated 102:8
interact 34:15	326:8 336:3 359:7	interpretations	investigating
144:2 398:5	interestingly	477:12	493:8
interaction 93:14	178:20	interpreted 114:9	investigation 32:3
180:10 202:1	interests 46:11	341:3	94:13 196:14
203:13,20 217:14	102:4 365:15	interrogate 493:3	226:5 367:9
271:15 278:1	435:10	interrogatory	480:10
404:14 420:16	interface 267:6	241:3	investigational
interactions 67:18	interference 482:6	interrupt 23:12	93:2 94:18
74:17 124:1,3,14	interferes 271:7	25:14	investigations
131:7,11 139:3	intergovernmental	interruption	106:13 195:11
141:20 143:8,11	2:6 22:2	150:2	199:7 367:5,6
143:15 144:12	interim 112:19	interstate 27:20	investigative
177:17 178:3	397:20 413:20	31:22 159:8	245:15 480:12
181:7 225:16	intermediary	423:19 424:18	investigator
271:16 277:16,22	424:15	intervention	366:21 367:4
339:19 359:18	intermediate	193:18 374:8	investigators
382:6 405:2	372:6	439:20 497:11	143:19 183:10
459:11	internal 21:6 35:2	intoxicating 43:2	189:8 283:7
intercellular	133:17 282:11	80:19 104:21	investing 49:9
269:21 270:7	international 2:7	122:21 323:1	303:7
interchangeable	10:15 11:17 14:21	intracranial 271:5	investment 247:12
307:16	15:13,19 22:4	intranasal 270:14	304:12,22 326:19
interdependencies	47:6 95:17 109:3	intrastate 71:18	investments
383:13	110:19,20 134:17	411:13	246:16
interest 4:16	192:13 235:10	intricate 383:12	invitation 481:17
26:20 27:2 33:14	322:17 330:20	intrinsic 123:1	invite 499:5
33:20 37:11,19	331:10 335:18	introduce 20:22	inviting 481:16
45:16 74:1 76:18	347:16 379:5	25:21 287:20	involve 93:11
88:14 89:21 94:3	390:22 391:15	326:21	involved 48:2
154:12 164:3,5	423:2 425:12,18	introduced 122:11	58:11 171:22
171:10 200:21	426:3 427:4	379:22	283:3 334:6
246:4 247:3	442:15,18 443:2	introduces 46:14	393:14 413:14
301:11 345:12	451:3 467:7	introducing	419:22 420:13,22
420:5 432:10	international's	488:10	483:12
435:17 445:15	145:3	introduction	involvement
453:5 497:9		454:8	181:10 391:16

involves 456:1	issue 32:16 38:8	issuing 170:5,7	johns 4:18 11:3,8
involving 106:13	53:10 62:3 91:2	433:11	40:1,4,6 209:22
ionization 189:19	102:11 103:9	it'd 80:22 86:19	join 26:11,22
iop 473:19 475:6,9	112:19 113:3,4	309:19 310:5	36:16 57:13
ip 264:16 355:17	115:13 121:11	it'll 297:22	440:10
419:13,15 421:18	141:14 155:5	items 154:4	joined 38:7 173:1
irb 227:1 333:16	157:15 160:21	304:16 455:12	361:16 501:3
453:10	193:5 194:21	iteration 319:3	joining 26:15
ironically 440:1	218:15 242:13	iupac 447:22	172:20 282:4
irony 441:8	244:16,18 253:8		482:17
irrational 373:14	263:7 268:2	j	joint 65:4 248:17
irrelevant 228:14	272:22 284:14	jaelyn 11:16 235:5	249:1 250:4 358:2
irrespective 436:1	292:14 302:7	235:8	454:1 469:5
irresponsible 85:5	334:17 340:5	jacqueline 15:4	jolly 6:8 70:18,20
242:12 353:17	388:1 389:1 396:4	400:6	70:21
irresponsibly 85:3	398:1,1 405:14	jama 40:21 334:21	jon 50:6,7
irritability 223:10	436:20 449:19	335:9	jonathan 5:4,6
irritate 492:19	457:8 471:3,3	james 6:10 7:4	47:17
irvine 274:14,15	480:14 487:10	14:4,18 16:8	jones 61:11,12
ischemia 269:6	492:1 500:7	72:11,13 91:6	joseph 9:20 161:6
ischemic 484:7	issued 32:17 35:8	356:15,16 383:19	josh 13:4 303:3,4
ish 206:10	60:11 109:18	384:5 456:18,21	journal 483:9
iso 133:21 135:5	121:4 463:9	january 236:20	journalist 245:16
291:3 363:9 372:1	464:16	247:14	journals 312:16
378:21 490:9	issues 38:17 71:16	jaqueline 400:9	journey 461:13
isoform 180:13	72:5 119:5 146:5	jarilyn 2:14	joy 399:20
isolate 148:10,20	147:18 150:15	jason 4:21 42:14	julian 6:16 81:5,7
230:1,12 234:6	151:1 163:17	42:17	july 27:6 53:2
277:5 289:1	193:6 194:12	jeffrey 15:6	66:9 104:7 109:17
303:18 305:15	196:15 217:3,3	406:14,16	110:15 124:17
307:19,21 350:20	218:12 236:15	jerry 12:8 263:17	164:2 368:5 501:1
372:15 410:11	253:19 263:8	263:18	june 49:3 422:3
417:14	264:12 278:11	jersey 244:9	448:11
isolated 58:1	280:22 290:22	jet 426:11	jurisdiction 27:21
106:21 292:11	291:11 343:8	jin 61:10	139:22
323:22 326:22	349:3,9 351:11,11	job 1:20 51:2	jurisdictions
327:1,10 418:9	387:4,17 398:22	236:1 321:14	90:13 253:11
isolates 84:7 124:5	399:15 417:22	437:16,17 463:19	justice 121:4
418:8	421:9 423:13,14	498:19	204:18,20 205:2
isolation 232:14	428:15 440:14	jobs 43:12,18 45:2	429:14
232:15 234:4	477:9 496:15	52:7,8 108:21	justification 65:2
israel 293:7	497:1 499:16,16	208:16	justify 258:8
israelsen 104:11	499:17 500:11	joe 161:8	436:3
		john 16:14 466:20	
		466:22	

justin 12:18 287:15,18	kid 57:7,13 227:4 499:19	know 30:17 31:7 33:22 37:12 43:6	284:16,18,20 285:20 286:10,22
juvenile 402:3	kidding 275:1 276:17	56:5,6,8 64:19 75:3,3,5,12,15,18	287:4 291:14,17 292:1,19 293:4
k	kidney 281:10	97:2 103:7 108:4 109:22,22 115:1	306:16 307:14,15 308:10 312:17,19
kamer 5:20 61:14 61:15,16	kids 57:14 375:5,9 375:22 376:15	122:1 128:20 129:9 131:22	313:8 314:3,9 315:22 327:9,20
kandypens 452:13	kight 7:14,15 104:13,14,15,16	137:8,9 140:12 141:1,17,19 142:2	334:20 335:2 336:7,9,13 337:4
kansas 221:7	kill 376:16	148:6,8,9 149:15 149:16 155:9	344:4,22 346:6 347:18 348:17
karen 7:12 101:19 101:21	killed 56:19 376:4 376:6,9	158:8,10 162:1 164:10 171:19,20	352:13,19,22 373:11 374:15
kari 8:19 142:13 142:14	kills 374:13	172:2,15 178:4,8 178:16 180:9,11	380:11,12,14 383:4 385:8 391:9
kazmira 14:7,9 361:17,20 362:22	kilograms 347:12	181:5,6 184:2 186:2,5,12,14,18	391:10 401:16,20 403:7,16 405:6,20
keep 47:14 54:3 245:8 378:4 497:17	kimless 13:8 316:20,21 317:2,4 321:1	205:12,22 206:1 206:18 208:6	418:11 421:2,5,19 430:19 433:19
keeping 354:20	kind 56:9 87:6 127:8 141:14	210:3 213:17,18 216:2 217:9	448:4,10 452:22 455:6,8,12,13
keeps 58:3	182:16 186:3,5 205:12 211:10	219:17 225:4,11 227:4 228:6,9,11	458:9 459:10 461:14 466:2
keith 8:15,17 135:9,13	213:5 228:14 231:1 239:9 247:4	228:13,22 229:19 229:22 230:11,12	468:9,16 470:2,3 471:9 473:6 474:5
ken 111:4	247:5 255:4 308:12 310:4	230:18,20,20,22 231:1,2,10,12,13	475:10 483:19,20 484:7 485:6
kentucky 43:13,15	343:21 345:12 346:11 349:4	231:14,16,17,18 232:2,14,16,16	488:13 494:2 497:19 499:14,20
kept 168:18 411:21 479:21	352:22 368:10,15 393:21 420:19	234:10,12,12,19 234:20,22 239:7,8	499:21 knowing 269:16 442:8 446:6
kevin 137:13,15 137:22	421:3 424:1,12,15 482:10	246:19 249:2,10 251:16 252:4,9,11	knowledge 34:21 96:22 97:6 100:11
kevon 1:21 502:2 502:15	kinds 30:6 128:17 184:18 209:10	254:1,11,14,16 255:3,19,20	119:15 176:19 262:15 272:1
key 38:17 51:3 78:12 83:15	247:16 424:19	256:16,20 259:16 259:16,21 267:15	386:14 416:21 431:21 434:7
146:13 160:9 218:12 237:16	king's 334:16	277:17 278:19 279:3 281:5,9	440:21 455:8 500:5 502:7 503:6
238:19 348:9 386:7,21 389:10	kingston 10:14 192:6,7,8 197:4	282:22 283:5,19	
427:6,15 463:22	198:2,15,22 199:4 199:20		
kg 51:10 203:2 270:17 272:7	kline 7:16 107:2,4 107:5 110:5,7,16		
340:13 358:16 359:6,8,14,15,16	110:22 111:2		
361:2 397:6,7	knew 339:8 374:3		
kgk 12:11 268:9 268:12,15			

<p>known 27:14 28:19 46:5 65:5 65:17 107:7 132:16 144:2 166:12 167:4 177:13 195:15 222:2 260:17 302:16 306:15 359:22 360:1 377:3 382:3 387:7 409:14 410:7,8 426:6 452:2 457:6 489:3</p> <p>knowns 177:12 178:14</p> <p>knows 288:22 441:22 449:11 459:12</p> <p>kosher 342:19</p> <p>koturbash 10:17 192:14 200:9,10 200:12</p> <p>kratom 205:17</p> <p>kristina 7:8 95:14 95:15</p>	<p>238:2,21 299:5 314:20 331:3,15 351:11 366:8 369:20 380:22 381:3 391:5,9 403:8 438:4,11 448:13 450:18,20 461:3 479:7 480:3</p> <p>labeled 116:19 222:11 320:10 335:1,5,5,6,7,7 399:22 466:1 479:9</p> <p>labeling 38:6 53:22 64:14 97:22 105:11 110:10 121:16 131:15 139:5 143:14 148:6,8 149:9,18 154:17 165:12 166:17 214:4,8 235:21 254:6,19 265:10 267:16 272:19 273:5,12 279:1 303:15 304:11,17 325:19 337:8 364:15 369:14,16 399:15 400:2 409:14 414:9,20 425:5 428:1 478:19,20 478:22 491:3 499:16 500:11</p> <p>labels 57:2 84:13 97:13,17 131:17 188:15 235:22 329:22 344:14 479:2,15,18</p> <p>labor 421:18</p> <p>laboratories 49:17 132:21 133:18 134:13 135:4 145:2,17 283:14 319:16 363:18</p>	<p>364:3 379:7 382:14,16,21 443:2,4 444:2,17 479:9</p> <p>laboratory 67:14 109:15 132:15 133:7,14,20 134:2 134:18,21 204:10 211:11 213:15 214:19 220:17 223:21 224:5 265:20 286:19 305:20 345:21 370:17,17 391:10 392:5 424:12 427:17 428:10 443:9,20 445:3,12 445:16 463:12</p> <p>laboratory's 134:11</p> <p>labs 13:21 97:20 205:2,6 251:15 288:20,20 289:17 347:10,11 349:14 349:16,16 351:13 351:21 380:21 381:5 442:14 479:6 489:20</p> <p>lack 34:5,5 47:1 59:22 61:16,20 82:12 116:16,18 136:15 145:5 156:17 160:6 188:10 304:4 328:7 360:21 371:10 389:6 477:20</p> <p>lacking 78:12</p> <p>lacks 338:8</p> <p>lacquer 491:1</p> <p>ladies 119:22 127:10 200:10 293:17</p>	<p>lady 231:17</p> <p>laetrile 62:4 63:7</p> <p>lag 82:18</p> <p>land 44:1 368:1 450:14</p> <p>landscape 96:3 108:10 329:13 430:12 432:6</p> <p>lane 379:10 438:1</p> <p>lanes 323:8</p> <p>laney 402:2,22</p> <p>laney's 402:2</p> <p>laneys 402:22</p> <p>language 135:2 279:7</p> <p>large 24:12 79:21 136:10 288:8,15 309:6 336:12,18 344:4 433:3 453:19 476:10 500:1</p> <p>largely 28:14 266:3 332:21 333:8 431:19</p> <p>larger 289:3 411:17</p> <p>largescale 227:15 227:21 347:11 348:6</p> <p>largest 43:9 82:15 87:21 156:11 342:6,8 345:2 366:6 384:9,21 395:9 433:19 499:8,22</p> <p>larry 11:4 216:6</p> <p>lasted 318:14</p> <p>lasting 89:12 173:10</p> <p>lastly 169:4 192:11 257:2 286:22 293:3 415:16 418:10</p>
l			

<p>late 122:4 175:9 286:20 388:9 467:4 474:5</p> <p>launching 97:14</p> <p>lavender 151:6,9</p> <p>law 7:15 8:3 15:9 29:3 32:3,12,15 35:7,17 49:14 81:13 104:14 118:7 119:2 146:8 189:13 205:3 241:1 265:18 354:14 355:1,10 355:13 356:9 377:11,22 400:3 413:11,11 419:21 419:22 420:2,7,10 420:14,17 421:1,2 421:10,18 422:5,8 422:8,14 450:14 471:18 482:6,7 499:22</p> <p>law's 77:10</p> <p>lawful 82:10 112:21 113:13 273:8 437:18 476:18 477:18</p> <p>lawfully 32:13 322:3</p> <p>lawfulness 48:18</p> <p>lawmaking 420:21</p> <p>lawnmowers 246:22</p> <p>laws 28:1,3,7 29:4 57:1 88:19 156:2 159:3 166:16,19 175:6 182:12 221:2 256:6 258:13,13 266:4 354:12 369:9 393:8 414:8 415:17 421:10,11 422:11 429:17</p>	<p>430:7 434:8,9,14 482:5 500:16</p> <p>lawsuits 241:4</p> <p>lawyer 240:21 429:15</p> <p>lawyers 107:13 240:18 406:19,19 422:12 430:15 432:4</p> <p>layer 474:7 495:2</p> <p>layers 283:3</p> <p>lazy 335:13</p> <p>lead 41:10 107:5,5 143:2,20 238:4 265:4 291:3 366:20 370:3 378:20 385:10 388:19 390:13 404:6 490:1</p> <p>leader 390:22</p> <p>leaders 48:4 107:10</p> <p>leadership 89:3 117:6 157:11 163:12 421:22 422:11</p> <p>leading 47:20 58:12 87:18 115:22 267:18 338:22 400:17 435:1 458:13 494:10</p> <p>leads 46:20 351:11 356:11</p> <p>leaf 150:21 151:2 279:20</p> <p>learn 127:19 221:16 266:10 411:22</p> <p>learned 40:10 50:1 59:9 267:4 275:1 317:11 333:3 358:14 360:4 471:11</p>	<p>leave 36:19 234:7</p> <p>leaves 116:16 171:18 285:20</p> <p>leaving 78:11 152:6</p> <p>led 39:11 49:16 138:11 259:15 386:6 388:7 449:1 451:7</p> <p>lee 15:12 451:1,2,2 451:7 455:16 456:14</p> <p>left 145:7 148:21 169:14 230:2 244:19 253:21 265:15 361:17 453:22 469:16 490:13</p> <p>legal 15:7 29:17 43:21 45:12 49:15 51:16 68:21 71:6 77:14 81:12 82:4 82:7 105:4 116:5 121:7 130:11 155:3 159:11 160:1 163:18 165:5 166:2 205:18 240:17,22 253:10 254:18 260:19 286:14 296:2 306:22 324:2 353:8 354:10 367:19 407:1 421:12,17 423:12 424:4,5 432:20 448:11 449:6 453:8 462:11 477:11</p> <p>legalities 291:19</p> <p>legality 116:7 170:2 209:8 329:15</p> <p>legalization 39:13 224:20 367:2</p>	<p>373:10 386:6 393:11</p> <p>legalize 121:4 253:13</p> <p>legalized 61:17 121:7 150:17 257:5 265:14 470:13</p> <p>legalizing 376:17</p> <p>legally 66:14 90:13 99:1 108:5 108:5 123:2 168:7 395:20 453:7</p> <p>legend 342:16</p> <p>legislation 2:7 22:3 38:20 42:19 48:8 160:16 257:4 411:3 445:20</p> <p>legislative 79:15 396:16 420:1 430:3</p> <p>legislators 62:1 430:16</p> <p>legislature 160:17 162:17 182:1</p> <p>legitimate 91:3 219:11 336:13 371:19 431:3 440:5</p> <p>lenabasum 93:2 93:10,17</p> <p>lends 361:1</p> <p>lengths 473:8</p> <p>lennox 140:17 338:17 447:15 449:3</p> <p>lenses 457:9,11</p> <p>lesser 69:20</p> <p>lethargy 193:15</p> <p>letter 346:7 395:15</p> <p>letters 35:8 77:3 162:7 284:8,11 291:10 439:3</p>
---	--	---	--

<p>level 51:20 81:12 88:20 99:14 100:2 114:13 115:9 125:18 160:13 165:2,10 169:21 195:4 238:14 243:10 316:17 317:17 327:4 345:9 349:15 363:14 364:9 387:3 392:15 397:8,18 399:9,11 408:13 409:18 410:12,20 413:17 424:16 437:11 467:9 470:22 481:3</p> <p>levels 45:20 61:1 68:8 69:3 80:1 84:7 109:16 113:17 114:3,16 115:1 133:11 144:1 146:21 160:15 178:20 179:1 181:2 201:20 239:10 283:16 288:9 301:12 302:12 309:3 327:14,16 330:3 331:22 337:7,13 338:10 340:15,19 360:9 363:3 377:3 396:10 397:4 399:20 413:17 437:11 439:8 444:12 467:7,19 468:1 470:18 492:17</p> <p>leverage 331:5 leveraged 332:11 levodopa 385:14 lewis 2:10</p>	<p>lgill 252:4 lgs 174:17 341:9 449:5 liability 490:5 liberating 126:14 liberty 481:21 482:4 library 126:1,4 license 226:16 283:22 286:11 297:1 319:6 333:10 346:11,20 478:6 licensed 109:15 161:16 283:13 292:6 317:7 319:16 325:12 332:20 367:9 licenses 319:20 licensing 322:18 lied 175:12 lies 371:15 life 45:3 70:17 92:22 132:6 293:13,20 319:14 332:4 334:5 338:6 338:16 401:2 458:4 460:10 473:11 481:21 482:3 490:15,17 490:20 lifesaving 401:16 403:18 404:17 475:8 lifestyle 252:21 253:4 325:4 light 25:7,11,13 lighter 385:5 lights 132:11 likelihood 488:7 lily 61:10,11 lilyhemp 5:11 53:7,11</p>	<p>limit 99:18 191:16 240:5 314:10,16 341:2 360:11 446:1,12 469:14 469:22 491:9 limitation 287:1 limitations 23:2 24:21 72:4 165:12 limited 63:13 65:5 82:12 140:15 171:20,22 182:9 183:8 221:20 288:18 387:8 491:12 limiting 38:19 121:13 limits 51:19 57:1 100:1 218:2 258:8 327:1 330:22 340:19 394:3 451:19 464:9,11 464:18 line 37:13 109:8 171:8 173:3 281:21 291:14 304:9 387:5 452:16 454:11 lineberger 26:8 lines 264:20 296:3 296:7 319:18 402:20 411:16 link 36:14 48:3 479:4 linked 58:2 479:3 linoleic 45:21 lipids 234:8 lips 496:18 liquid 205:9 206:21 211:9 liquids 205:1 206:4,8,9 liquor 230:3 232:19 234:18</p>	<p>lisa 11:20 245:13 245:14 252:4 list 58:2 123:15 166:22 206:3 225:10 237:2 276:1,9 310:3,6 351:3 370:19 listed 79:5 116:22 185:11 238:2,8,20 300:7 311:20 329:21 listen 481:18 listened 231:17 listening 125:13 279:12 377:18 402:16 496:11 498:15,16 listing 238:15 literally 263:1 308:11 403:2 496:1,5 literature 49:9 78:17 80:15 175:3 177:14,15 180:11 180:15 186:14 222:19 224:15 270:16 325:15 492:4 litigators 11:19 240:17 little 41:17 44:7 70:4 76:19 86:20 113:22 122:1 127:12 128:14 132:9,11 137:18 148:4,16 149:19 150:1,11 159:4 172:14,15 179:8 187:14 190:13 191:5,19 212:8 216:9 221:11 222:7 226:13 228:2 236:22 241:7 281:16</p>
--	--	--	---

289:22 294:8	157:8 160:14	214:21 219:16	279:10 325:6
298:13 326:16	236:7 253:11	223:9 224:16	448:4
332:18 353:14	265:8 413:17	225:11 237:12	looms 433:3
356:17 358:7	414:8 464:19	239:15 245:10	loren 104:11
371:6 380:13	467:6 478:6	249:21 252:3	lose 25:3 109:2
384:6 391:14	locally 488:16	253:4 261:6 262:6	224:2 286:6
402:1 405:14	located 24:14 61:6	262:15 264:21	382:12 403:1,3
407:4 422:18	263:20,22 270:1	267:22 274:1	losing 108:11
430:5 447:17	274:1 297:16	277:19 295:6	208:16 403:6
451:6 457:17	328:20 366:5	299:8,17,20 301:2	loss 58:14 189:2
458:7 459:7	498:3	301:9 311:13	385:10 472:3
461:15	location 1:16	320:19 326:4	474:9 475:13
live 260:8 385:1	locations 229:2	333:17 350:1	lost 472:14 484:18
401:7 482:5	locked 57:18	352:2,17 365:17	lot 36:12 40:10
liver 51:13 67:17	295:1	397:13 398:3	74:17 90:16
141:10 174:19	loggers 127:5	404:11 415:9	124:21 129:10
177:9 201:3,5,14	logical 120:19	422:20 429:6	147:19 149:7
201:18,19 202:16	logistics 292:5	452:20 453:2,22	164:13 172:2
202:20,21 203:5	293:9	456:7 457:7 466:8	181:5,5 213:17
203:12 270:19	london 334:16	467:15 468:19,20	219:6,7 222:18
272:16 280:22	long 26:4 89:12	468:21 469:2,5,8	224:15 227:19
281:2,10 339:9,14	117:4 139:10,16	469:21 470:12,14	228:11 236:12
339:15 360:1	156:18 157:2	471:2,4 475:4,14	239:13 242:3
404:13	163:6 186:17	483:8 493:10	245:6,7 248:12
lives 54:12 58:6	208:15 213:19	497:11,20 500:6,7	249:7 252:11
87:22 96:8 243:3	225:17 241:19,19	500:8,16,16	253:4,9,19 255:11
338:13 379:18	246:22 304:14	looked 164:16	255:20,21 275:16
401:10 403:3	346:17 377:11	242:19 343:6	276:18 277:8
429:18,21	391:15 406:18	397:1 469:15	285:14 286:6
livestock 46:13	407:19 426:15	looking 59:17	288:10 290:12
living 377:10	440:19 471:10	131:19 165:15,19	302:11 305:14
384:10,22 460:10	485:2 489:17	175:22 177:13	312:6,12 334:14
llc 6:7 8:3 9:8	longer 29:2 58:3	179:9 180:16	345:21 348:17
12:19 14:5,7,9,17	82:3 93:9 286:3	186:21 203:22	349:18 350:12
15:11 16:17	longest 220:11	223:21 244:20	359:1 360:5 387:7
llp 15:15 476:5	longstanding	251:10 254:4	396:1 398:2,4,4
lo 264:19	167:13	273:22 274:3,5	399:6,6,7,11
load 100:2 224:7	look 74:9 80:9	282:19 286:19	403:12 421:8
lobby 173:9	90:19 100:12	288:4,6 312:4	423:1,3,7 424:3
lobbyist 287:21	130:16 145:18	335:18 395:12	483:2 498:11
lobbyists 175:6	155:11 164:15	398:15 401:22	500:3
245:7	166:3 171:1	420:6,20 423:20	lotion 34:13
local 48:18 88:20	180:20 183:18	looks 74:7 157:14	lotions 154:5
96:5 156:3,7	185:22 199:21	160:20 219:20	

<p>lots 27:2 36:1 302:11</p> <p>lotus 205:17</p> <p>louder 137:19 384:6</p> <p>love 151:21 152:13,21 153:1 201:9 252:2 291:1 498:8</p> <p>loved 338:16 376:19</p> <p>low 28:21 46:14 69:3 120:7 150:21 201:18 202:12 212:12 217:12 239:10 270:10 271:4 277:3 340:15 358:16 388:5 390:5,8 402:21 455:4,5,19</p> <p>lowell 3:18 21:4</p> <p>lower 271:9 285:14 352:12,14 433:14 450:9 473:17 494:10</p> <p>lowering 276:5</p> <p>lowest 200:3 280:19 281:3</p> <p>loyalty 255:15</p> <p>lozenges 41:15</p> <p>lps 227:21</p> <p>lubricated 495:3</p> <p>lubricating 488:22 491:15</p> <p>lucid 230:8</p> <p>lucille 12:14 274:10,13</p> <p>luck 321:16</p> <p>lunch 24:7,9,10 268:6 274:10 281:18</p> <p>lunches 24:12</p> <p>lupus 482:15</p>	<p>luther 142:14</p> <p>luxembourg 253:12</p> <p>luxury 117:1</p> <p>lying 243:5</p> <p>lymphatic 262:20</p> <p>lymphoid 264:20</p> <p style="text-align: center;">m</p> <p>ma'am 68:15 69:13 140:6 257:19</p> <p>mac 212:7</p> <p>machine 490:8</p> <p>machines 246:21 490:9</p> <p>maciora 111:4</p> <p>mackay 13:10 321:9,10,10 326:17 327:16 328:5</p> <p>mad 58:8</p> <p>madison 10:8</p> <p>maelstrom 37:21</p> <p>magical 149:2</p> <p>magnitude 120:15</p> <p>magnolia 96:1</p> <p>main 126:18 132:14 205:18 253:3 269:21 350:11 375:14 494:14</p> <p>maine 261:14</p> <p>mainstream 125:21 126:11 230:20</p> <p>maintain 122:18 262:9</p> <p>maintains 263:2 341:15</p> <p>maintenance 359:16 427:9</p> <p>major 62:2 97:14 202:5 203:10 218:14 227:22</p>	<p>277:22 357:22 464:13 465:10</p> <p>majority 150:13 202:4 227:20 247:21 249:19 251:7 300:4,11 318:17 358:9 441:16 464:16</p> <p>makers 77:12 382:13</p> <p>making 43:1 59:21 64:22 91:2 94:8 108:6 122:19 141:4,5 147:8 149:11 157:7 158:3 289:14 291:14 305:4 316:14 352:20 365:16 374:3 388:3 456:8 487:13 491:18 500:12</p> <p>males 174:10 359:4</p> <p>malevolent 174:12</p> <p>malignant 264:19</p> <p>malkin 15:14 413:3 419:6,8,9</p> <p>man 206:16 395:17</p> <p>man's 207:5</p> <p>manage 207:14 321:15</p> <p>manageable 124:2</p> <p>management 59:18 89:6 134:11 362:18 363:7,16 365:7 427:18 428:2 445:15</p> <p>manager 57:7 442:13</p> <p>managing 263:19 413:10 428:2</p>	<p>mandate 109:14 329:8</p> <p>mandated 382:20</p> <p>mandates 283:18</p> <p>mandatory 194:8 269:11 439:4 464:1 480:3</p> <p>manifest 262:4</p> <p>manipulation 204:18</p> <p>mankind 46:6 127:14</p> <p>manner 62:11 98:7 116:21 119:5 290:3 291:18 316:11 477:6</p> <p>mannion 13:12 328:17,18,19</p> <p>manufacture 78:2 194:17 311:21 325:18 332:7 333:13 342:9,10 343:7,11,14 344:13,15 345:10 346:18,21 348:11 353:18 380:20 450:19 479:3</p> <p>manufactured 112:16 116:21 194:1 240:5,7 314:18 317:19 319:7 333:6 370:1 370:14 372:4</p> <p>manufacturer 66:18 67:1 101:9 101:10,11 206:22 207:6,11 208:11 285:1 287:3 288:8 292:6 297:1 308:16,21 310:19 310:22 342:6,8 346:4,9 352:20 353:8 366:9</p>
---	---	--	---

manufacturers	463:4,11 464:15	374:12,13,16,20	435:19 437:7,18
6:5 7:3 12:17	478:10 487:5	374:21 375:3,7,8	440:7 441:11,17
18:13 19:4 38:15	488:11 489:10	375:11,15,16,19	445:2 446:5
64:21 66:21 76:4	490:6 497:3	375:20,21 376:1,4	451:14,18 452:11
87:17 100:19	manuscripts	376:5,5,7,10,10	454:9 477:19
107:9 147:1	203:7	376:11,12,17	478:4 491:21
156:22 218:5	manward 8:7	377:5 395:4	marketable
231:5 287:5,12,16	125:9	413:12 421:3	230:19
289:21,21 290:16	map 302:14	432:20 433:2	marketed 27:18
306:12 310:15	384:12	470:6,14 471:15	29:19 31:14 32:9
346:12,12,14	marcel 211:7	473:16	32:14 51:20 85:3
349:13,19 350:1,6	march 77:22	marinol 30:6	105:19 106:11,14
351:6 362:5,10,17	485:16	marked 130:2	106:16,18,20
363:9,15,19 364:3	margaret 220:14	191:11 329:13	117:22 138:20
365:18 382:18,19	223:20	markedly 188:20	164:18 189:1
406:10 415:8,10	margarine 448:7	market 30:22	200:3 222:3 269:1
415:15 426:21	margin 143:22	31:10 45:18 46:12	269:3 272:11,12
448:20 478:17	269:16,16	46:15 50:18,22	323:8 355:5 374:6
480:2,13	margins 269:9	51:6 52:4 54:16	377:2 433:10
manufactures	340:18	76:15 77:7 82:18	438:2 440:18
480:6	marijuana 5:13	83:4 84:16 90:21	marketer 438:5
manufacturing	5:15 6:15 21:13	91:1 108:4,19	438:13
38:6 39:15 52:9	21:18 28:3,4,5,11	109:2 112:11	marketing 9:12
53:22 74:6 87:21	28:12 29:1,1	117:2 129:11	33:14 35:6,10
92:19 123:8	56:15,17,19,21	154:13 162:11	38:3 83:20 105:11
151:18 152:4	57:4,8,22 58:2,12	164:8,12,13,22	105:21 106:9
185:9 192:3	59:6,8,13,14,18	166:2 168:8 169:1	111:21 113:13
292:13 303:6,12	60:3,5,12,13,18	188:13 192:1,19	121:14 130:10
304:10,16 305:8	60:19,22 62:10	192:21 194:14	153:4,8 198:20
309:8 311:10	77:22 78:3 91:22	195:3 196:11	199:17 220:19
319:13 328:19	92:1,10 101:1	197:11 198:13,15	235:22 239:11
331:2,9,14,19	145:7 146:7 173:6	199:1 210:16,17	256:16 273:7
332:12 333:10,12	173:9,13 174:5,12	214:4 228:22	325:20 354:7
335:22 343:5	175:2 218:22	239:9 246:6,6	355:2 375:3 381:1
345:13,20 348:4,9	240:19,22 241:7,9	254:18 284:18	381:20 414:18
350:3 354:6	241:10 242:1,7,8	306:22 322:3	423:14 452:9
361:20 362:12,22	242:17,19,21	325:1 338:8	491:13
364:9 367:16	243:2,3,4,6,20	346:15 348:18	marketplace
368:12,17 370:7	244:12,18 245:1,4	349:4 353:19	64:16 76:20 84:15
370:12 371:16	260:2 294:1	354:15 360:8	95:1 97:5,17 98:4
393:15 404:20	322:15 341:6	395:13,14 396:13	102:18 112:7
415:20 416:5,8	367:5,6,8,9,12,20	402:21 405:19	114:6 116:8
425:16 460:3	370:18,20 373:8,9	407:11 409:2	120:12 154:1
461:18 462:19	373:11,21 374:5,9	423:18 431:10	155:6 162:5,7,12

163:4,19 165:2 170:6,7 171:2 193:8 230:21 236:4,20 237:8 246:17 312:13 354:3 355:12 356:11,12 408:2 428:7 437:20 441:9 476:10 markets 62:20 78:8 90:9 146:1 156:10 253:17,20 258:4 283:18 357:16 371:12 411:6,17 423:19 430:1 452:17,21 marla 457:15 married 57:14 marwan 13:18 341:22 342:4 maryland 13:19 261:9 294:11 342:1,4,5,14,17 344:9,19 379:3 502:17 mask 59:18 mass 119:16 153:22 189:19 338:8 374:5 massachusetts 59:7 61:7 242:10 massive 52:2 master 72:1 311:20 355:15 485:4 match 486:5 matched 191:4 material 45:17,20 45:22 95:8 100:9 132:22 218:14 285:19 296:4,17 296:18,20 302:19 312:1 322:20 323:2 327:18	348:15 369:10 388:19 393:21 428:16 450:20 materialize 440:8 materials 43:16 64:14 100:22 130:17 133:10 168:16 218:17 219:10 296:22 302:18 309:6 311:3,22 331:17 351:2,5 363:2,20 372:6 381:14 392:3,11,18 393:5 394:17 411:14 427:10 489:17 490:18 matrices 371:9 matrix 351:15,19 352:1 matt 16:2 442:11 matter 71:18 150:12 185:16 204:14 339:3 360:2 406:10 matters 184:3 matthew 442:12 mature 145:22 357:15 452:21 matz 9:11 153:3,5 maximum 449:21 maya's 174:22 mayl 3:6 21:10,11 mayne 413:2 mazanet 13:14 332:16,17 337:17 mazloun 13:2 298:8,8,11,11,15 298:15 mccoll 5:12 173:2 173:4 meg 302:12 mcguffin 7:18 111:7,9,10 114:1	114:4,20 115:12 mcmurphy 17:4 481:14,16 486:8 md 1:19 2:2 4:6,8 5:20 6:6 7:4 8:17 10:9,17 12:12,14 13:8,14 15:4 18:7 67:1 264:18 mdmb 206:13 mead 13:16 337:22 338:1,1 meal 168:13 170:15 mean 55:11,13,17 75:1 103:5,6 113:22 114:4,5 141:14 214:16 239:13,20 308:10 312:3 313:11 326:17 327:7 399:18 405:20 418:9 424:11,17 437:16 468:7 469:4 meaning 28:20 29:20 84:6 264:12 271:6 meaningful 333:21 455:8 meaningfully 460:20 means 32:12 83:4 106:14 148:19 239:17 265:6,8 267:4 341:5 402:14 444:5 460:14 469:1 477:10 meant 68:20 239:16 255:16 473:3 measure 39:14,18 measured 51:7 180:3 320:22	449:14 453:15 measurement 446:10 471:15 measurements 134:7 345:16 measures 50:1 471:19 measuring 305:17 mechanically 488:16 mechanism 68:12 139:12 301:8 302:1 313:9 mechanisms 235:16 414:8,20 media 22:22 23:1 23:16 27:2 236:16 381:22 medical 6:3,15 10:13 12:15 26:10 28:3,16 33:5 57:3 59:6,8 60:15,18 60:19 62:10 63:17 63:20 73:3 77:21 78:3,17 80:2 93:10 97:7 98:2 107:12 122:12 138:21 139:4 146:1 156:3 174:13 188:1 192:21 193:2 194:2,2,11,20 198:6 200:13 216:21 218:21 220:4,18,21 221:2 221:12 224:16 244:18,18 256:11 258:11 259:11 260:2 263:21,22 264:1,6,10,20 265:1,14 266:1 267:11,13,16,21 274:15,16 275:1 276:21 294:1
---	--	---	---

317:7 319:5,20	167:7 241:11	55:15,18,21 56:3	315:16 316:5
332:19,21 333:14	245:15 259:8,21	56:12 61:5,8	320:19 326:8
336:14 357:11	260:1,5,14,16	65:22 66:1,10,11	327:13 328:1
379:17 381:5	261:3,6,21 262:13	66:15 68:11,16,17	337:12 352:9
386:4 400:10	263:6,10,12 264:6	69:5,10,11,14,17	379:1 390:1,3
408:19,20 409:14	264:7,11,15 266:8	70:6,12 74:12,22	399:14 405:5
410:13 415:4	267:12,12,14,14	75:7 79:18 80:12	413:4 429:13
421:3 426:16	267:14 282:11	80:21 85:14,16,19	434:6,17 440:21
431:3 482:11,21	284:21 285:5	86:2,8,9,11,14,17	442:4 456:10,16
483:1,7,13,14	286:16 317:5	86:18,22 87:4,6	466:11,17 475:21
487:14 490:8,22	327:5,8 374:6	89:14 90:8 94:21	481:7,12 493:17
491:18	376:22 379:2	95:10,16 100:21	494:9
medically 261:19	400:12 483:9	101:4 103:3,13	members 20:21
482:19	485:8 486:10,12	104:5,9 110:12,17	23:13,19 48:1,7
medicated 404:3	medicines 76:5,8	111:1 113:16	49:8 83:12 90:10
medication 38:22	76:13 92:20 94:9	114:2,16 115:4	103:18 107:8
140:21 179:14	98:12,21 260:15	118:10,20 124:12	154:13,21 247:6
250:16,17 251:3	337:3 338:11	124:16,19 128:1,4	275:21 284:5
277:18 280:17	341:16,17 458:10	128:9,12,13 129:1	406:15 427:12
334:13 338:14	491:21	137:3 140:5,7,12	428:17 444:21
341:10 389:20	medieval 274:22	141:2,7 144:10,14	membership 87:8
403:18 404:17	mediums 229:2	152:15 153:14	166:13
436:18 459:21	meet 63:10 77:14	157:16 158:4,7,11	memo 121:5,11
460:4,7	97:11 226:22	158:15,18 161:1,4	memory 173:17
medications	245:6 346:21	164:7,10 165:6	211:16 223:3
130:22 139:4	368:2 369:15	169:12,20 170:17	men 174:8 223:19
142:20 143:9	478:2	170:20 171:12	224:12
144:3 188:14	meeting 23:15	172:4,9 185:14	menstrual 493:7
277:16 280:15	27:5 36:6 88:8	186:7,20 196:20	mental 57:18,20
338:5,13 339:19	95:20 184:1 243:9	197:22 198:10,11	59:12 242:20
402:6 415:4 458:6	249:4 344:10	198:17 199:3,10	243:1
459:11 460:8	363:1 386:8	200:7 214:14	mentality 408:10
461:6	389:11 443:5,15	215:5,11,18,21	mention 78:20
medicinal 10:10	449:3	226:2,8,11,13	124:13 219:5
61:18 123:10,12	meetings 160:8,10	232:7 233:1,8,17	411:18
181:21 182:3,7,11	344:8 395:6	233:18 252:7	mentioned 31:17
264:5 343:21	meets 319:12	257:18,20 258:5	36:18 66:7 69:18
467:11 480:18	369:12 380:22	263:19 273:17	79:2 85:17 110:18
medicine 2:20 3:8	megan 7:20	274:6 279:14,19	110:19 113:17
3:16 4:16,18 11:8	115:17,19	280:1,3,5,7,8,20	128:17 144:11
22:14 26:10 37:11	mellow 206:7	298:10 307:6,8,11	180:7 184:17
37:19 40:2 60:14	melting 315:5	308:6,9,20 309:3	195:20 198:17,18
63:9 92:1 122:11	member 52:21	309:11,16,19	199:13 202:1
126:2,4 147:20	53:4,15 55:2,6,9	310:9,11,13	210:12 217:20

237:5 253:18 307:12 308:3 309:21 315:16 384:21 408:20 466:12 mentioning 80:16 497:6 merchandising 154:22 mercury 490:1 mere 106:6 merely 125:21 merits 467:11 mess 291:15 message 58:9 439:5 messages 38:1 389:10 met 134:15 306:21 332:9 354:12 427:6 meta 293:1 metabolic 177:14 metabolism 178:5 178:17 180:12 202:4,5 270:19 465:15 metabolite 177:3 179:1 metabolized 177:1 178:18 179:19 180:8 metabolizing 177:18 179:10 metal 60:10 330:10 345:14 480:5 metals 60:12 72:5 102:22 146:12 234:10 237:13 278:14 306:10 312:5 319:15 330:7 335:21 352:2 362:2	363:22 372:8 417:1 428:11 442:21 meth 374:12 method 41:3 315:11 319:11,12 327:17 351:14,16 351:17,19 354:16 392:6,7 394:11 465:16 487:15 methodologies 371:8 methods 133:17 134:7 144:22 311:17 312:1 316:3 348:16 349:14 351:8,14 351:21 364:6 378:20 381:8 391:7,8,11,18,20 392:2,4,16,17,20 392:21 393:4 394:14 416:3 428:10 445:8 metrics 362:16 mettler 3:10 21:20 21:20 mg 51:10,22 63:2 63:3 120:10,12 189:17 203:2 211:8,12,14 212:21 213:10 270:16,17 272:7 277:2,7,9 278:7 279:2 280:18 301:12,13,15 318:21 319:2 327:21 340:13,14 341:4 358:16 359:5,6,8,14,15 359:15 361:2 397:2,6 468:22 469:1,5,5,6,7,9,10 469:12,17,18,20	474:21 mic 137:21 298:14 mice 202:18 360:5 michael 7:18 23:15 111:7,10 michelle 10:20 204:5,12 246:10 michigan 317:8 319:4,20 micro 288:14 microbes 330:6 335:20 microbial 100:2 286:2 330:8 331:21,21 352:3 362:2 363:22 372:10 480:4 microbials 319:15 microbiological 146:11 442:22 microbiology 145:3 393:17 microbiome 493:9 micronucleus 271:3 microorganisms 99:19 microphone 25:8 187:13,18 210:20 356:22 447:4 451:5 mid 342:7 345:3,5 midazolam 180:13 midst 63:8 migraine 138:22 275:14 migraines 261:7 261:11 milanova 17:6 486:20,21 487:1 489:9 492:8 493:15,19 494:13 495:13,16	mild 51:13 69:20 69:22 70:8 211:12 213:2 300:5,12 301:5 318:5 milder 70:7 mile 13:21 347:10 347:10 miles 9:15 155:17 155:21,21 157:22 158:6,8,12,16,19 milestones 460:9 military 208:2 282:20 294:6 millennia 145:10 408:8 millennials 248:21 miller 5:4 47:17 47:19 211:7 milligram 95:8 279:3 281:3 milligrams 51:10 milliliter 211:8 million 43:14,15 43:17 84:18 108:18 116:9,10 161:18,22 238:7 239:18,22 248:11 260:2 314:9 344:5 347:14 348:20 385:1 400:18 430:14 482:8 millions 49:9 145:14 247:6 342:12 347:21 348:1 430:13 435:12 mind 245:9 281:8 468:18 mindboggling 432:11 mindful 24:17 mine 24:2 269:8 425:9,10 475:3
--	--	---	---

mineral 448:21	mission 50:20	models 135:18	302:20
minerals 486:2	100:6 200:15	322:17 398:16,19	monograph 122:3
minimal 109:11	282:13 353:15	493:3 494:2	450:14
276:21 278:5	354:20,21 393:12	moderate 211:13	monographs
minimize 331:4	397:15 422:9	300:12 318:6	365:10
minimum 117:3	462:10	moderating 20:9	monopoly 52:3
304:4 407:14	missioned 393:21	modes 183:18	436:4
409:12 411:6	mississippi 11:5	186:1 453:21	month 96:4
412:7	188:8 189:13,14	454:21,22	120:14 141:1
minnesota 10:15	191:11 192:10,15	moheyeldien	154:8 215:20
192:9,22 194:3,9	195:10 216:9,21	13:18 341:22	290:7 347:13,14
194:10 196:3,22	217:6 218:15	342:3,4 347:6	403:11 490:20
197:13,14 198:6,7	423:8	moiety 105:12	months 26:3 35:4
minor 210:17	mistake 126:10	106:4	227:3,3 248:6
211:1 492:11	448:18	moisture 332:2	260:8 291:15
494:15	mistaken 112:9	372:9 488:6	319:22 348:21
minus 238:1	mistakes 39:11	molasses 448:6	413:22 447:13
minuscule 174:6	127:19 257:3	mold 72:4 283:16	457:19 458:21
175:10	mister 15:16	372:10 404:21	459:18 460:11
minute 25:10	117:10 434:20,21	moldy 59:13,14,18	461:21 472:22
122:4 172:21	434:22 441:8	molecular 232:21	monumental
184:14 244:19	442:8	molecule 176:21	54:19
281:22 287:19	misuse 33:6	molecules 151:10	mood 130:2
295:13 300:16	mitigate 35:13	mom 373:7 375:21	300:10 385:19
372:18 378:3	105:9 131:1	moment 408:17	morgan 6:2 15:18
minutes 37:3 41:5	229:18	410:10 421:6	63:16,18,19 66:4
41:6 91:18 132:10	mitigated 42:11	moments 178:22	66:14 425:8,9,11
155:18 166:9	mix 390:7 406:19	moms 14:15 376:8	morning 21:3,7,10
173:3 244:20	mixed 205:12	monascus 396:11	21:20 22:1,6,9
298:3 300:18	mixture 448:6	money 127:13	24:11 26:15 36:19
318:11 495:20,22	mj 173:14 174:8,9	355:18 403:12	37:2,17 42:16
miracles 260:13	ml 469:11	482:20 483:4	43:1 45:7 47:19
miraculous 260:4	mm 280:4	485:10	61:15 62:12 63:18
mirroring 94:17	mobility 253:4	monica 8:8 129:17	70:20 77:3,20
misinformation	mode 451:15	129:19	81:7 87:15 95:15
228:3	model 177:3 196:8	monitor 99:13	98:10 101:21
mislabeled 312:13	224:5 241:1,2,2	124:22 199:8	104:12,15 107:4
349:5,7	304:18 343:6	339:15 451:20	111:9 119:1 122:8
mislabeling 497:2	365:2 398:10,10	459:10	125:8 135:12
misleading 38:3	442:18 443:17	monitored 141:9	137:14,14 144:20
73:16	444:11 445:19	217:15	147:7 150:9 153:5
misrepresented	475:6,17 485:9,19	monitoring	155:21 166:10
190:9 312:13	491:11 494:8	101:13 192:4	173:4 176:16,21
		194:8 206:2 208:4	177:6 187:11

188:6 192:7 204:6 209:19 233:20 396:4 417:3 morris 9:17 158:21,22,22 161:3 mortar 207:18 208:2 mother 96:4 230:3 232:19 234:18 motility 389:3 motions 241:2 motives 453:2 455:18 motor 385:10 386:22 387:4,9 mou 167:14 mouse 202:3 359:20 397:5 398:10,10,11,13 398:15 475:6,17 move 24:4 37:14 58:22 79:22 98:3 104:13 137:21 155:7,13 187:13 210:20 265:11 282:8 287:11 290:10 291:16 293:2,11 298:13 356:21 373:1 451:5 462:2 500:9 moved 373:7 431:6 496:6 movement 385:12 467:4 moving 40:10 59:1 61:11 66:17,19 70:18 77:18 81:4 83:6 91:5 129:17 144:16 155:15 176:11 183:16 187:2 233:3 258:21 263:16 275:15 295:12	310:18 337:4 386:19 428:21 489:6 490:6 498:18 mpp 15:21 429:12 429:19 431:20 433:17 mpp's 430:3 mra 446:20 mr 67:16 mucosa 493:18 494:1 mueller 13:20 347:8,9,9 352:17 multi 133:14 453:19 454:22 472:4 multibillion 290:19 multicenter 318:19 493:6 multidisciplinary 192:18 multinational 93:7 multiple 44:3 49:1 52:17 57:19 93:4 108:22 126:3 134:2 143:8,17 181:6 192:22 221:12 230:13,16 260:22 269:1 294:5 298:22 300:3,15 301:17 301:18 302:5,16 307:20 340:16,17 344:8 411:11 453:20 469:17 474:7 multistate 476:10 multitrack 217:17 multitude 54:8 munchies 215:1	municipal 467:20 murders 376:6 muscular 262:21 mustn't 38:18 39:11 mutagenic 271:2 mutual 195:13 436:3 444:21 mutually 453:16 mycotoxin 302:9 mycotoxins 231:22 234:8 237:14 286:2 302:10,17 372:8 myoclonic 402:3 myth 340:22 n n 2:1 3:1 4:1 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:2,2 19:1,1 20:1 179:1 318:20 nadia 213:1 najla 12:10 268:6 268:9 name 21:1,3,10 25:5 37:18 40:3 42:16 50:7 59:4 61:15 70:20 72:13 77:20 78:1 81:7 83:10 91:19,20 92:17 98:10 101:21 104:15 107:4 111:5,9 119:1 122:8 125:8 132:13 135:12 137:15,22 142:14 144:20 147:7 150:9 161:8 173:2 181:18 187:21 192:7 200:11 204:12 227:13	263:18 274:13 278:15 279:17,21 293:18 317:4 321:10 328:18 342:3 347:9 353:5 361:15 362:3 366:2 373:6 378:18 406:16 413:10 419:9 425:11 447:22 451:2 456:20 462:8 496:1 named 91:21 narco 242:11 narcotics 189:15 narrative 173:8 320:11 narrow 180:1 305:2 nasc 83:12 84:10 85:7 nascent 38:1 108:16 nasser 58:22 59:1 nation 62:4 125:14 159:3 162:1 368:10,15 374:15 471:5 nation's 384:21 national 6:21 7:17 11:5 16:3 26:6 78:22 82:10 83:11 88:21 89:22 107:2 107:6 126:1,4 134:7 147:17 156:14 158:1 182:2 183:10 188:2 189:9 192:10 195:9 204:17 219:3,14 219:18,20 224:14 236:7 242:4 247:13 294:6 295:1 331:11
--	--	--	---

336:7 400:17 424:14 442:14 445:20 451:17 467:7 476:7 483:10 485:1 nationally 88:17 133:15 478:14 nations 467:8 nationwide 163:15 207:19 395:11 natural 7:13 11:6 15:3 101:20,22 102:6,16 106:19 126:22 127:11 130:22 139:8 188:3 189:9 192:11 195:9 196:9 286:7 323:3 323:7 395:8 490:21 naturally 112:3 113:17 114:8 323:4 357:11 naturals 9:8 nature 37:22 102:18 127:21 188:11 nauseam 468:8 navigate 283:1 navigating 461:12 477:10 nce 93:13 nci 398:14 ncia 107:7,8 110:9 nd 13:10 ndi 72:1,3,6 77:13 102:15 103:15,22 104:3 218:2 269:13,17,18,20 271:22 273:6,7 324:11 438:20 439:12 440:1 477:21	ndin 354:11,17 355:3,16 356:3 ndis 77:14 nearing 238:6 nearly 107:8 108:21 116:14 156:20 229:15 233:11,15 238:9 319:22 356:10 385:1 426:2 neat 133:10 necessarily 40:17 254:11 255:12 307:15 395:5 486:14 necessary 48:8 49:1 133:18 139:6 256:6 278:5 332:9 355:20 410:4 451:20 necessitates 219:9 necessitating 181:2 necessity 88:16 266:7 ned 4:6 18:7 20:10 25:22 need 24:5 33:16 36:2 38:3 41:22 42:4 44:20 46:17 48:15 56:22 57:1 57:2 58:11 64:6 65:8 77:6,12,14 82:14 83:19 88:21 90:1,18 94:19 108:22 109:1,21 129:5,7 131:5,18 131:22 132:2,5 149:10,12 165:3 168:17 177:12 182:18 183:1 184:16,22 185:3 185:22 199:14 201:15 205:4	213:21 214:12 217:4,15 218:4 219:6,7,14,15,18 220:1 221:9 222:1 224:19 225:1,7,11 225:12,18 226:3 231:19 254:18 256:11,14,15,16 257:11 259:16,20 266:5 267:20 278:11,16,16,17 278:19 287:6,6 291:16 294:7,15 295:8 296:15,19 297:2,18 298:13 305:22 306:2 312:17 336:15,16 349:20 352:2,17 360:12,12 377:6 378:16 379:21 380:4 383:10 387:5,21 389:11 389:14,15,18 391:11 404:16 406:9 411:12,14 413:22 414:6,11 414:15 415:17,22 416:10 421:21 424:22 429:22 441:6 446:2 455:9 473:13 475:7 needed 30:12 46:1 84:19 129:13 136:21 169:18 203:19 213:17 224:19 259:16 381:21 403:6 452:5 460:3 463:3 463:18 needless 475:13 needs 60:21 73:13 77:2 83:21 95:21 148:16 184:12 186:5 262:15	267:1 294:19 363:14 381:2,15 396:2 409:1 431:17 436:14 437:20 442:2 446:2 449:20 450:12 457:13 464:20 497:13 nefarious 209:9 negative 173:10 215:16 301:21 330:4 340:12 475:17 negatively 82:7 467:14 negatives 183:3 negligence 244:11 negligent 244:10 383:3 neighborhoods 377:10,15 neighboring 43:13 neither 111:19 458:17 502:8 503:7 neonates 138:4 nervous 262:20 270:1 300:3 301:20 net 56:9 101:7 network 40:21 288:8 networking 95:17 networks 288:20 291:3 neuro 484:4,10 485:3 neurodegenerati... 385:9 388:14 389:15 neurologic 300:19 300:22 302:3,4 474:11
---	---	---	---

neurological 264:4	427:2 437:8 438:16 441:11	151:15 210:15 212:19 215:15,15	453:16 491:20
neurologists 386:1 386:10 387:11,13 458:13	460:3,9 475:12 478:16 485:9 497:12	227:12 238:16 293:22 323:1 329:18,20 340:1 350:16 363:3	noted 79:4 160:5 313:18
neurology 400:11	newest 428:14	387:4,9 409:9,16 411:5 464:17 467:2 477:2 480:18	notes 112:1 321:1 321:4
neurons 385:10	news 171:14 282:3 336:7,10 383:5	noncompliant 228:21 229:17	notice 433:11 440:15
neuropathic 183:6 183:13 184:8	nice 172:22	nonexistent 125:18	noticed 31:12 482:22
neuropathy 276:4 276:16	nicely 25:14	nonprofit 98:19 122:10 132:17 246:20 451:3 462:10	notices 323:14
neuroprotective 122:22 269:3	nick 2:5 22:1	nontoxic 104:21 122:21 202:17	noticing 277:5
nevada 228:19,21	nickel 490:1	nonverbal 130:4	notification 167:4 271:22 273:6 350:7 438:17,20 439:12 440:2,3
never 32:17 39:7 174:3 245:22 263:6 272:12 317:14 398:18 406:11 473:9,18	nicotine 40:12 204:20 205:14,16 205:22 206:9 452:3 454:8,18	noramco 13:7 310:21 311:13	notifications 77:13 218:3 268:15 269:14 324:11 477:21 480:14
new 1:18 26:3 27:13,21 30:12 31:1 32:15,16,20 33:14 43:18 44:9 50:21 74:11 76:13 77:9 96:4 97:16 105:15 130:14 145:15 147:3 157:3 167:18 183:16 185:8 221:5 227:9 242:18 244:9 254:17,17 256:4 267:5 268:15 269:13 279:6 290:14 295:7 307:5 323:17,19 323:19 333:9,9 338:15 347:17 350:7 355:19 356:7 368:6,12,14 368:17,18 369:2 373:1 396:21 416:9,9 419:19 420:2 421:2,3	nida 184:7 186:12 216:15 218:19 283:7,10,12 284:19 451:9 471:16	noramco's 313:3	notwithstanding 105:17
	nida's 183:6	normal 51:10 400:2	novel 93:1 205:18 488:12 497:12
	night 373:16	normalcy 266:12 375:11	november 453:9
	nightingale 61:20 63:6	normalizing 375:11	nsaids 318:7
	nightmare 293:10	north 9:21 161:10 161:14,17,20,21 162:15,16 175:16 207:22 228:16,17 229:4 233:2,5,9	nuleaf 9:8
	nih 26:6 79:4 296:10 440:9 471:16	notably 62:2	number 24:12 30:20 37:5 47:17 56:16 58:21,22 59:2 61:10,11,13 63:16 66:18,20 70:16,18,22 72:11 75:22 77:5,19 83:8 87:14 91:6 92:15 95:14 98:8 101:19 104:11,13 107:1 111:4,7 115:17 118:22 125:7 129:16 132:12 135:7,9 137:13 142:13
	nimble 185:4	notary 502:1,16	
	nimbleness 185:5	note 27:11 31:9,20 56:19 67:21 121:18 132:9 151:4 209:21 240:3 249:15 398:21 417:9,10 417:18 430:1	
	nine 58:21 84:16 273:20 335:5 457:19		
	nobody's 182:15		
	noel 269:15		
	noels 219:17		
	non 4:20 11:11 18:10,22 42:15 43:2 78:10 79:2,7 80:14,17,19 86:5 93:19 99:17,18 104:21,21 122:21 122:21 142:4		

144:18 147:4 161:6 166:5,7 176:4 181:13 182:10 183:5 187:9 192:6 199:5 200:9 201:11,21 204:5 206:20 209:18 210:14 211:18 216:6 217:2 222:5 223:21 227:11 235:6 238:19 240:11 247:11,20 248:16 250:22 252:15 254:5 258:22 261:2,20 263:17 268:7 273:21 275:10 287:13,15 293:16 295:17 297:6,10 297:10 298:7 303:3 310:19 311:11 316:20 327:20 328:17 332:16 335:10 340:2,7 341:21 343:12 345:21 347:8 353:4 356:15 361:6 366:1 373:2 375:13 378:12 383:19 384:11 395:1 407:17 422:17 425:8 429:9 434:20 442:11 446:1 447:21 454:12,16 462:3 470:4,4 481:14 483:7,18 484:18 numbers 37:12 65:19 115:2 277:3 463:20	numeric 37:6 numerical 342:2 numerous 104:19 441:6 nurse 5:19 59:3 nutraceutical 78:4 78:7,15 271:14 nutraceuticals 65:1 227:18 nutrient 273:10 323:16 nutrition 1:2 7:21 15:17 115:18,21 289:21 325:3 434:22 440:8 nutritional 45:16 79:10 86:5 168:20 169:1 170:15 273:5 372:13 396:9 nutritionists 45:10 nutritive 328:2 nuts 240:22 nutshell 226:18 nyu 400:11 o o 18:2 19:1 20:1 oak 1:17 objection 31:13 499:6 objective 389:11 393:1 435:18 objectively 105:11 obligation 415:12 obligations 446:1 obliged 94:6 observation 391:3 observations 34:1 observe 69:21 observed 202:21 300:1,16 301:12 301:15	observing 203:18 obstacles 93:18 obstruction 202:22 obtain 389:20 446:17 465:8 478:5 491:16 obtained 222:8 299:8,15,18 301:10 319:21 363:9 obtaining 363:15 obvious 377:19 obviously 55:14 149:9 182:15 184:16 218:22 228:9 230:9 256:1 256:13 258:17 299:13 326:9 401:15 403:20 405:9 418:11 420:5 occasional 86:6 occasions 122:15 occur 41:8 143:12 222:21 271:18 330:8 451:21 488:8 occurred 119:13 220:3 301:5 466:13 occurring 112:3 113:17 114:8 od 16:16 odds 397:14 offer 53:17 98:15 132:20 267:5 305:1 offering 366:9 444:2 472:1 offers 76:20 office 2:7,12,16 3:4,8,12,15,20 4:4 7:15 20:8 21:2,12	21:13,22 22:3,4,7 22:10,13 70:21 104:14 245:9 276:6 officer 77:21 150:10 357:4 384:5 400:10 429:12 502:2 offices 347:16 official 99:1 166:20,21 167:9 381:8 391:20 392:17,20 officials 9:14 18:19 123:22 155:16,20 156:1 159:2 166:12 167:22 189:14 268:1 offset 139:7 offsite 444:8 oftentimes 193:13 oh 69:17 91:20 149:3 158:7 240:15 274:21 298:5 311:8 378:7 412:15 448:3 455:16 475:16 486:10 487:9,10 oil 12:19 34:14 124:7 168:13 170:14 249:6 270:13 274:21 275:4 276:7 277:4 277:10 287:18 290:9 299:2,6,14 301:3,10 302:11 308:17 309:9 321:19 372:14 404:4 417:16 448:15,16,19,20 448:21,21,21 449:9 457:4 459:1 459:17 469:12
---	--	---	--

485:22 oils 96:12 127:7 191:7 211:7 256:3 257:5 362:14 364:18 365:1 418:9 ok 451:2 okay 50:5 55:15 66:10,15 70:18 75:19 86:2,14 91:17 104:13 118:20 128:12 129:16 144:14,16 150:4 158:11,15 167:13 170:16 171:12,17 172:9 172:10 181:18 199:3,20 200:7 209:19 215:21 240:15 244:2 245:7,20 248:15 258:19 277:6,21 280:1,5 282:2,10 295:13 298:5,9,9 298:15,18 307:10 308:6 313:16 334:20 335:1 357:2 368:14 378:10 384:19 434:4 447:3 449:11,19 484:2 484:19 486:2,10 oklahoma 482:4,8 oklahomans 17:5 old 96:4 127:4 208:21 226:16 227:4 254:16 260:7 375:1 447:12,13,15 457:20 472:15,15 472:22 473:3 older 127:5 452:16	oldest 46:5 395:9 472:21 olds 491:10 olsen 7:20 115:17 115:19,19 118:17 omega 12:21 45:21 293:20 once 54:20 59:5 62:6 76:15 100:14 106:18 118:2 191:1 203:10 229:11,20 234:12 248:6,8 296:5 309:7,7 345:18 395:3 oncologist 26:7 oncoming 493:1 onerous 94:19 ones 49:3 63:2 236:19 283:8 338:16 376:19 422:19 ongoing 140:1 212:9 216:18 273:19 439:8 444:8,10 online 62:19 125:13 148:1 222:8 225:12 246:7 249:16 251:17 278:12,20 362:6 396:21 461:2 onset 41:9 186:16 onsite 372:2 444:8 onslaught 156:9 onus 415:8 oops 488:16 open 27:6,6 36:22 40:22 47:7 90:9 127:19 278:8 299:5 326:6 426:8 501:1,1	opened 428:15 448:13 opening 18:6 20:2 26:1,13 149:18 156:12 openness 381:17 opens 355:6 477:15 operate 346:7,13 358:22 411:11 478:7 operated 465:5 operates 321:17 operating 78:6 96:5 244:2 268:16 349:8 361:21 411:6 462:15 operation 367:10 370:8 465:6 476:15 operations 121:1 366:3 370:2 463:12 operators 127:6 464:9 465:7 476:11 477:8 opine 182:19 opinion 39:13 75:6 222:5 231:2 326:22 407:1 409:22 441:1 opinions 200:17 opioid 39:12 241:5 250:19 260:9 261:10 318:2 482:14 484:17 485:12 opioids 67:10 224:7 271:9 opportunists 131:19 opportunities 44:9 47:7 52:11 90:15	opportunity 45:14 46:7 49:21 52:16 65:21 72:8 74:9 77:17 79:16 83:13 85:13 88:9 89:9 94:20 104:16 124:11 129:8 151:16 153:7 155:10 156:5 157:13 161:8,12 163:20 187:11,21 204:7 216:8 259:5 268:2 273:15 317:3 326:4 328:22 352:8 373:5 378:15 384:4 413:9 418:1 425:13 429:5 431:8 439:6,14 462:7 486:22 opposed 84:1 87:1 140:9 opposite 271:8 474:12,14 ops 288:13 optimal 79:10 285:10 optimistic 283:20 optimization 126:12 option 255:14 317:12 341:11 options 27:8 123:7 223:8 287:6,6 394:9 optometrist 471:13 oral 4:13 18:8,18 20:13 37:1,15 81:10 93:2 155:19 173:1 186:11,16 211:12,22 224:6 270:15 278:5 299:6 301:3,10
---	---	--	--

313:10 358:12 366:10 388:21 orally 41:6 211:15 212:15 270:12 299:2 orange 387:13 454:11 order 24:11,21 25:3 37:6 72:7 81:20 141:1 168:7 228:5 229:18,18 230:18 232:20 342:2 369:22 382:7 389:20 412:11 414:7,13 461:10 463:14 ordered 23:6 57:20 417:3 orderly 383:7 orders 120:14 170:7 oregon 291:22 468:21,21 oregon's 469:14 organic 7:13 50:8 101:20,22 102:6 102:16 342:20 organism 302:14 organisms 442:22 organization 47:21 54:7 95:17 98:20,22 103:19 104:20 131:4 142:16 166:13 235:19 240:18 246:16,20 268:11 295:19 376:20 385:3 393:14 400:17 462:10 467:2 477:1 481:8 organization's 49:2 313:20 organizations 199:6 220:12	243:19 377:9 379:5 427:15 445:12 organized 37:6 organophosphates 278:15 organs 382:7 488:18 origin 99:5 369:10 original 334:4 453:6 orlowitz 15:20 429:9,10,11 434:4 434:12,18 orphan 93:6 94:9 orthodox 61:22 ossowski 12:2 252:15,16 257:19 258:3,10 otc 76:5,7 122:3 131:2 436:18 outbreak 366:20 367:9 outcome 135:1 264:14 502:13 503:12 outcomes 93:3 220:4 223:18 225:14 492:5 outdated 38:19 outer 495:2 outgrew 447:14 outlets 172:2 outlined 326:9 350:3,9 outlines 369:14 outpatient 92:7 outrageous 127:16 outreach 135:14 outside 24:4,8,14 24:15 37:4 89:19 93:15 96:3 119:13 139:4 140:19	208:2 213:14 251:15 341:8 353:1 408:9 432:4 outstanding 219:12 outweighed 431:1 ovarian 259:12 overall 80:1 238:11 292:19 293:2 306:17 453:22 overarching 30:15 overdose 41:11 207:8 overdosed 245:3 overflow 176:5 overlay 420:15 overnight 119:17 overregulation 54:15 290:18 433:19 overseas 288:1 358:10 423:6 oversight 76:20 116:16,18 123:8 181:10 209:7 222:7 303:14 312:18 329:5,16 331:6,8 338:9 370:9 371:6 408:12 414:5 431:8 overuse 285:15 overview 18:4 420:12 422:18 overwhelming 80:4 109:9 318:18 320:6,21 321:6 owner 144:21 287:22 owners 96:14 oxidative 484:6 oxley 268:16	oxycontin 250:20 oxygen 332:3 p p 2:1,1 3:1,1 4:1,1 5:1,1 6:1,1 7:1,1 8:1,1 9:1,1 10:1,1 11:1,1 12:1,1 13:1 13:1 14:1,1 15:1,1 16:1,1 17:1,1 20:1 p450 177:2 178:19 179:11,19 180:8 180:13 271:17 p450s 359:21 pace 119:9 package 174:17 packaged 87:18 114:7 255:11 450:5 490:11,12 packaging 13:19 110:10 121:16 206:12 278:12 289:20 332:3 342:1,5,6,14 364:14 428:1 469:7 478:19 491:5 packed 27:1 packet 167:18 pacts 411:13 page 18:1,3 19:2 44:22 121:10 433:4 pages 107:15 109:12 paid 43:15 393:10 456:22 485:10 pain 39:16 127:9 138:22 183:6,13 184:8 207:14 208:22 224:5,7,8 248:17 249:1 250:4 261:8,11 274:4 275:8,8 277:18 286:21
---	--	--	--

299:7 317:5 318:3 318:4,6,7,10,12 318:14 320:6,12 387:17 482:14 painful 58:4 painless 474:3 painquench 276:10,13 pains 127:8 432:8 pam 9:15 155:17 155:21 158:18 pamela 5:12 173:2 173:3 176:2 pamphlets 491:5 pancreatitis 260:21 panel 20:21 23:13 23:21 52:21 53:4 55:2,6,9,15,18,21 56:3,12 61:5,8 65:22 66:1,10,11 66:15 68:11,16,17 69:5,10,11,14,17 70:6,12 74:12,22 75:7 79:18 80:12 80:21 85:14,16,19 86:2,8,9,11,14,17 86:18,22 87:4,6 89:14 90:8 92:13 94:21 95:10 100:21 101:4 103:3,13 104:5,9 110:12,17 111:1 113:16 114:2,16 115:4 118:10,20 124:12,16,19 128:1,4,9,12,13 129:1 137:3 140:5 140:7,12 141:2,7 144:10,14 152:15 155:15 157:16 158:4,7,11,15,18 161:1,4 164:7,10 165:6 169:12,20	170:17,20 171:12 172:4,9 185:14 186:7,20 196:20 197:22 198:10,11 198:17 199:3,10 200:7 214:14 215:5,11,18,21 226:2,8,11,13 232:7 233:1,8,17 233:18 252:7 257:18,20 258:5 273:17 274:6 279:14,19 280:1,3 280:5,7,8,20 298:10 307:6,8,11 308:6,9,20 309:3 309:11,16,19 310:9,11,13 315:16 316:5 320:19 326:8 327:13 328:1 337:12 352:9 385:7 390:1,3 394:20 399:7,14 405:5 406:20 409:19 413:4 417:10,19 434:6 434:17 440:21 442:4 456:10,16 466:11,17 475:21 481:7,12 493:17 494:9 498:21 499:1 panelists 24:1 50:4 293:18 panels 152:2 153:1 379:4 panic 374:20 pantry 236:9 paper 40:21 100:10 261:16 335:9 491:1 papers 242:5,9 336:8 473:20	paradigm 145:10 327:6 paradigms 285:4 285:5 325:4 paragraph 343:19 parallel 320:13 parameters 270:22 299:8,14 345:22 413:16 paramount 53:17 83:3 paranoid 373:15 pardon 55:20 parent 130:5 336:21 467:4 472:9 parents 55:12 244:22 449:5 472:7 473:7 483:6 park 261:8 parkinson's 14:19 383:20 384:6,9,10 384:14,20 385:8 386:7,10,13 387:6 387:18 388:1,6,8 389:1,13,21 390:4 482:16 part 1:11 28:8 38:9,16 54:20 71:4 74:10 75:11 90:4 114:18 134:17 156:15 160:16 176:12 178:17 180:21 194:4 245:18 247:3,12 277:19 309:6,17 395:4 422:1 427:20 452:8 476:13 484:21 498:3 partake 104:4 participant 23:12 23:13	participants 51:12 85:5 213:9 participate 27:4 72:8 157:13 168:22 218:6 participated 121:19 participating 135:3 153:19 participation 160:7 427:16 444:9 particular 33:3 56:10 69:8 154:18 183:19 199:12 202:2 206:12 207:21 267:9 279:8 351:7,22 382:6 393:20 394:8 484:10 particularly 46:11 66:6 80:16 130:14 164:11 187:3 217:4 225:15 249:4 253:9 256:10 330:4 380:3 437:19 441:2 474:11 477:21 479:16 parties 100:17 107:16 348:12 380:1 446:8 502:9 502:11 503:8,11 partner 216:16 499:22 partnered 265:22 357:22 partnering 166:3 267:22 partners 5:21 61:14,16 96:1 230:18 288:2 489:18
--	---	---	---

partnership 145:16 368:21	434:1 437:18 440:6	94:9 96:7,11 99:16 130:16	pcqi 342:14 372:2
partnerships 3:11 21:21 160:15 247:5 427:14	pathogenic 99:19	131:15 132:4,5 135:11 138:4	pcr 493:9
parts 40:11 84:3 159:15 172:5 238:3,7,9 239:18 239:21,22 314:9 348:11 368:7 369:4 474:7 490:8	paths 105:6 184:15 407:11	140:8,19 141:9,17 173:14 181:9 182:10,22 183:20 196:4 197:15 201:1 217:10 223:6,22 260:3,4 261:10,11,17,18 266:4 270:18 272:9 277:17,21 280:21 285:13,15 286:20 294:2,18 299:6,22 300:9 301:4 315:12 317:10,13 318:17 318:21 320:6 321:3 333:22 334:8 339:7,16 340:8 341:8,17 359:8,12 379:18 380:1,3,15 383:2 383:16 386:4 390:4 456:19 460:4,20 461:8 472:9 482:15 485:19 493:7	pd 384:11,22 385:1,4,16 386:1 386:11 388:3,8 390:8,15
party 132:18 192:19 199:7 305:5 325:18 342:20 345:21 349:16 351:13 370:17 380:21 383:13 479:6	pathway 31:11 42:4 47:9 48:9 65:13 76:14 85:10 94:17 113:13 116:5 155:8 163:18 166:2 176:22 214:11 225:3 228:7 231:1 303:22 322:2 323:15,18 328:14 339:2 356:6 364:17 365:18 378:16 433:14,14 457:8 477:20 481:1	301:4 315:12 317:10,13 318:17 318:21 320:6 321:3 333:22 334:8 339:7,16 340:8 341:8,17 359:8,12 379:18 380:1,3,15 383:2 383:16 386:4 390:4 456:19 460:4,20 461:8 472:9 482:15 485:19 493:7	peace 10:20 204:5 204:6,12 246:10
pass 229:21 278:2 478:13,15	pathways 35:1 83:20 139:14 297:13 326:9 407:1	patricia 261:8	peak 41:7 211:22
passage 480:3	patient 60:5,17 62:17 67:15 69:8 131:9 135:9 177:9 179:22 180:20 267:10 278:22 280:9 285:8,10 318:5 340:7 360:18 379:12 386:16 387:16 456:18 460:16 461:4,19 462:9,13 463:13	patrick 9:3 144:18 144:20	peddling 131:20
passed 48:14 82:17 283:17 430:10	patient's 70:2	patrol 425:4	pediatric 30:6 130:13 132:4 137:15 138:1 272:9 374:10 403:15 458:13
passing 379:14	patients 8:14 16:7 18:15 19:6 30:9 35:17,17 38:14,22 59:12,15 62:18 64:8 65:6,20 67:4 67:7,10 68:7 69:12,21 93:8	pave 430:4	pediatrics 483:9
pat 320:14		pay 24:22 201:3 203:1 485:9	peer 39:5 156:20 312:15 325:14 444:20 491:16 492:4
patches 276:15		paying 24:10	peeve 279:1
patchwork 88:19 138:10 159:3 163:14 290:15 477:11		payment 108:8 148:1	penalties 241:17
patent 79:3 80:16 292:20 319:1 483:16,18		pays 403:11 485:13	pending 319:1
patented 234:21 234:22		pc 7:15 212:7	penetrating 94:16
patents 230:14			penn 171:20
path 77:6 100:15 101:14,15 105:7 106:6 195:18 217:16 303:1 320:14 346:5,19 347:3 358:21 430:4,5 433:8,15			pennsylvania 10:3 166:7 170:4,9 171:21 328:20

222:22 241:14	72:4 74:20 84:8	463:19	75:10 128:3 170:3
243:5 244:2,21	85:16,22 108:17	performance	245:21 247:10
245:9 246:1,1	142:18 148:13,14	189:2,3 211:14	personnel 381:5
247:9,16,21	190:4,6,10,18,18	392:8 425:22	446:3 463:16
248:11,13 249:19	191:1,16 193:17	426:11	perspective 200:1
250:1,15 251:12	199:14 201:1,13	performed 201:7	210:2,7 211:10
252:12 255:20,21	207:3 211:3	265:17 302:17	366:19
257:9,14 275:18	222:19 223:7	354:1 363:20	perspectives
276:19 277:2,6	228:20,21 229:16	364:1 446:11	400:14
278:18 280:16	232:3,16 237:22	performing	pertaining 166:17
290:2,15 293:9,13	238:1 239:1,5	351:18 364:8	442:19
305:14 308:3,19	240:2,4 248:6,10	period 37:1,1	pesticide 72:5
309:22 310:6	248:17,19 249:12	164:1,5 306:2	100:2 237:13
312:6,8,19 335:12	249:13,21 250:3,4	318:15 355:3	238:7 330:13
335:13 337:3	250:5 251:1,7,20	periodically	362:2 366:13
340:17 345:16	261:9,10,12,19	134:17	368:4 372:9 394:9
346:17,17 347:21	275:6,8,11,16,19	periods 34:19	480:4
376:3,6,9 377:20	295:19,19,20,20	peripheral 270:2	pesticides 60:12
377:21 382:2	296:1,6 299:22	permanently	131:13 138:13
385:1,4,16 386:9	300:9 309:10	468:17	146:12 232:1
386:11 387:17	313:16,18 314:3	permissible 108:5	234:10 238:6,6
388:8 389:1,21	314:10,17 315:6	108:5	278:15 286:2
390:8,13,15	318:13 320:4	permissive 470:12	312:4 319:15
391:17 397:17	334:22 335:4,6	permit 72:3 185:6	330:7 331:18
399:6,7,7 400:13	341:2 368:3	272:21 435:22	345:14 363:22
401:4,20 404:2,9	375:19 386:3	465:1,3	366:14 392:12
404:12,18 406:1,5	402:7 424:16	permitted 23:1,20	394:3 428:11
406:8 410:15	449:15 450:17	268:21 464:17	442:21 464:6,14
429:21 430:13,14	453:17 469:2,12	permitting 112:20	464:17,18 465:10
430:18 431:14	469:13,17,19	117:16	pet 33:12 167:11
432:4,9 448:5	473:4 480:2 485:7	peroxide 59:20	168:19,21 170:4
454:21 455:3	485:14	person 22:18	171:4 193:4,9,12
457:13,13 465:12	percentage 211:4	26:21 34:15 40:19	197:3,7 279:1
482:9,14,20 483:4	254:12 468:12	41:7 63:3 172:22	289:20 357:4
483:5,20 484:13	percentages	281:9 375:12	peter 4:15 9:11
486:11 497:6,10	453:18 455:11	388:6 465:14	37:10,14,18 153:3
498:10 500:12,14	perception 125:21	481:21 501:3	petition 73:18
people's 87:22	percocet 250:20	personal 75:3 88:5	75:11 167:2
244:20 297:7	perfect 111:1	88:15 96:7 243:10	petroleum 448:21
304:6 401:10	384:19 417:3,5	465:17	pets 193:10 252:8
perceived 126:16	470:10 489:12	personalized	252:10,13
477:14	490:11	264:15	ph 242:4 450:6
percent 28:21	perform 354:16	personally 54:10	492:19
46:9 51:11 69:1	358:1 382:16	55:11 73:22 74:14	

pharma 13:3 298:12,16,19 302:10	331:11 463:9	physician's 404:4	pizza 376:14
pharmaceutical 92:19 103:12 120:19 122:16 139:9 187:22 285:6 303:22 310:22 311:6,15 314:21 321:20 326:18 330:16,19 331:2 332:8 353:1 358:15 374:14 396:8 403:21 405:7,13 435:10 435:18 483:1 485:15 496:20 497:9,21 500:2	pharmacovigila... 194:16 214:3 319:21	physicians 38:14 39:4 130:1 141:10 142:3 278:17,19 339:15 380:1,16 484:16 485:7	pk 298:22 299:8 299:13 318:20
pharmaceuticals 7:7 13:13 52:18 92:20 131:2,11 227:19 328:20 338:2	pharmacy 96:21 176:17 188:1 192:8 457:7	physiological 270:22 271:12,18 488:19	place 53:20 54:3 117:14 149:12 162:18 163:2 236:17 242:16 251:14 269:7 326:20 349:11 379:18 397:3 409:18 414:20 416:7 423:22 436:8 438:13 441:20 450:6 491:1 493:12
pharmacies 153:10	pharmd 10:7,14 16:8	phytocannabinoid 138:12 168:17 293:20	placebo 143:21 173:19 222:1 299:4
pharmacist 457:10	phase 93:4,7 142:21 282:19 284:15,17 286:13 286:15 298:20,20 298:21 299:3,5,9 300:13,15 301:10 301:16,17 360:17	phytocannabino... 95:4 233:21 310:1	placed 120:18
pharmacists 38:15 39:4	phd 2:2 3:14 4:17 5:6 6:14 7:2,6,10 8:15 10:12,17,20 11:2,4,7 12:6 13:2 13:14 14:4,6,16 14:18 15:2,12 16:20 40:8 50:8	phytochemicals 200:19,21	places 44:6 133:16 288:19
pharmacokinetic 177:4 179:17 273:22	phenomenon 122:14	phytocompounds 47:12	plain 255:10
pharmacokinetics 186:15	phenotype 267:9	pi 216:21	plan 100:9 274:7 345:19 375:3 386:18 407:22 466:16
pharmacological 300:11	philadelphia 336:8	picked 336:7 406:4	planned 397:12 459:1
pharmacologica... 210:19 221:11	philip 6:6 66:22	pictograph 229:14	planning 24:9 146:19 312:12
pharmacologist 270:4	phillip 66:20	picture 129:22 199:22 203:3 219:20 262:22 283:9 320:10 467:15	plans 89:7
pharmacology 185:8	phone 172:20 173:1 282:5	pieces 33:17	plant 27:17 28:8 54:21 61:17 68:21 70:17 72:21 73:5 84:2,3 100:9 103:8,11 113:21 114:5,7,18 133:10 145:9 146:6,9 151:7,11 165:18 218:13 221:18 228:12,14,20 243:8 261:18 267:9 285:19 294:15 302:15,19
pharmacopeia 7:11 138:17	phones 250:11	pile 125:17	
	photo 457:15	pill 385:15	
	photographs 245:9	pilot 299:4 317:22	
	phrases 417:13 418:4	pioneers 357:10	
	phthalates 238:8	pipe 375:12 454:1 454:15	
	physical 59:5,12 67:11 243:1	pipeline 493:1	
	physician 62:15 278:3,13 279:2 282:11 338:9	pipes 375:10	
		pitched 422:3	
		pitts 4:15 37:10,17 37:18	
		pivotal 93:7 368:19	

307:22 308:11 312:5 324:4 327:17 333:11 335:13 336:15 338:20 339:11 368:8 369:4 388:19 392:3,11 392:18 393:20 394:17 410:7 411:14 416:9 418:6 424:10 486:12 plantar 276:15 plants 59:13 123:12 151:16 171:15 172:5 285:18 294:16 368:1 382:6 plasma 181:2 493:22 plastic 417:4 491:2 plasticizers 237:13 plate 38:5 372:11 499:4 platform 165:22 264:8 266:14,18 267:17 361:12 platforms 50:14 145:1 play 71:15 421:20 423:17 424:15 465:14 485:9 playbook 121:10 played 368:19 players 109:3 playing 187:17 316:17 345:9 plays 51:1 87:20 379:11 488:19 please 21:1 23:17 23:22 24:1,9,17 24:22 25:4,18	26:10 37:12 66:12 68:11 77:11 91:18 91:19 122:5 137:19 144:7 152:11 155:9 172:19 226:13 249:14 259:17 347:2 356:22 372:21 400:15 412:14,17 434:2 446:15,16,19,21 451:5 455:15 461:16 471:1,2 475:21 486:7 489:11 490:7,15 491:4 492:7 500:13 501:1 pleased 26:19 153:5 429:11 pleasure 200:11 252:17 pledge 286:11 plenty 399:4 436:7 pllc 10:16 15:7 plots 288:15 plural 39:10 plus 56:19 229:16 238:1 256:8,8 321:19 412:10 pmb 9:4 144:21 pms 276:4 podcasts 172:1 podium 23:22 25:2,8 26:11 166:7 point 72:17 76:6 76:12,17 77:5 108:14 109:4,20 116:15 132:14 140:14 149:3 185:22 201:21 213:8 223:15 231:6,20 255:2 286:18 287:5	288:7 292:5 294:21 295:11,14 295:17 300:17 305:16 315:4,5 336:19 340:20,22 351:8 388:11 430:2 458:6 pointed 256:13 pointers 216:10 pointing 489:7 points 51:3 76:6 83:15,18 107:20 182:4 203:10 213:14 244:19 254:3 275:9 285:3 288:12 294:21 315:9 413:19 428:3 poised 43:20 poison 193:9 197:7,9 200:1 376:21 431:13 poisoned 207:20 poisoning 60:10 377:20 polarizing 220:22 police 346:22 policies 39:21 65:17 470:13 policing 60:3 policy 2:7,15,16 3:7,11,12,19,20 21:5,11,12,22 22:3,21 27:8 35:22 42:19 58:12 59:18 107:5 120:21 146:4 155:5 221:9 253:3 253:15 265:19 368:7,9,15 369:3 369:14 393:10 467:6,9 486:13 pond 497:12	pooled 261:17 poorly 138:15 212:3 populace 360:22 431:17 popular 41:13 122:13 237:3 398:13 popularity 44:4 131:20 population 33:3 33:22 60:17 138:5 140:15 320:5 360:18 361:5 388:13,14 399:1 439:19 451:16,19 451:20 452:11 456:4 477:17 482:8 populations 213:22 214:1,1 271:20 272:4 318:1 340:8 398:8 468:2 470:19 porous 488:5 portal 313:5 portion 20:13 159:14 pose 77:16 84:21 118:6 191:20 position 21:1 38:12 85:1 103:20 111:19 112:6,12 113:7 116:6 134:22 157:17 162:10,13 313:3 350:2 401:14 435:4 positioned 90:16 452:14 positive 54:9,11 92:5 96:12 183:8 213:10 223:22 288:5,6 290:11
--	--	--	--

306:3 318:3 positives 183:3 possession 28:6 possibility 401:11 possible 23:17 24:13 44:21 62:14 94:18 109:2 116:4 118:9 217:16 220:3 257:13 258:14 280:19 334:9 450:10 461:10 possibly 71:11 112:19 279:6 281:3 356:12 post 45:17 82:8 192:19,21 194:14 196:11 277:6 300:18 325:1 408:9 409:7 posted 343:19 pot 375:1 potato 147:15,15 potatoes 147:13 potency 57:2 61:1 175:3 237:14,17 242:21 285:12 319:14 369:17 371:9 372:7 377:3 394:9 416:22 438:18 465:11 479:10 potent 94:16 260:14 potential 28:14 33:6 35:1 39:8 49:6 52:10 63:21 64:1 72:21 88:19 109:13,16 110:8 123:2 126:11 130:18 131:10 138:12 139:6,16 176:18 177:16 178:2 180:2 181:6	191:19,22 192:4 196:7,15 199:8 201:5,22 203:13 203:21 208:15 213:5 217:3 267:13 271:2,11 271:15 284:3 334:14 338:20 356:7 380:9 404:13 405:1 439:18 452:2 472:13 484:14 493:3 potentially 46:14 82:15 94:8 95:1 128:19 180:17 182:6 193:21 336:9 339:8 354:15 355:19 401:2 410:8 473:4 474:6 potentiation 202:16 pouches 491:2 poultry 46:3 pounds 289:9 power 127:21 408:5 powerful 126:7 260:11 339:18 practical 94:12 407:10 practically 119:17 practice 12:15 39:20 192:3,18 194:16 197:5 274:18,18 314:8 practices 49:13 54:1 59:11 134:6 195:6 196:18 303:12 319:13 350:3 363:17 368:12,17 446:11 463:10 482:21	practicing 62:15 260:1 practitioners 181:10 prayers 459:21 pre 325:1 precious 355:18 precipitous 409:7 precisely 380:8 preclinical 177:22 339:10 492:18 493:2 preclude 112:2 precluded 81:19 102:6 predators 131:18 predatory 375:3 377:4 predictability 65:14 predictable 322:1 437:18 440:6 predicted 360:3 predominant 205:10,14 210:3 preemption 356:6 prefer 277:13 278:3,13 preference 397:3 preferred 452:22 pregnancy 123:17 124:13 213:22 399:21 pregnant 34:16 173:22 225:1 271:21 340:8 375:20 415:5 preliminary 45:19 372:13 premises 55:9 premium 73:1 239:9 preparation 203:8 330:9	prepared 320:7 487:18 503:3 preponderance 109:9 prescribed 38:22 458:10 prescribing 66:13 120:9 281:6 prescription 33:5 81:19,21 123:3 139:2 245:17 284:20 286:15 324:10 407:12 410:11 436:18 448:14 459:20 461:6 prescriptions 250:19 285:6 409:20 presence 102:21 114:8 189:21 330:3 479:19 480:4 present 37:3 75:17 81:10 106:15 108:17 109:10 116:2 133:13 146:5 156:5 166:9 204:7 240:7 264:5 298:17 308:19 317:3,16 328:22 337:11 396:19 406:22 449:13 462:18,22 465:13 487:3 491:18 496:11 presentation 23:12 172:21 181:16 320:17 366:1 391:2 447:8 500:21 presentations 10:5 18:18,20 20:15,16 23:4
--	---	--	---

25:3,16 155:19 176:11,14 349:6 365:14 presented 219:16 317:13 418:12 463:2 presenter 495:18 presenters 23:14 24:18 27:3 348:19 presenting 75:12 220:14 341:22 451:9 462:21 preservative 366:14,15 preserve 404:16 405:9,10 preserved 29:6 329:6 preserving 405:12 president 37:18 83:11 87:16 92:18 98:11 111:10 129:19 142:15 155:22 159:1 192:11 220:15,16 263:19 268:9 321:11 328:19 353:6 471:14 press 8:7 23:14,20 125:10 pressure 276:5 281:6,11 388:5 473:15,17 474:2 pressures 44:4 276:6 465:5 presumably 217:2 pretty 127:4 199:1 275:9 335:9 349:6 349:17 376:20 395:22 429:18 471:10 496:7 prevalence 155:5 162:12,15 164:16 164:19,21 384:13	453:14 454:7 prevalent 189:1 452:1 prevent 35:12 99:16 100:14 105:10 182:15 454:2 500:9 preventative 146:19 preventing 160:11 prevention 195:15 216:17 467:5 483:9 preventive 342:17 previous 118:11 178:5 252:20 253:18 359:20 360:4 471:12,22 471:22 previously 113:12 151:22 200:1 329:4 price 485:11 prices 46:8 primarily 102:2 156:4 221:20 243:5 263:3 309:1 357:5 385:9 390:5 476:9 primary 62:15 83:18 145:18 159:14 168:4 277:17 353:15 359:17 principal 2:3 3:19 21:4,8 188:2 449:19 principles 312:7 327:19 407:10 printed 20:17 341:21 prior 33:22 77:9,9 97:21 111:18 215:20 451:22	454:6 465:8 472:2 priorities 65:18 76:7,10 121:2,9 121:12 122:16,16 387:16 prioritize 120:22 prioritizing 492:13 privacy 252:22 private 43:9 47:7 132:21 274:18,18 367:12 425:20 privilege 96:7 361:10 privileged 54:10 483:4 privy 96:10 priyanka 14:6 361:7,15 364:8 proactive 58:13 119:5 probably 120:1 200:2 209:14 243:7 254:6 255:21 272:14 279:6 280:16 340:15 391:3 405:15 499:6 probe 180:12 problem 140:3 208:19 230:21 243:12 290:19 294:12 340:3 384:3 390:7 413:7 455:20 484:22 problematic 185:10 221:13 problems 11:8 68:3 102:20 124:4 210:11 220:10,12 223:1,17 224:1 242:2 246:9 349:18 351:12 385:18 390:14,15	450:4 procedure 479:13 procedures 22:22 23:3 99:6 133:22 134:5,6,8 311:18 316:3 317:11 331:9 proceed 20:12,14 358:3 434:15 468:1 470:18 proceeding 502:3 503:4 proceedings 22:21 81:9 485:1 502:4 502:6 503:6 process 11:13 43:18 50:16 73:17 76:13 89:4 90:6 101:7 104:4 122:20 133:10,22 134:11,19 155:11 160:7 167:16,17 168:3,9,12 182:16 196:12,17 225:15 227:2,14,15 229:9 229:11,15 231:7 232:8,12,14,15,20 233:22 234:4,11 234:13 266:13 269:20 282:17 283:5 284:6,22 289:17,18 290:3 297:20 309:8 331:20 335:22 339:4 341:16 348:5 355:16 356:3 363:12 365:6 370:7,10 383:7 396:19 410:2 426:9 437:5 444:12 446:18 478:15 487:7,9,12 488:2
---	--	--	---

<p>processed 46:19 280:3,6 284:4 286:3</p> <p>processes 90:22 229:17 230:13,14 230:17 291:4 292:13 305:4 317:10 319:12 330:16,20 331:3 331:19 332:7 362:13,22 365:16 367:15 380:19 381:11 425:17 427:11 428:13 429:3 436:8,14 460:3 461:18 466:13</p> <p>processing 228:5 229:11 231:4,14 231:21 289:5 297:17 308:13 317:7 319:11 330:12 424:15 427:18</p> <p>processor 319:5</p> <p>processors 43:14 43:16 45:9 49:19 108:9 161:20</p> <p>proclaim 207:3</p> <p>procured 237:8</p> <p>produce 41:1 105:2 184:8 211:12,22 212:18 224:8 296:19 311:14 314:5 330:4 342:11 351:9 358:20 362:5 371:3 468:22 477:18</p> <p>produced 43:3 207:2 311:17 315:13 358:8 374:6 441:3 488:10</p>	<p>producer 369:8 392:6 395:18</p> <p>producers 46:4,13 47:14 132:22 227:22 303:20 305:7 410:22 444:14</p> <p>produces 46:9 211:20 347:12</p> <p>producing 66:2 82:19,20 169:15 170:18,21 171:9 219:10 308:16 312:9 361:21</p> <p>product 27:19 29:18,19 40:9 42:1 43:14 51:21 55:17 57:2 62:21 74:13,19 75:4 76:8 79:5 84:13 99:8,12,13 101:6 103:11 114:6 117:22 118:2 123:4,7 129:21 131:7,19 132:22 133:6 139:2 146:20 161:17 171:1 174:17 175:3 186:11,12 188:10,15 189:9 189:16 190:2,3,8 190:10,18,20 191:12,15 192:11 192:20 193:7 195:10 196:9,11 196:19 199:12,15 200:4,6 206:11 211:5 213:11,12 217:3 219:20 226:19 228:6,21 230:1,3 233:14 235:17,21 238:5 239:1 240:7 246:4 247:8 248:7</p>	<p>251:19 255:9,16 255:17 265:10 266:10 267:8 268:14 278:13,20 279:8,17,21 280:3 280:6 293:22 294:13,14 295:3 295:10 296:6,6,8 296:19 302:8,18 304:3 305:13 306:11 308:21 311:7 314:20 315:7 316:14 319:18 324:16,21 325:2 327:5,21 328:14 329:22 330:2,17,19 331:1 331:3,12,14,15 332:3 333:5,19 334:3 336:1,4 343:11,13 345:18 345:20 346:15,16 349:12,20 350:1 350:20 352:2 362:4,7,17 363:3 363:5,8 364:9,16 365:6 369:18 370:15 379:11 380:20,22 381:3,9 381:20,22 382:19 383:1 402:13,15 403:1,21 404:19 405:3 408:2,8,10 414:9,21 415:15 415:21 416:4,8,12 421:5 423:9 425:16,21 427:2 428:6,20 437:1 438:2,6,18,20,21 439:4,16 440:20 441:4 446:12,19 451:18 452:16 453:7,14,19 454:13 455:1,4,5</p>	<p>459:3,7 460:5,16 462:19,20 469:11 469:16,19 479:2,4 479:12 480:1 490:5,21 491:13 496:20,20,22 497:3,22 498:1 499:10</p> <p>product's 188:20 380:8,9</p> <p>production 38:18 47:9 78:2 86:16 99:17 134:12 160:20 162:16,19 163:2 165:16 166:17 171:7 228:1 230:12 233:10,16 289:6 305:10 315:11 319:8,14 347:15 350:4 370:21 429:3 478:18 479:7 497:8</p> <p>productive 72:21 265:21</p> <p>products 1:8 6:13 7:19 11:6 15:3 20:5 26:17 27:9 27:12 29:7,11,12 30:3 32:4 33:11 33:15,18,20 34:7 34:17 35:1,6,9,11 35:15 36:1,11 38:5 40:14 41:12 41:14,19,21 42:6 42:9,10,22 43:3 44:4,11,18,19 45:3 46:15 47:11 48:13,19 49:15,20 50:22 51:5 52:2 52:15 53:18 55:4 60:12 61:1,2 62:8 62:10 63:1 64:2,4 64:9,13,17,20</p>
---	---	--	--

65:6,10,12 66:2,6 66:13 69:4 72:15 73:2,10,13 74:4 75:9,19 76:1,3,11 76:15,19,21,22 77:7 78:5,7 79:8 79:12 81:10,14 83:14,21 84:14,15 85:3 87:22 88:13 88:15 89:1,16,18 90:10,12,19 91:1 96:9,15,19 97:1,5 97:20 98:17 100:15 102:3 105:2 108:1 109:5 109:14,17 111:8 111:11,16 112:13 113:17 114:11,17 116:16,19,20 117:9 118:13 120:7,11,17,19 123:10 125:1 130:9 131:3,12,15 131:17,21 132:2 133:3,8 138:7,8 138:11,19 139:8,9 139:17 140:8 142:5,10 143:13 143:16,17 144:5 145:13,16 146:14 147:1 150:21 152:3,11 153:15 153:17,22 154:3,6 154:14,18,22 155:4,6 156:4,9 157:4,9,20,21 159:7 162:4,6,10 162:12,15,16,19 163:3,3,10,19 164:14,20 166:2 167:11 168:7,14 168:17,19 169:1 169:22 170:2,4,6 170:10,14 171:3	174:9,21 182:10 183:7,13,18 184:6 184:18,19,20 185:2 188:3,8,12 189:4,8,11,18,22 190:5,6,12 191:1 191:6,10,13,17,18 192:2 193:7,11,12 193:20 194:1,2,15 194:18 195:3,22 196:1 197:11 199:9 203:21 204:8 205:3,5 206:17,21 207:1,4 207:20 208:1,6,11 210:16 211:3 212:5 213:13,20 214:3 217:18 219:8,21,22 222:2 222:12 226:4,9 228:18,18,22 230:19 231:18 236:6 237:4,15,22 239:3 240:5 242:8 243:3 245:8 246:6 247:10 254:1,2,10 255:8,8,11,22 256:9 257:10,12 258:2 265:6,15 266:22 267:21 268:19 272:3,15 272:21 276:10 294:10,18 297:8 297:12 302:9 303:11 305:4 306:5,8,13,16 308:18 311:5 313:16 317:19 321:18 322:4 325:10 326:3 329:3,6,7,10,14 329:21 330:9,13 330:18 332:8,12 333:18,22 334:8	334:22 335:10 336:14,20 337:16 337:18 338:7 341:1,11,14 343:5 347:3,14 348:15 349:5,22 350:12 350:17,18,21 351:3,5,17,21 352:20 353:11,19 353:22 354:2,7,9 354:19 355:4,7 356:12,19 357:12 357:13,20 358:9 358:20 359:1 360:13 362:1,8,21 363:21 364:2,7,14 365:8,20 366:9,15 367:8,15,18 369:11,15,22 370:6,12,14 371:3 371:17 372:4,7,15 373:12 377:2 378:17 379:18 380:5,17,18 382:1 382:8,13,17 390:5 390:6 394:16 395:8,13 396:9,12 397:10,14 398:7 399:19 407:3,8 409:10,16,17 414:11,19 415:7 415:20 416:6,9,15 416:19,22 417:6 417:16 420:3,11 422:16 423:14 424:19,20 425:17 427:10 429:4 432:11,20,21,21 437:3,6,12,19,22 438:9 440:17 444:4,13,14,17 446:6 450:10 451:14,21 452:5,8 452:20 453:3,4	454:2,8 456:2,6 457:9 463:5,8 464:1,12,14 465:11,13,18,20 465:21 466:1,3 467:13,18 469:15 470:3,6 476:18 477:5,16,18,19 478:11,18 479:20 480:15,16,18 481:4 486:5 490:19 491:19,22 492:1,14 500:12 professional 97:7 368:21 439:21 professionally 207:2 professionals 5:17 12:5 18:12 19:3 58:18,20 98:2 107:12 138:3 174:13 194:11,20 258:21 259:1 282:5 460:21 461:8 professor 181:20 187:22 192:8,9 204:13 400:11 422:7 proficiency 132:21 133:15 370:16 393:6 444:10 proficient 135:3 profile 51:5 126:5 177:5 179:17 303:5 418:5,8 464:12 profiles 205:13 372:8 394:11 418:9 profiling 195:1 profit 59:10,21 60:15 377:4 467:2
--	--	--	--

471:3 485:15 profiteering 174:14 program 37:1 45:8 49:12 92:7,8 122:9 141:15 145:4 177:22 178:15 179:5,14 180:9,22 186:20 194:3,4,5,10 195:15 196:3,5 197:20 198:6 214:3 216:11,15 216:17 217:6,20 218:1,7 219:18,21 219:22 282:3 294:17 295:6 297:4 301:18 302:20 317:20 342:17 359:12,13 367:20 368:11,16 368:21 369:5 390:22 391:1,12 398:15 400:12 421:4 422:22 429:16 462:13,14 463:13 464:3 programs 4:9 21:16 51:16 121:20 132:16 133:15 135:13 192:21 195:20 217:19 218:16,22 219:2 220:5 295:3 296:13 320:15 393:7 394:16 400:21 408:19 421:15 422:18 progress 100:8 progressive 368:11,16 371:13 prohibit 32:22 111:20 144:3 468:4 470:21	prohibited 435:5 prohibition 54:18 105:21 106:10 409:7 484:21 prohibitionist 408:9 prohibits 31:21 105:8 project 8:5 122:9 123:12,21 124:2,6 235:10,11,13,18 projected 25:1 54:17 289:8 306:22 projection 108:22 125:21 projects 393:16 proliferation 119:12 220:20 329:13 prolonged 34:19 promise 44:5 82:17 promised 73:15 promises 149:12 promising 488:20 promote 88:4 124:10 253:14,15 253:16 304:21 353:14 381:7 445:1 460:5 promoted 106:17 promotes 88:20 promoting 256:19 366:17 381:13 483:13 promotion 156:16 promotional 64:14 prompt 120:3 prompted 340:10 promptly 112:17 113:3,15	pronounce 150:7 proof 259:7 483:15 propagation 370:10 proper 72:2 195:12 283:14 349:10 455:10 465:22 478:1 properly 134:5 163:18 193:22 289:4 422:13 properties 269:5 273:22 328:7 488:22 property 264:16 375:18 prophylaxis 277:1 proponents 38:13 218:11 473:21 proportion 113:20 114:5 233:2 453:20 proposals 115:11 propose 123:9 337:13 proposed 115:6 proprietary 320:8 487:7 490:8 propylene 205:11 prosecutor 429:16 prospectively 196:6 protect 33:6 61:2 62:6 88:17 90:7 99:9 100:14 110:2 146:16 175:7 195:7 266:4 305:5 307:2 329:8,12 337:6 353:14 435:10 468:3 470:20 480:7 protectants 484:4 484:11 485:3	protected 67:7 306:21 433:15 protecting 30:16 126:8 136:22 145:12 326:2 332:6 379:11 425:22 435:17 protection 118:5 161:10 344:17 355:17 456:3,6 protective 495:2 protects 322:2 protein 45:20 46:3 protocol 370:5 453:10 protocols 68:13 266:20 497:5 prototype 471:17 prove 256:17 295:11 proved 224:17 proven 54:4 102:14 117:14 124:8 401:17 403:14 409:10,17 provide 44:18 48:8 49:12 61:3 65:13 69:6 75:17 77:15 83:21 85:9 89:3,9 91:3 97:10 98:1 107:13 115:3 123:13 136:11 147:20 150:21 151:22 152:13 153:1,7 154:14 155:7 157:11 163:20 183:2 194:20 200:16 214:11 242:2 269:14 284:3 324:20 325:9 347:3 355:16 359:1 393:7 413:20 414:22
--	---	--	--

422:10 425:13 433:15,15 434:13 437:8 440:11 443:13 457:11 477:4 490:4 provided 31:15 84:21 102:3 121:7 134:19 162:9 239:15 354:10 363:14 439:3 provider 193:1 482:21 providers 132:22 provides 43:12 49:18 52:16 76:14 84:10 188:9 261:3 323:1,6,10 325:2 381:3 417:7 444:1 444:5,11 445:12 providing 44:5 46:1 52:11 62:21 68:7 73:1 88:12 96:2 99:10 168:2 169:9 192:18 194:15 326:2,5 357:7,19 361:12 437:17 445:16 proving 410:6 provision 326:20 355:9 435:7,7,9 435:16 provisional 346:11,20 provisions 32:7,17 111:20 112:1 113:6 114:10,14 prudent 217:17 psas 67:17 psoriasis 276:15 psych 57:19 92:4 psychiatric 213:22 psychiatry 181:20	psychoactive 28:15 78:11 79:2 79:7 80:14,17 205:19 212:19 214:15 390:10 psychoactivity 468:22 psychosis 92:5 334:15 376:10 390:14 468:15 psychotic 271:13 376:6,12 psychotropic 409:9,16 411:5 ptsd 260:11 276:2 277:1 282:21 318:2 482:16 public 1:11 4:16 9:2 16:11 18:16 19:7 20:6 22:20 22:20 23:3,20 25:17,19 26:3,5 26:16 29:10 30:17 36:7,22 37:11,19 38:10 39:13 42:10 42:21 44:15 50:21 51:1,16 52:16,22 58:5 59:9 60:20 61:2 62:1,3,7 68:3 71:16,20 73:9,13 74:1,5 76:8 79:14 80:4 88:8,18 90:7 94:3 98:20 99:9 99:10,15 100:5,14 101:12 107:5 109:6 110:2 122:15,19 123:6 124:10 132:20 134:20 140:3 144:7,17,19 145:13 146:16 149:6,12 154:1 156:6 168:1 173:8 174:15 175:7,20	183:2 185:1,2 187:11 191:22 197:8 199:22 200:16 204:2 209:7 222:4 265:4 265:18 266:4 278:10 286:11 313:12 314:15 328:22 329:9,12 331:4 332:6,13 353:1,15 354:19 361:13 365:3 366:17,17,21,22 368:6 379:21 381:20 393:13 397:15 399:12 407:2,9,17 408:6 416:6 425:20 455:9,10 456:3,6 456:11 457:3 462:3,5 468:3 470:20 471:2 480:14 500:21 501:4 502:1,16 publication 166:21 167:2,9 334:21 335:3 393:3 publications 100:7 publicly 81:16 112:4 315:3 358:17,19 publish 100:10 391:19 published 40:21 51:9 124:2 126:3 167:9 180:11 203:6 261:15 325:14 335:18 346:1 384:15 385:6 publisher 125:9 128:5	publishes 99:1 publishing 206:15 pubmed 78:18 325:16 pueblo 375:1,6,15 375:22 pulak 14:8 361:16 361:18 pull 152:6 176:6 181:15 384:2 pulling 308:1 pulp 45:17 pumping 458:6 pura 12:19 287:18 purchase 24:8,9 62:19 97:22 131:12 207:13 226:18 247:10 purchased 189:12 206:20 207:10,21 208:1,11,12 246:2 247:10 461:2 purchaser 57:4 purchases 207:17 purchasing 407:3 pure 13:9 212:11 213:5 214:19 265:12 316:14 317:6,10,11 319:4 319:19 448:5 purification 229:20,22 232:12 347:11 348:7 370:6,11 purified 142:22 323:21 324:5 488:1 purify 350:20 purity 60:22 99:7 138:18 163:9 222:14 315:14 331:15 363:21 409:13 410:1,12 438:18 449:13,15
--	--	--	--

461:19	278:20 288:22	364:12,16 365:7,8	264:10 273:17
purport 382:14	353:22 470:2	365:19 366:12	275:6,7,10,11,12
purported 270:9	q	367:16 370:5	275:14,18 279:14
purporting 157:4	qa 265:9 289:18	371:16 372:4	305:13 307:6
purpose 59:20	qc 265:9	379:1 382:17	309:11 310:11
74:13 98:3 99:8	qm 289:18	383:9 387:7 405:7	352:10 390:1
343:21 403:11	quackery 63:11	423:10 425:16,22	405:11 424:4
452:19 498:10	qualifications	426:7 427:18	434:7 435:19
purposefully	134:3	428:20 429:2	436:7,12 450:11
93:15	qualified 47:6	458:4 473:11	456:10 466:11
purposes 170:15	273:10	477:5 487:4	468:10
226:11 233:4,10	qualify 324:14	489:13,16 490:4	questions 33:9
480:19	qualifying 260:19	492:14	34:9,20,22 36:1
purpureus 396:11	qualitative 493:9	quantified 302:10	50:5 61:4 92:13
pursued 365:9	qualities 243:6	quantify 302:16	131:8 139:10
pursuing 321:20	quality 37:22 38:6	quantifying 39:15	148:10 154:15
372:1	38:18,20 45:3	quantitate 264:14	169:6 186:22
pursuit 127:14	46:14 49:17,20	quantitation	225:22 227:6
481:22	50:2 53:18 64:7	314:16 360:11	241:3 247:16
purview 138:9	65:5 68:5 76:9,21	394:3	252:1 258:18
316:15	96:15 97:3 98:16	quantities 112:3	263:15 264:9
push 228:22 286:9	99:13 100:8,18	quantity 157:5	293:14 298:5
put 31:2 35:11	101:8,17 102:3	190:2,16	307:9 326:6,12
38:4 92:6 100:22	118:4 121:17	quarter 154:9	328:5 332:14
104:6 110:14	132:6 133:4 134:4	question 23:14	339:5,10 352:8
127:21 130:4	134:14 135:21	52:21 66:11 71:20	380:15 390:15
136:16 163:1	138:18 188:10	79:18 80:12 85:14	394:19 399:13
171:8 174:9	200:6 207:3 209:8	86:9,18 89:21	409:19 412:21
184:19 211:10	213:16 214:8	90:8 91:7,13	414:14 417:11
243:19 250:11	217:3 218:6,7	94:21 95:9 103:3	419:2 420:17
279:2 282:16	219:19 223:12	110:17 115:14	424:1,3 425:6
284:21 286:12	235:12 236:15	118:11 124:19	429:7 438:17
297:21 337:19	290:3 296:19	137:7,10 140:5	460:22 463:2
343:16 346:15	303:8,13 304:12	141:13 152:16	475:20 490:16
397:7 409:3	305:8 315:14	164:7 165:9	493:16 499:13
422:17 434:10	319:19 325:10	169:12 171:12	quick 52:21
447:18 469:22	329:3,11 330:17	185:14 189:3	110:12,17 152:15
473:20 493:12	331:2,3,14,15	195:17 196:21	156:14 169:12
puts 35:17 267:20	332:9,12 333:2	197:13 198:12	216:10 233:1
267:21	334:16 336:5	199:10 214:14	262:6 273:17
putting 32:22	348:10 350:4	222:17 226:2	275:13 279:14
103:16 148:14	351:1,4 353:6	232:3,7 233:1,7	434:6 466:11
158:14 161:2	362:7,11,15,17	233:18 239:7,12	quickly 24:13
186:2 236:8	363:7,13 364:10	244:1 257:18,20	36:12 37:14 44:21

107:19 108:2 109:2 116:4 117:2 118:9 168:11 233:19 343:8 352:7 436:21 440:13 453:5 455:17 quilt 376:8 quit 60:14 374:4 quite 140:11 158:13 179:2 195:3 246:8 307:20 312:11 336:3 399:2 411:19 412:13,15 471:11,19 488:12 quo 76:12 138:7 266:19 quote 139:8,8 217:8 quoted 493:14	299:3 401:17 range 5:7 33:15 50:6,10,13 82:4 105:14 114:22 120:10 146:10 183:21 191:20 206:10 260:16 261:2 270:15,21 306:18 309:5 358:13 359:14 397:7 426:10 432:11 437:6,10 439:3 451:18 452:7 ranged 189:16 190:10 191:2 300:17 ranging 96:20 rapid 144:22 219:22 388:18 rapidly 67:12 154:7 161:15 182:21 322:6 382:1 rare 92:21 130:1 130:13 132:4 200:4 269:2 457:6 457:13 493:3 rash 207:19 rat 431:13 494:2 rate 300:16 375:8 465:15 480:3 rates 200:3 470:14 ratio 51:7 205:12 301:11 rational 88:2 rationally 93:13 382:11 rats 271:3 340:10 488:21 raw 296:17,18,20 296:22 302:17 322:20 331:17 351:2 361:22	362:4 363:1,20 369:10 372:6,14 388:19 411:14 450:19 489:16 490:18 ray 13:12 328:17 328:18 488:11 rays 490:12 495:7 rct 493:6 reach 197:14 460:9 485:19 reached 299:11 reaches 490:14 reaching 85:11 158:12 reaction 206:19 208:8 reactions 208:5 465:12 reacts 465:14 read 122:3 179:8 242:21 261:1 335:9 336:17 374:20 readers 125:11 127:1 129:7 readily 97:21 230:11 readiness 146:22 ready 100:16 168:22 218:8 282:2 291:15 372:22 389:18 444:5 478:1 481:2 real 33:8 38:12 39:19 103:9 182:22 186:21 229:1 233:18 234:20 263:7 284:14 286:4 292:17 421:18 449:10 realistic 85:7	realistically 133:14 reality 241:14 360:6 430:12 realize 40:13 82:22 243:12 311:12 435:16 realized 64:1 392:19 473:1 realizing 343:7 really 56:7 69:12 86:19 87:7 91:1 129:11 141:14 142:9 149:17 152:19 165:1,19 171:8 177:20 178:1,21 182:14 197:1 201:9,14,15 202:13 203:16,18 206:17 215:22 219:1,3 221:22 223:14 225:4 226:18 236:11 238:8 239:11 242:15 245:22 247:18 249:3 253:19 255:12,14 256:9 266:4,14 276:2,20 283:2 309:19 314:4 316:3 321:14,15 333:3,5 334:17 336:3 337:2 347:18,20 348:3 349:1,11,17 350:2 350:4 351:9,14 352:16 387:5 422:10 455:13,16 456:12 467:10 475:10 483:19 485:13,13 490:16 492:9 498:18,18 realm 217:14 219:13
r			
r 2:1 3:1 4:1 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 20:1 rabbit 475:2 494:8 rabbits 488:21 race 304:5,8,9 435:19,20 436:1 radar 375:5 radiation 67:8 radical 371:13 raise 52:12 149:14 428:18 raised 139:2 193:6 raises 271:6 ramifications 178:2 ran 373:17 randall 2:18 randomized 136:10 222:1			

reardon 9:20 161:6,7,9 164:9 164:15 165:14 reason 47:3 175:17 229:1 248:16 316:7 332:22 333:15 357:17 452:6 494:14 reasonable 77:15 105:1 269:14 482:19 reasoning 74:21 reasons 32:21 142:6 259:5 328:11,15 401:13 449:7 rebecca 3:2 22:6 recall 146:22 344:18 439:4 480:9,15 recalls 367:7 464:16 466:12,13 receive 201:2 269:20 337:1 346:7 461:20 489:20 received 185:19 202:18 206:16 208:9,20 209:4 284:2 343:13 458:15 461:21 491:20 receiving 179:22 receptor 71:10 221:15 receptors 93:14 262:7 269:22 474:7 488:15 493:20 494:6 reclassification 175:4 reclassify 176:1	recognition 104:2 443:19 444:21 recognizable 266:18 recognize 73:2 341:7 recognized 29:9 31:3 99:1 167:3 179:7 262:15 305:9 354:10 427:3 440:4 442:15 443:11 recognizes 143:5 408:7 recognizing 170:2 368:7 recommend 44:11 47:5 108:2 152:12 196:2 275:20 280:11 304:13 375:20 433:22 434:1 463:16 491:8 recommendation 305:22 recommendations 130:10 142:4 225:14 272:18 393:22 394:1 430:6 433:22 434:15 recommended 118:15 136:9 390:9 recommending 280:8,9,21 recommends 294:22 reconcile 414:1,6 414:7 415:17 reconsider 47:10 reconstitution 165:16	reconvene 281:18 record 23:3 103:17 104:6 172:18 281:20 372:20 395:16 434:10 502:6 503:5 recorded 23:9 502:4 recording 23:10 134:8 503:4 recordkeeping 325:21 records 186:22 480:11 recreation 6:17 81:6,8 248:18 250:6 431:4 recreational 28:4 28:5 68:2 78:2 265:14 433:16 453:8 482:18 recreationally 253:10,13 recruited 429:15 recycled 450:6 red 25:11,13 127:16 283:3 396:11 redeem 244:14 redman 16:14 466:20,21,22 reduce 80:17 89:2 235:2 248:16 445:22 485:18 reduced 67:12 224:3,6 502:5 reducing 139:18 446:2 488:7 494:22 495:3 reduction 181:3 230:7 257:2 275:16 318:10	refer 144:7 reference 132:22 166:19 312:14 391:6,8,11 392:4 392:21 393:5 referenced 426:4 references 313:19 440:12 referencing 428:5 referred 435:8 referring 103:3 refined 73:3 371:2 refinement 367:14 370:11 reflect 188:15 399:2,3 427:1 reflected 111:15 341:20 reform 160:12 232:21 refractory 216:20 261:19 refreshments 24:7 refusal 477:21 refused 57:10 regard 103:17 171:13 regarded 151:9 486:4 regarding 81:10 82:6 83:4,13 84:14 97:17 123:17 128:2 139:10 193:6,22 194:14 195:11 204:10 208:5 273:9 315:9 358:5 360:9 479:3 regardless 31:8 99:8 106:16 146:6 229:10 313:11 315:11 348:22 regards 149:20 202:8 205:3
---	---	---	---

353:10 408:6 491:19 regime 119:14 408:21 412:4 regimens 180:19 regimes 409:10 476:20 477:3 478:21 479:17 480:20 regions 52:11 register 283:21 290:16 registered 26:21 26:22 126:1 161:19 260:2 311:1,3 316:15,16 325:12 342:15 368:1 438:10 registration 20:18 196:11,17 218:5 322:18 367:22 370:2 415:22 416:1 464:20 registrations 311:4 416:2 regret 317:16 regular 222:20 248:10 283:5 478:8 regularly 139:17 446:7 regulate 29:7 40:12 44:11,18 71:22 73:5 75:19 112:10 119:19 124:10 182:19 230:22 297:18 324:20 329:7 347:1 350:19 409:17 411:5 412:6 416:11 471:4 480:19 486:3	regulated 27:19 30:1,15 34:6 36:11 38:5 51:15 51:20 62:14 138:15 144:4 153:22 168:1 188:14,18 194:5 195:4 231:3,9 242:10 246:2 283:18 317:20 319:12 320:15 323:2,12 329:19 333:8 343:2 367:19 409:2 412:8 414:22 416:12 421:5 424:20 476:20 478:4 479:17 480:17 regulates 29:11 33:16 147:11 262:3 367:21 369:6 regulating 40:14 60:5 71:21 72:2 73:10 255:4 304:14 352:11 363:10 407:13 408:16 420:7 456:5 regulation 27:8,12 32:18 34:9 36:4 41:18 49:13 73:19 74:3 81:14 112:19 112:22 113:3 117:16 129:13 138:8 162:18 192:2 240:6 244:17 251:14 253:21,22 254:5 265:13 273:1 291:22 303:22 304:4,5,19 307:2 321:22 332:11	347:2 352:6 367:21 371:14 377:19 396:15 397:20 407:7 411:3 417:5 423:2 429:22 431:19 433:11,13 456:1 476:16,17,21 477:20 478:1 481:4 regulations 32:16 40:9 41:21 44:10 50:17 52:3 83:3 88:22 89:12 95:6 105:1 108:12 113:1,11 123:4,11 128:22 129:6 131:14 135:2 138:11 145:20,20 146:12,18 151:13 159:5,16 162:21 166:16,19 214:7,9 226:20,21 273:3 273:12 306:10 322:8,14 323:3 324:19 325:20 331:9 332:7 348:22 369:2 371:7 383:11 414:1 426:5 434:8 438:12 447:7 462:16,17 476:12 477:11 478:3,22 482:5 486:4 regulators 48:18 84:11 99:9 100:19 133:2 134:19 154:2 156:4,8 157:8 231:16 266:9 383:10 391:22 393:8 417:8 425:19 426:21 444:13 445:19 446:2,14	446:17 463:17 466:7 477:9 regulatory 2:15 2:19 3:12 4:9 21:16,22 33:13 37:20 38:9 41:16 41:22 42:4,11 47:22 48:16 52:14 63:12 65:13 76:19 79:21 83:19 85:1 88:3,17 89:4,10 91:3 94:19 100:15 108:1,3,7,9 117:13 119:14 120:3 131:18 133:5 139:18 142:6 145:5,15,22 146:3 150:18 153:13 154:17 155:2,11 157:15 159:9,14 160:21 162:3 163:1,8,13 165:10,15 167:22 170:5 192:12 196:7,9 200:16 204:1 210:2,7 214:11 222:7 225:3,14 243:21 268:1 283:1 297:20 298:12,16 304:9 306:19 311:22 321:12 322:1,17 323:18 325:4 327:6 329:16 331:6,7 338:3 341:13 353:7 357:13 362:19 363:4 364:5 365:14 366:4 367:11 368:22 371:6,19 378:16 380:2 381:6 409:5 412:4 413:16,21 414:4
--	---	---	---

415:19 416:1,14 422:14 426:18 429:1 430:2 431:21 432:5,10 436:16,22 438:1,7 451:8 452:4 457:8 477:3,14,22 478:9 478:21 480:14,20 480:22 491:16 493:11 reimbursement 39:21 336:22 reinvent 414:12 reiterating 436:6 rejecting 418:14 related 27:8 34:10 61:4 63:22 64:13 68:3 102:17,20 103:11,20 107:9 125:1 150:14 157:12 165:17 198:13 199:11 216:13 217:2,18 227:18 235:14 273:18 300:1,5,12 301:1 312:7 314:2 314:11,14 399:15 422:16 445:11 463:4 484:7 502:8 503:7 relates 102:21 157:11 356:3 420:16 425:4 462:19 relating 55:3 relation 191:19 relations 111:6 relationship 43:4 135:16 136:13 181:8 262:16 407:22 419:19 relationships 489:17	relative 37:20 198:13,20 259:20 315:6,20 355:15 454:7 474:16 502:10 503:10 relatively 201:15 340:15 359:4 361:4 455:11 relax 218:12 relaxation 219:9 relaxing 215:10 277:11 released 101:5 110:9 172:3 345:20 relevance 426:7 relevant 28:1 29:5 29:16 38:1,12 89:3 204:16 303:16 422:15 425:1 444:4 480:11 reliable 88:12 100:3,18 136:11 319:10 383:13 394:14 444:6 relief 224:8 260:4 260:12 318:14 381:18 relieve 207:14 208:22 reliever 320:12 religious 410:14 relish 151:16 rely 267:15 337:3 relying 49:8 159:17 237:6 446:13 remain 33:9 103:2 139:10 418:18 remainder 159:16 remained 300:18 remaining 25:10 361:18	remains 29:2 106:20 139:12 477:22 501:1 remark 110:12 remarks 18:6 19:9 20:2 25:6,12,18 26:1,13 400:8 500:19 remember 40:15 40:16 276:21 remind 23:19 100:21 500:22 remotely 26:22 removal 404:5 488:9 494:17 495:5 remove 272:20 308:13 removed 28:19,22 34:4 119:16,18 308:5,10 487:17 removes 487:9,12 removing 128:19 226:6 render 106:8 renders 319:1 renowned 26:7 reoccur 301:6 rep 483:1 repeat 38:18 39:11 54:20 170:19 322:9 496:18 repeated 201:17 301:3,22 repeatedly 284:6 repeating 373:15 replace 46:7 250:15 replicate 417:22 replicated 364:22 415:7 replied 158:10	replies 158:13 report 109:18,18 110:9 123:21 124:3,14 135:22 180:14 183:10 208:7 214:19,21 247:3 315:2 318:3 384:15 385:5 386:3 397:2 430:13 434:14 481:8 reported 43:14 46:12 60:7 67:15 142:21 193:12 198:3 208:10 238:12 270:15 299:17,19,20 300:19 301:20 314:5 318:17 320:4 359:9 430:21 453:20 454:2,6,16 455:4 492:5,11 reporter 1:21 242:19 245:15 reporting 60:4 87:1,3 134:8 194:8,9 197:17 198:21 199:1 209:13 219:21 269:11 325:21 360:21 393:22 438:13 480:9,13 reports 11:21 84:17 110:14 125:2 154:8 157:3 194:12,21 207:19 243:19 245:16,19 246:3,19 247:4,13 381:13 459:8 represent 34:20 67:1 76:4 88:5 89:22 147:9 166:11 216:8
---	--	--	--

275:18 360:13 395:8,10 411:19 482:13 representation 89:15 representations 105:12 representative 188:11 247:14 403:5 418:5,8 465:22 representatives 23:1 155:16 377:17 represented 190:1 245:21 248:14 representing 52:7 72:14 115:22 119:6 132:19 138:2 159:1 209:22 310:21 421:8 427:13 429:12 435:1 476:8 represents 70:22 82:15 87:18 104:17 107:8 156:3 176:10 248:11 304:18 418:5 reproductive 262:18 repurposing 130:22 reputable 97:20 380:6 reputation 382:22 request 44:8 135:1 167:3 169:4 324:12,13 346:19 369:13 413:20 427:5 467:22 470:17	requested 113:3 requesting 73:18 73:19 418:16 requests 112:16 require 30:21 31:1 53:21 103:22,22 112:22 150:18 193:18 273:6,7 277:4,5 306:6 340:10 461:16 465:18 478:9 479:1 486:15,15 required 50:18 87:1,3,4 143:15 194:9 251:14 323:10 337:6 350:8 371:20 409:20 411:8 418:19 464:2,6 465:7 478:5 requirement 31:5 133:16 269:11 439:13,20 442:1 479:17 requirements 29:17 30:20 31:16 133:5 134:14 151:18 154:20 194:11 209:7 227:1 325:21 331:13 337:9 364:15 369:15 382:20 392:8 415:11,12 416:2 436:16 439:1,1 440:19 441:14,19 442:3 443:3,5 444:13,15 445:4 445:22 478:2 479:11,22 requires 33:4 101:8 135:3 147:1 185:9 284:16 369:3 370:1,22	380:20 456:3 465:5 478:16 requiring 174:19 185:7 305:7 368:1 383:9 479:18 480:9 requisite 35:14 324:11 354:16 355:20 research 4:10 8:9 10:10,18 11:6 12:13 14:21 21:17 34:1,5 39:9 40:8,8 40:10,14 41:17,20 42:5,7 47:1,6,7 49:5 54:8 58:12 84:19 89:7 96:17 108:16 116:13 125:4,20 128:6 129:4,20 131:6,8 135:17,19,21 136:21 137:5,9 139:19 142:7 156:17,20 157:2 157:12 170:13 171:20 174:2 175:3 181:21 182:9,15,17,19 185:6 188:3,4 189:9 192:11 195:10 200:14 203:19 210:6,11 210:19 212:21 216:12 218:14 219:6,7 220:4 221:19 224:19,20 225:8,11 226:11 240:20 249:8 256:14 259:17 263:3 265:18,22 268:10 270:11 271:10 278:16,17 282:6,12 283:22 286:12 292:11,17	292:22 294:5,12 295:4 297:5,13 315:1 327:12 333:21 340:12 341:15 356:18 357:18,19 358:4 379:2 381:7,9 382:10 386:18,18 387:5,8 389:8,14 389:19 390:21 400:21 405:3 408:10 410:3 414:15 418:10,11 418:13,15 419:1 423:6,10 427:16 435:12,18 437:9 439:9,17 440:7,10 451:4 456:8 462:12 472:2 473:13,20 474:1 483:17 485:14 487:3 492:2,14 493:1,14 494:13 researched 259:9 433:1 researcher 40:4 210:3 226:7,10 researchers 42:3 45:10 130:19 173:18 214:12 219:11 246:10 256:13 287:5 290:22 295:2 researching 338:21 339:11 resemble 102:10 360:7 resembles 286:4 residency 274:17 residual 308:8 319:14 360:10 362:1 363:21 372:8 428:11
---	--	---	--

residue 100:2 residues 72:5 169:14 237:13 372:9 394:9 resistant 143:2 458:2 resolve 163:17 260:10 265:7 396:3 440:14 resolved 301:5 resolves 263:8 resource 155:10 323:7 446:2 resources 123:15 159:20 168:10 355:18 393:7 respect 29:10 35:22 67:14 113:5 121:11 241:20 304:16 326:18 407:13 413:15,18 414:2,18 416:5,17 417:9 418:4,10 436:15 486:16 respected 312:16 439:10 respectful 24:4 respectfully 94:11 155:6 169:4 354:4 354:22 355:14 443:4 486:15 respective 411:5 respects 117:8 217:19 414:16 415:11 respiratory 262:19 respond 174:11 322:5 responded 159:11 391:22 responding 159:22	response 21:12 60:8,9 70:2 83:16 125:17 202:9 219:22 284:7 344:16,21 391:21 427:5 455:7 471:21 474:16 responses 159:11 202:13 241:2 455:12,21 responsibilities 123:14 responsibility 146:15 245:5 460:19 responsible 7:21 15:17 61:22 82:7 84:21 85:11 115:18,21 145:12 151:5 166:16 179:3 202:3 321:21 322:12 326:1 346:4,12 353:8 354:6,13 356:10 393:8 434:22 442:13 responsibly 136:9 379:22 rest 82:19 122:5 234:7 385:11 395:22 446:22 restaurant 156:14 restlessness 223:11 restrained 173:15 restricted 217:8 restriction 114:9 255:19 256:1,9 258:16 restrictions 93:22 165:11,13 192:3 218:13 219:10 256:5 258:1 337:9 470:2	restrictive 28:13 431:9 restrooms 24:14 result 29:1 67:15 108:10 167:8 245:3 250:18 330:10 441:13 451:21 resulted 34:8 37:21 112:6 193:13 resulting 82:8 results 96:12 97:21 143:18 161:1 183:8 190:22 234:15 235:1 238:16 275:13 277:9 278:11 315:2 318:3 330:1 351:10 371:10 380:5 394:5 453:13 454:14 resume 342:2 retail 42:10 53:12 159:17 165:11 213:13 238:13 246:6 249:14 251:16 344:7 362:6 461:2 retailer 53:17 55:2 189:12 retailers 9:6 16:19 18:17 19:8 147:4 147:6 154:2 156:11 191:10 236:7 431:16 452:10 481:15 retained 487:16 retaining 81:14 retention 488:6 retina 471:19 474:8	retinal 67:16 retire 485:12 retired 67:2 return 82:22 returned 440:3 revenue 46:2 52:6 54:17 235:1 revenues 412:10 review 49:3 107:16 117:19 126:6 167:7 168:11 203:8 224:15 269:18 275:13 331:8 354:18 409:4 410:2 423:21 443:8 445:7,9 480:10 reviewed 39:5 53:1 156:20 168:15 312:15 325:14 491:16 492:4 reviews 49:2 167:17 206:5 394:3 439:10,18 492:4 reward 271:7 rewards 407:11 rhetoric 414:16 418:18,21 rhetorically 65:2 rheumatoid 208:22 rice 396:11 rich 197:1,20 201:12 203:12 323:16 340:2 398:9 465:11,21 richard 12:20 293:16,18 rick 10:14 192:6,7 rid 128:21
---	--	---	--

ridiculous 225:6	314:22 329:11	rodman 8:2,3	270:14 388:17
right 20:11 24:15	365:6 380:14	118:22 119:1,2,2	routinely 303:11
44:20 58:22 61:13	478:7	rola 13:2 298:8,11	318:14 398:18
66:16 86:17 90:6	rigors 381:11	298:15	rti 15:13 451:3
101:2 109:1,22	rise 432:12	role 27:11 29:10	453:10
113:18 115:2	rising 225:1	38:11 50:22 58:12	rubs 127:7 175:1
126:2,14 137:11	risk 35:12,17 42:9	63:12 71:16 87:20	ruined 56:19
157:22 158:14,18	61:12 77:17 84:9	96:6 259:13 313:9	429:21
166:6 171:7 172:4	84:10,22 88:3,22	368:19 379:10	rule 105:17
176:3,10 187:18	89:6 108:11 118:6	429:12 488:19	112:20 240:6
187:19,20 189:7	127:12 173:21	roles 160:14	355:1
199:20 202:12	174:10 175:9,14	471:22	rulemaking 48:10
204:6 221:22	175:17 181:9	rolling 240:20	89:6 116:4 117:4
222:2 231:3 241:4	214:1 217:1	room 20:18 23:18	117:11 323:9
248:3 249:17	267:20 331:4	23:22 24:5,8,15	433:12 440:15
250:1 251:6 256:7	332:14 349:11	125:15 176:6,9	rules 98:1 253:22
267:19 275:2	374:18 383:3	179:15 208:1	268:20 393:8
276:6 284:15	399:16 404:12	209:9 276:9 289:1	437:22
287:10 290:6,8,20	407:10 472:14	307:20 385:7	run 25:17 133:17
291:6 292:4,22	474:21 479:13	481:21 488:11	318:1
293:3,14 297:14	489:5 491:5,6	496:12 498:15	running 132:9
305:16 308:22	494:10,22 495:4	rooms 207:8	150:3 172:14
310:18 316:10	risks 33:1,8 89:17	490:10	293:3 318:19
344:5 348:19	110:3,9 136:16	root 75:16 396:12	398:16
351:20 364:18	143:11 173:22	rooted 102:2	russell 5:20 61:13
368:13 385:15	175:1 191:20	rosbeck 8:19	61:15 261:14
389:19 395:21	225:12 315:19	142:13,14,14	ryan 11:2 209:18
396:1 401:4 407:5	329:18 380:10	144:13,15	246:10
419:8 420:21	382:3 399:17	rosemary 13:14	rye 147:12
425:6 447:4 448:1	401:8 451:16	332:16	s
453:13 455:16	rita 180:15	roughly 153:10	s 2:1 3:1 4:1 5:1
459:22 460:16,16	road 375:18	232:15 359:5	6:1 7:1 8:1 9:1
460:17 477:13	roadside 471:18	rounds 283:15	10:1 11:1 12:1
481:21 485:8	robert 7:6 15:18	roundtable 5:5	13:1 14:1 15:1
489:13 498:17	66:18,19 92:15,18	47:18,20 48:20	16:1 17:1 18:2
rightfully 303:10	425:8	49:16	19:1 20:1 179:18
303:15	robust 98:16	route 40:19 104:3	s.a. 14:17
rights 244:16	99:21 136:17	167:22 177:7	sad 58:9 337:2
486:12	194:8 321:22	184:2 211:17	sadly 57:22
rigidity 385:12	331:6 332:10	218:10 352:22	safe 16:13 30:19
rigidly 266:1	341:14 360:19	routes 41:13 75:13	31:2,4,8 34:11
rigor 50:18 325:1	370:5 461:17	167:6,8 184:17,21	43:2 44:18 45:2
rigorous 60:22	rod 7:14 104:13	185:15 186:8	49:4,7,15 51:19
121:19 123:8	104:15	257:21 258:7,9	53:18 54:3,7,22

60:18 62:21 64:8 66:6 68:6 69:8 73:14 74:4 76:16 79:12 88:12 102:14,14 103:14 104:19 109:5,8,22 112:15 115:9 116:19 118:4,12 124:8 126:7 127:11 132:5 151:10 152:2,11 152:22 154:22 156:22 167:4 174:6 175:11 225:6 231:11 248:2 251:20 266:7 291:17 317:12 320:2 323:1 325:10 343:12,14 347:3 349:2,20 350:1 354:18 355:21 357:20 359:1 361:4 362:9 396:20 397:2 437:14 439:8,11 462:9,11 464:1 465:6 477:2 486:4 492:14 safeguard 332:2 safely 33:4 73:5 75:19 105:2 306:1 323:2 338:8 463:18 477:6 480:16 488:10 safer 51:8,8 139:9 safety 1:2 5:21 9:2 16:11 18:16 19:7 33:10 34:10 35:11 44:15 49:10,19 50:2,19,21 51:4 52:16 56:4,9 57:2 60:6 61:14,16 65:7,8 73:9 76:8	86:18 103:2,19 104:6 109:6,11,13 110:3 117:8,11,14 117:19,20 123:1,5 125:16 126:4 128:2 131:6 132:3 136:3,12 137:1 138:15 140:1,3 143:22 144:17,19 145:11,13,20 146:5,18,20,22 151:17 152:18 160:11,12 163:6 167:6,20 168:5,6 168:16 169:3 184:13 186:9 193:1,5 194:12,21 195:1,2,19,21 196:15,18 198:8 200:18 203:20 217:3 218:7 222:4 235:12,17 246:9 247:1 251:11,15 251:18 253:16 269:15,19 271:22 272:1 277:13 278:10 282:14 295:15 298:21 299:5 301:9 302:7 304:3,7,20 305:9 312:18 313:13 314:15 317:18 320:13 324:13,17 327:3,19,22 329:3 329:11 330:17 331:4 332:9 337:6 339:6 340:18 352:18 353:22 354:16 355:20 358:2,5 359:2,11 359:12 360:19 362:17 363:16 364:11 365:5,6,16 365:19 366:17	367:7,16 369:7,18 371:16 372:3 379:12,15 386:15 389:8,11 391:15 397:6 408:16 425:16 426:13 428:20 435:19 436:7,8,10,12,15 436:20 437:1,2,4 437:15 439:7,15 440:3,7,12 460:13 461:18 462:3,5,19 462:21 463:3 464:12,13 468:3 470:20 476:21 478:13 480:7 481:5 497:4 safetycall 10:15 192:12,16 safeway 147:14,16 salads 151:2 sale 59:21 78:2 154:17 155:3 166:18 170:7 284:20 319:4 499:9 sales 43:14 48:3 78:4 116:9,12 159:12,21 160:1 414:19 491:9 sally 5:14 56:15 56:17 salmonella 372:12 salve 186:3 sample 207:5 208:18 351:15,19 352:1 449:14 453:11,20 samples 207:10 208:20 209:4 236:19 237:8 sampling 134:5 191:9 465:22	san 10:11 294:11 457:2 459:2 sanctions 439:5 sandwiches 156:15 sane 152:11 saneto 261:14 sanitary 227:15 sanitation 428:1 sat 344:11 496:5 satisfaction 460:13 satisfied 250:5 satisfy 324:13 sativa 28:8 84:3 sativex 299:17,19 save 57:7 58:13 275:13 saved 96:8 saving 176:8 saw 59:13,14 185:14 261:9 262:5 276:7 279:15 349:6 398:8,17,18 399:20 421:21 500:11 saying 57:10 80:13 148:12,18 149:15 173:10 175:13 276:14 375:12 405:9 406:3 418:19 421:11,11 451:12 486:14 494:9,12 says 32:15 149:3 173:17 296:1 313:15 314:8 326:20 343:17 375:22 376:13 467:17 sbir 471:17 scale 214:21 227:15 275:8
--	--	---	---

292:12 314:18 318:7,8,12 scannable 479:2 scans 67:16 scared 206:17 291:9,13 scares 402:17 scary 231:18 scenario 105:4 403:20 scenarios 321:11 scented 151:6 schatz 185:7 schedule 28:12,13 29:2 39:1 93:21 94:6 119:16 132:10 172:13 210:9,10 226:15 283:13 296:5,7 333:10 scheduled 205:19 263:12 scheduling 28:17 98:6 259:20 schell 3:14 22:12 22:12 schematic 283:2 scheme 145:6 165:10 322:18 416:1 431:9 432:5 432:10 schemes 145:22 413:21 414:4 415:19 416:14 430:2 431:22 schiller 3:18 21:3 21:4 schindel 5:14 56:15,17,17 58:17 scholarships 375:2 school 4:18 26:9 26:10 40:1 176:17 259:11 274:16,16	275:2 276:22 358:1 375:2,6,9 400:12 schools 375:17 422:8 science 6:17 12:11 30:12 36:3,8 42:1 54:4 63:9 81:5,8 87:16 88:4,22 98:13,16 100:13 122:10 123:19 145:4 150:10 173:9 175:11,15 182:6 204:13 214:11 220:19 221:9 236:2 241:1 242:3,3 243:20 244:13 252:22 253:5 268:9,12,15 293:21 303:8 335:17 357:3 380:7 381:21 382:15 383:12 391:1,12 393:2 396:21 398:4 399:2,3 406:20 451:8 485:10 sciences 10:13 13:11 187:22 188:1 200:13 224:14 321:12,17 323:9 324:8 325:6 356:18 485:2 scientific 1:8 20:4 26:16 41:18 49:5 49:8 50:18 61:21 63:13 68:9 74:20 98:19 100:3,10 127:20 129:3 131:6 135:13 156:17 168:6 177:14 183:2 192:12 204:16 220:11 222:19	259:7 287:7 317:14 321:11 324:2 339:13 380:20 381:4,15 384:5 425:14 scientifically 99:10 273:9 scientist 188:2 451:3 scientists 107:12 259:6 283:11 287:6 391:17 432:3 scleroderma 93:5 sclerosis 8:20 142:15,17 260:22 scope 323:11 427:8 443:22 score 318:7,12 scores 455:20 scott 13:6 14:20 390:18,20 scottsdale 12:13 282:6,12 scratched 42:8 scratching 126:10 203:17 338:18 screen 303:5 311:20 313:19 screened 397:10 screening 280:21 302:13 screenshots 452:13 se 182:3 seal 148:17 sealable 491:2 search 237:3 seat 176:8,8,9 372:21 seated 20:21 seats 176:4 seattle 449:4	second 43:10 52:1 76:12 106:6 108:14 146:17 181:15 190:1,22 215:21 247:21 249:6 252:16 255:2 276:17 316:22 324:15 342:7 348:9 363:7 364:17 382:19 384:1,18 393:18 404:8 409:5 412:22 413:22 452:22 457:16 489:19 495:6 secondary 46:2 193:20 283:11 secondly 415:8 secretary 354:8 secretary's 355:8 secrist 14:2 353:4 353:5,6 section 105:5,7 106:10 273:1 321:2,5 419:22 421:1,16 435:7 sector 87:21 119:11 192:1 264:11 sectors 88:5 426:3 security 236:2 238:17 294:6 342:18 428:13 sedating 215:10 sedation 67:12 179:4 sederberg 15:11 476:4 see 26:19 48:16 62:17 63:22 66:5 70:7,8,9 76:17 80:5,7,7,22 86:3 113:21 114:3,17 152:10 165:7
--	--	--	--

167:12 169:21 170:9 176:22 179:4 197:20 206:10,11 207:1 212:9,15,17 213:6 215:3,3 219:20 223:10 229:13,19 231:18 236:10,16 237:22 238:3,6,11 239:3,8,12 240:1 248:13 249:12 250:3 254:10 265:12 276:3 277:3 280:18 281:4,9 282:13,18 282:21 283:6,10 283:19,20 284:1 284:13 285:2,4,15 285:16 287:4 293:6 296:16 299:11,13 309:4 320:11 326:12 341:22 349:4,9,15 358:20 372:18 375:9 384:16 395:4 399:19 400:13 406:19 420:19 424:1 452:13 453:13,18 454:1,5,11,15 455:3,11,20 457:18 464:7 472:4 474:20 493:22 499:7,7 seed 31:13 168:13 168:13,13 170:14 170:14 322:18 323:14 325:12 411:20 417:16,17 418:9 424:10 499:9 seeds 168:14 seeing 80:5 97:16 170:3,4,17,20	171:13 198:14 246:5 277:8 279:2 310:14 320:20 327:15 399:17 420:9,14 421:14 422:22 472:9 seek 60:15 133:3 195:5 222:22 223:6 404:12 seeking 97:4 154:14,16 162:17 385:20 387:18 seeks 339:6 seemingly 127:11 seen 33:20 69:18 73:22 80:15 119:8 170:22 171:14,17 184:3 200:3 204:22 207:19 241:21 244:11,13 263:5 275:22 276:1 308:19 328:12 338:12 354:3 360:8 409:8 431:12 448:2,5 492:9 494:3 499:3 sees 155:2 292:19 segment 37:7 52:4 140:15 227:10 282:6 segments 52:17 seizure 105:3 142:19 143:9 177:3 178:11 179:13,14 336:21 402:5 404:6 seizures 30:6 130:2 143:2 207:14 261:20 400:19,20 401:5,7 401:12,19,22 402:8 439:4 447:14 457:19,21 457:22 458:8	460:7 485:18 select 55:21 444:6 selected 55:19 236:19 312:14 358:10 selective 234:14 selectively 152:6 152:16 self 44:18 49:13 60:3,4 79:21 285:8,10 346:22 356:2 363:10 373:10 388:3 443:15 486:16 492:5 sell 55:11 90:10 105:2 243:22 247:9 335:14 344:20 376:21 sellers 266:9 selling 35:8,15 64:17,22 112:8 236:1 241:10 431:17 seminars 484:15 senate 395:21 senator 395:15,16 send 206:19 208:18 439:5 sending 158:17 289:1 senior 3:7 21:11 87:16 240:16 375:2 390:20 499:22 seniors 375:6 452:17 sense 75:3 164:12 238:17 314:3 318:18 320:7,21 321:6 373:15 399:11 484:5 sensible 123:4 414:22 417:7	sensitive 130:14 224:11 272:4 sensitivity 224:7 239:21 sent 162:7 207:7 283:13 284:11 373:21 sentiment 175:20 separate 33:13 101:1 168:18 273:13 322:8,10 separately 106:17 350:15 separating 487:8 488:2 separation 276:8 295:22 sepehri 4:2 22:9,9 september 402:9 sequentially 437:17 series 201:7 serious 35:13,19 39:9 57:18 84:17 140:18 180:4 191:21 220:1,2 269:11 338:6 341:8 401:2,8 404:13 430:21 492:10 seriously 65:8 98:6 seriousness 153:13 serve 30:19 95:19 95:22 161:9 365:19 366:3,8 379:4 390:22 391:19 served 26:9 57:15 71:21 156:15 167:22 288:1 395:17
---	--	---	---

<p>serves 379:7 413:12</p> <p>service 26:5 109:6 156:14 445:13</p> <p>services 9:19,22 108:11 132:20 161:11 374:8 400:22 444:7,14 445:17 446:6 484:1</p> <p>serving 26:5 70:3 118:15 265:20 294:2 340:19 469:1,7,13</p> <p>servings 469:14</p> <p>sesame 448:21</p> <p>session 22:18 24:6</p> <p>sessions 87:10</p> <p>set 56:5 205:9 241:12 268:20 321:15 394:13 399:10 413:15 444:13</p> <p>sets 304:10</p> <p>setting 73:4 272:16 338:8 340:19 362:7 366:16 368:3 371:22</p> <p>seven 154:10 173:6 248:9 301:3 301:4,15,19,22</p> <p>seventeen 209:4</p> <p>seventy 375:19</p> <p>severe 51:13 57:17 272:6 300:6 338:21 374:22 403:15</p> <p>severely 451:19 473:10</p> <p>severity 300:12</p> <p>sexual 189:3</p> <p>shackles 126:14</p>	<p>shadows 382:10</p> <p>shady 129:10</p> <p>shape 73:12 426:19 432:6</p> <p>share 57:9 76:9 88:11 109:2 197:15 201:9 259:5,19 266:22 325:7,9 326:4 429:5 455:17 460:6 476:14</p> <p>shared 112:15 326:1</p> <p>sharing 100:7 194:6 196:3 496:13,13</p> <p>sharkey 14:4 356:15,16,17 357:1,3</p> <p>sharma 14:6,8 361:7,8,15,16 364:8</p> <p>sharon 3:6 21:10 399:19</p> <p>sharpless 4:6 18:7 20:11 21:1 25:22 26:2,11,14 36:21 217:20 396:5 398:14</p> <p>shawn 15:10 476:2,3</p> <p>sheet 370:15</p> <p>shelf 54:1 96:19 96:21 332:4 344:19 346:16 350:13 490:15,17 490:20</p> <p>shelves 238:13</p> <p>sherene 4:2 22:9</p> <p>sheri 15:20 429:9 429:10</p> <p>shielding 131:18</p> <p>shiny 375:10</p>	<p>ship 296:3</p> <p>shipment 283:10</p> <p>shipments 82:11</p> <p>shipped 159:8</p> <p>shipping 349:12</p> <p>shock 489:5,21 491:6 494:13,19 494:22</p> <p>shocked 483:19</p> <p>shoddy 37:21 206:11</p> <p>shoes 130:4</p> <p>shop 375:8</p> <p>shopping 236:5</p> <p>shops 254:9 375:19,21</p> <p>short 127:3 130:21 183:7 188:9 208:14 293:3 303:5 305:21 317:15 392:9 396:14</p> <p>shortage 296:21</p> <p>shortly 206:15</p> <p>shot 92:11</p> <p>shout 498:5,7</p> <p>show 165:21 211:14 237:21 242:15 247:19 270:20 358:11 359:18 384:12,12 445:11 451:22 454:6 455:18</p> <p>showed 67:16 179:21 183:7 211:19 224:1 261:12 271:12 283:15 449:14</p> <p>showing 40:22 51:18 80:10 211:15 222:19 238:13 315:3 492:18</p>	<p>shown 44:5,17 76:15 105:11 152:22 179:2 211:12 213:2 222:10 293:22 314:18 330:1,2 334:13 358:15 359:20 385:14 488:21 492:22</p> <p>shows 45:19 47:13 108:22 119:20 220:20 250:1 258:7 263:4 284:9 284:13 286:8,17 335:12 340:12 385:3 387:12,13 454:12 483:10 494:14</p> <p>shredded 175:12 376:14</p> <p>shults 6:10 72:11 72:13,13 74:14 75:2,10</p> <p>sica 16:2 442:11 442:12,12 446:17</p> <p>sick 337:2</p> <p>side 24:5 69:20,22 70:6,9 193:4 217:13 251:6 256:12,21 277:11 318:16 320:3 340:2,12,14 358:11,11 359:9 360:21 361:18 387:21,22 388:12 388:15 389:7 405:1 453:22 473:14 492:10,11</p> <p>sides 197:5 223:20</p> <p>sigman 8:4 122:7 122:8,9 124:15,18 125:3</p> <p>sign 375:12</p>
---	---	---	---

<p>signal 196:14 198:9</p> <p>signaled 438:6</p> <p>signals 195:2 269:9</p> <p>signatories 446:20</p> <p>signatory 135:5 445:1</p> <p>signature 502:14</p> <p>signed 294:3</p> <p>significance 108:15</p> <p>significant 34:20 45:16 63:4 67:6 67:20 69:19 77:16 100:8 108:3 112:7 120:16 126:20 127:13 138:6 157:11 189:5 193:15,16 200:4 202:21 203:13 209:12 211:15 217:13 272:7 275:9 299:10 318:10 322:5 347:20 359:9 362:11 463:1</p> <p>significantly 90:9 108:8 191:14 324:5 334:22 458:8 468:9 473:11 495:3</p> <p>signing 81:13</p> <p>signs 119:21 492:10</p> <p>silage 45:16</p> <p>silence 24:2</p> <p>silenced 24:2</p> <p>silent 62:2</p> <p>silver 1:19</p> <p>similar 86:7 121:11 196:8 206:3 246:3 320:11 328:5,8</p>	<p>330:1 409:6,12</p> <p>similarly 32:3 478:16</p> <p>simple 71:20 88:21 114:11 129:7 228:7 230:10 231:6 262:13 345:11 460:21</p> <p>simplest 312:21</p> <p>simply 54:15 64:22 74:18 85:7 103:11 106:14 114:6 136:13,16 165:14 178:7 195:3 355:6 416:1 491:14</p> <p>simulate 236:5</p> <p>singing 337:5</p> <p>single 87:21 88:1 201:14 202:18 218:10 261:4 288:7 298:22 300:3 302:4 316:13 342:15 405:17 457:11 469:9,10,12 498:9 499:20</p> <p>sinusoidal 202:22 203:3</p> <p>sir 69:9 85:15 86:10 110:4 412:13 446:15</p> <p>sisley 12:12 282:1 282:6,10,11 297:15</p> <p>sister 472:15,15</p> <p>sit 172:19</p> <p>sitting 498:20 499:1</p> <p>situation 120:4 244:4 333:7 382:4 406:4,8 441:9 477:14</p>	<p>six 20:15 213:9 260:8 299:16 301:14 317:22 318:14 335:7 406:17 427:21 457:17 458:6 459:18 460:10 461:21 464:8</p> <p>sixty 249:21 335:5 485:14</p> <p>size 108:19 198:13 198:15 348:18 437:2 488:7</p> <p>sizes 118:15</p> <p>skeletal 262:21</p> <p>sketch 290:1</p> <p>skf 342:17</p> <p>skills 445:7 502:7 503:6</p> <p>skin 96:13 184:19 185:18 278:9 488:22 494:3</p> <p>skip 188:13</p> <p>skirting 209:8</p> <p>sku 290:16</p> <p>skunky 151:4</p> <p>sleep 223:12 248:20 250:7 274:4 275:10,11 275:12 276:19 382:13 385:18 387:4,17</p> <p>sleepiness 51:14 340:3</p> <p>sleeping 80:7</p> <p>sleeplessness 71:11</p> <p>sleeve 495:2</p> <p>slide 4:13 10:5 18:8,18,20 37:15 155:19 169:6 176:12,14 177:1 178:5 188:13 203:1 220:19</p>	<p>250:10 265:11,12 276:9 280:10 282:13,18,21 283:6,10,19 284:1 284:9,13 285:2,16 286:8,17 287:7,19 294:20 295:12 296:16 297:21 311:11 314:8 315:16 323:6 352:10 368:13 384:17 400:15 417:9 447:19 485:16 489:10 490:7,15 491:3 492:6,6</p> <p>slides 20:13,16 166:9 225:20 240:12 261:2 279:15 282:8 298:17 316:21 383:22 384:2,8,12 495:15</p> <p>slight 341:19 447:9 483:11</p> <p>slightly 250:2</p> <p>slip 327:7</p> <p>slot 25:2</p> <p>slow 125:18 389:3 392:20</p> <p>slowing 119:21</p> <p>slowly 80:9 382:10</p> <p>slowness 182:16 385:12</p> <p>small 46:13 47:8 62:12 71:16 140:15,17 184:7 191:9 199:1,4 217:7 224:9 285:12 288:21 290:5 293:12 341:3 359:4</p>
---	--	--	--

smaller 272:9	90:12 120:7	226:16 373:9,14	sought 397:21
smallest 279:4	138:20 155:1	373:17,17,22	soul 56:19
smart 5:13 129:13	156:10 162:1	374:10,14 447:12	sound 156:17
253:14 254:5	164:16 174:21	475:17	467:6
399:6,6 500:8	188:12 211:7	son's 56:18	sounds 124:20
smartphone 321:3	286:15 335:11	soon 23:17 121:3	254:8
471:21	343:21,22,22	373:10	source 31:8 46:3
smell 375:16	467:17 477:6	sooner 168:12	197:1 218:18
smokable 255:22	479:12	soothing 491:15	267:9 296:4
smokables 164:21	soldiers 207:22	sops 311:18	322:20 408:5
smoke 257:7	sole 193:1 198:2	sorry 66:11 69:17	423:8,9,10 451:11
299:1,10,11,16	379:20	83:8 91:12,12	471:16 480:21
375:16	soliciting 381:18	95:8 109:12 111:4	sourced 151:11
smoked 41:3	solid 195:18 315:5	137:20 141:5,5	369:4
92:10 224:6	380:6	144:10 150:2	sources 47:7
282:15 285:11	solowij 213:1	172:12 181:17	145:19 169:2
286:19 299:21	soluble 319:2	187:16 198:12	340:17 370:1
300:13 301:16	solution 38:16	210:22 239:22	404:5
smoking 91:22	126:22 270:13	252:15 268:18	sourcing 151:15
211:21,22 217:1	277:20 352:6	280:2 295:16	soybeans 44:2
223:2 341:6	397:21	305:1 311:8,11	space 90:1 119:7
smooth 245:6	solutions 12:7	341:20 342:7	131:19 176:5
smprs 392:8	85:6 115:6 366:5	344:5 357:1	227:20 247:13
snake 274:21	466:6 498:2 500:9	366:14 370:18	273:18 310:16
396:12	solve 473:8	378:5,9 384:16	327:11 333:14
snapshot 188:9	solvent 416:8	412:13,15 413:5	357:18 358:5
snow 373:17	487:19	482:19 486:9,10	395:10 406:17,18
snyder 8:6 125:7,8	solvents 319:14	488:16 489:6	420:11 422:1,11
125:9 128:3,5,11	331:17 360:10	495:14	422:13 441:13,15
128:21 129:5	362:1 363:22	sort 70:7 113:21	441:19,21 442:20
soaked 487:22	370:19,21 371:1	124:20 129:3	spangler 6:12
socati 13:5 303:5	372:8 428:11	141:5,21 148:17	75:22 76:2,2
social 173:5 374:8	449:13 464:15,21	157:17 160:2	spark 364:15
410:14 451:3	465:10	171:13,14 172:4	speak 42:12 58:8
society 8:18 138:2	somebody 240:21	185:18 264:7	58:9 72:17 74:9
383:8	242:13 335:14	326:8,13 333:6	104:17 126:2
sociodemographic	475:4	336:10 398:19	137:18 147:10
453:1	somewhat 215:10	420:13 421:22	158:9 160:22
sodas 151:3	283:20	422:20 423:21	181:19 187:11,21
soft 327:21 448:7	somnolence	448:6	219:1 252:18
softening 488:2	300:21 360:2	sorts 70:6 114:2	268:2 273:15
soil 312:5 330:11	son 56:18 91:21	114:16 310:3	274:13 384:4
sold 30:1 59:14	91:21 92:2 128:7	449:18	401:13 413:9
62:10,13 83:1	128:9 149:16		462:7 466:22

<p>481:19 495:21 speaker 37:12 42:13 47:17 50:5 56:14,16 58:21,22 59:2 61:9,10,13 63:15 70:16,18 72:10,11 75:22 77:19 81:5 87:14 91:6 92:15 95:14 101:18 111:4,6 115:17 118:11,22 129:16,17 137:13 142:13 153:3 155:17 161:6 166:4,8 176:10 181:12 192:5 200:8 204:5 209:17 216:6 240:10 252:15,20 253:18 258:22 263:17 268:7 274:10 293:16 298:6,7 303:3 316:20,20 328:16 332:16 337:22 345:6 347:7 353:4 361:6 373:2 378:12 383:19,19 390:17 394:22 395:3 406:13 425:8 429:9 434:19 442:10,11 447:1 451:1 456:17 466:19 471:7 476:1 481:13,14 486:19 496:4,5 speaker's 23:21 speakers 23:4 24:4,17,20 27:1 37:6 53:6 66:17 155:15 176:20 202:2 268:5 282:4 287:12 402:16</p>	<p>speaking 25:4 40:5 76:2 137:16 138:1 231:8 235:5 407:19 409:16 419:10,10,11 speaks 76:6 400:18 spearheading 367:5 spec 289:2 292:12 special 192:1 213:21 218:1,2 464:19 465:8 specialist 137:16 138:1 317:6 specialize 40:7 367:4 386:10,11 specialized 446:3 specializing 367:14 472:3 species 84:22 specific 33:2 34:2 84:13 117:21 133:4 139:13 152:17 157:5 177:9 198:18 280:9,10 312:17 324:14 337:13 393:4 408:22 410:11 425:2 439:8,15 443:20 444:13,15 452:11 465:5 specifically 31:18 35:3 69:4 75:14 93:13 94:15 116:3 134:1 157:21 177:17 196:2 208:4 233:4 235:18,21 253:7 294:6 304:15 311:19 312:14 348:8 358:5 360:9 397:1 407:21,22</p>	<p>416:10 specification 348:16 370:15 specifications 99:22 100:9 348:14 363:6 444:4 449:12 450:13 specifics 305:2 specified 400:1 445:4 specify 484:11 spectrometry 189:20 spectrum 12:21 42:5 67:19 68:5 68:18,19 84:4 96:11 148:10,13 148:18,19 229:12 233:20 234:2,3 263:8 275:4 277:4 277:10 279:5,5 292:14 293:19 294:3 303:7,17,18 305:15,15 306:14 306:14 307:12,13 307:19 308:1,4,4 308:6,20,21 310:1 366:9 417:13,14 418:5,7 424:7 485:22 speculate 128:14 speech 36:13 speed 306:20 spell 420:20 spend 127:17 184:14 244:20 355:17 spent 43:16 50:13 240:19 245:18 339:11 347:21 348:1 472:2 spiked 148:14</p>	<p>spiking 201:19 spin 245:7 spindle 4:17 40:1 40:3,4 spiral 57:17 spirit 443:16 spite 78:1 split 372:14 spokespersons 61:22 sponge 146:10 sponsor 101:8 sponsored 294:17 295:5 sponsors 76:14 sponsorship 247:5 spontaneous 86:22 197:17 198:3 spots 129:16 sprays 41:15 249:6 spread 122:12 221:16 spring 1:19 386:8 springs 496:3 498:4 square 161:18 squarely 416:14 stability 54:1 314:22 315:2 332:3 428:6 450:10 490:16,21 stabilized 180:21 stable 315:7 448:13 449:20,21 450:7,7 493:11 staff 24:15 134:4 197:6 445:7 stage 96:2 117:12 131:5 205:9 286:20 305:10 330:22</p>
--	---	--	---

stages 203:7 389:12 staggering 154:7 stairs 472:18 stake 432:5 stakeholder 2:11 20:8 88:8,10 89:5 90:5 389:10 426:17 427:16 stakeholders 27:3 44:22 48:21 73:21 82:14 85:11 88:10 89:8 153:19 352:5 358:18 364:5,20 365:15 386:7 426:9 427:7 428:9 429:1 456:9 496:10 stalks 171:15,18 stance 157:8 344:14 stand 298:2 343:17,18 346:6 481:2 standalone 156:12 standard 38:18,21 59:20 70:3 77:14 99:9,21 103:15 138:17 167:19 194:15 285:6 295:21,22 305:16 305:19 309:13 314:7 368:2 369:12 372:1 392:7 399:19 428:9 437:2,4 443:2,16,21 479:8 494:11 495:7 standardization 142:1 219:19 266:6 310:5 standardize 363:12	standardized 141:22 142:22 273:13 286:6 303:16 364:6 371:8 standardizing 408:11 479:12 standards 37:22 42:1 49:13 98:16 98:21 99:4,12,15 100:13,18 101:1,8 101:17 109:21 110:1 121:16 131:15 132:3 134:8 138:19 204:11 213:15 235:15 254:6 256:7 266:9,17 291:4 297:2 303:13 305:3 329:12 330:17 331:12 332:9,13 333:13 337:7 348:11 362:7,12 363:1 364:10 365:8,16,20 366:12,16 371:20 378:21 383:9,14 389:7 393:4 394:13 404:20 407:14 409:12 411:7 412:7 414:10 415:14 416:21 417:5 425:5,15,21 426:2 426:4,6,10,16,19 427:4,5,9,19,22 428:6,8,19 429:2 436:8 442:16 445:21 462:20 463:3,6,12,15 466:8,10 478:17 480:7 487:4 489:10 490:6	497:4 standing 220:11 369:9 standpoint 210:6 231:7,15 232:17 stands 100:16 119:11 staph 489:21 492:16 start 46:18 89:22 195:20 278:22 280:13,18 281:2 287:20 288:10 290:17 305:7 307:19 325:11 343:5 355:11 365:12 384:19 391:2 392:7 407:17 435:3 451:12 462:3 482:1 487:6 496:8 started 44:17 74:2 91:22 246:4,5,12 287:21,22 288:4 290:6 343:7 345:3 366:19 373:9 392:9 394:4,8 402:9 421:14 457:19 starting 174:20 221:16 304:9 309:6 311:22 318:7 323:1 327:18 402:13 430:2 starts 296:7 348:4 450:1 startup 342:10 state 9:14 18:19 20:15 21:1 25:5 43:8,13,17 48:17 51:15,20 52:6 60:4,7,11 61:5 62:1 88:19 91:19	94:5 113:4 121:7 138:10 145:19 154:2 155:16,20 156:3,7 157:8,17 159:22 160:8,14 160:17,19 161:16 161:20 162:8,17 164:11 165:10,20 169:21 171:21 182:1 188:8 189:12 191:10 193:3 198:5 218:15,21 220:4 228:17 242:11,11 265:8 266:2 283:17 294:17 295:5 296:3,7,13 317:19 319:5,15 319:20 320:15 329:16 342:16 344:9,19 353:10 356:9 357:14 362:21 369:5,10 369:15 371:7,7 376:4 382:20 407:13,14 408:12 408:21,22 409:18 410:21 411:2,4,9 411:12,16,17 412:4 413:16 414:1,7 415:17 419:19 421:10,11 422:4 423:19 424:13 428:22 430:1,2,7 431:21 432:16 434:8,14 462:16 464:2,4,4 464:22 466:7 467:7 476:9,12,20 477:3,11 478:4,6 478:8,20 479:11 479:17 480:20 481:9 498:8 502:17
--	--	---	--

state's 409:1 411:8 499:2	412:6 414:3 415:17 426:5 428:5 430:8,9 431:19 432:12,13 432:13,14,15 433:3,5,6 444:22 453:8 464:7,10,19 465:1,18 466:13 468:20 470:13,15 478:22 479:1 480:8 481:20 482:17 484:2 486:11 500:8,16	429:3 stephen 13:20 347:8,9 stepped 38:4 383:5 steps 47:5 55:3 77:4 183:1 230:6 230:10 sterilization 488:11 sterilize 490:10,11 495:6 steve 15:16 117:10 434:20,21 stewardship 196:19 218:6,7 366:18 stick 132:11 293:5 sticking 291:6 sticks 285:19 448:8 stifle 419:1 stifled 414:16 stifling 82:11 stigma 230:9 232:4 stimulation 271:5 stomach 177:8 stop 25:14 170:7 223:2,14 401:19 431:15 stopped 250:17,18 402:11 472:9 stopping 401:12 storage 330:9 332:1 store 55:9 96:18 207:19 226:17,18 238:13 249:14 251:16 376:21 450:2 461:2 storefronts 395:11 stores 153:10 156:11,12 208:2	254:9 375:17 stories 58:3 96:7 148:7 171:14 246:13 260:3,13 storm 470:11 story 58:1 91:15 92:13 204:16 252:10 374:15,19 402:1,2 448:18 strain 267:8 strategies 89:6 222:4 stream 46:2 54:17 232:9,11,18 233:19 234:18 streamline 371:19 streamlined 42:4 226:4 streamlining 225:15 streams 235:1 398:2 strength 33:3 99:7 99:12 163:9 315:15 331:15 352:14 strengthened 444:19 strengthens 160:14 strengths 352:12 stress 248:16 249:20 443:6 stressed 80:6 stretch 172:16 strict 95:7 348:13 366:11 490:2 strictest 370:4 strictly 121:13 471:4 striking 67:16 stringent 332:12 362:12 476:11
stated 103:13 111:19 121:5 151:22 468:21	stating 120:21 343:20 369:19		
statement 111:12 273:13 321:1 369:17 418:21 429:19 433:8 438:4	stations 62:19 statistical 134:5 statistically 318:10 stats 250:12 status 52:12 71:6 76:12 82:6 100:15 138:7 266:19 273:8 401:11 467:8 statute 354:9 435:22 statutes 353:16 354:5 statutory 32:4,17 163:17 397:21 stay 24:20 112:10 379:9 396:12 411:8 staying 71:21 steals 474:4 steam 152:5 steel 426:11 steinberg 16:4,5 447:1,3,4,5 stems 285:19 step 36:9 60:21 88:8 229:20 266:1 306:4 370:10		
statements 160:9 437:11 479:19			
states 1:1 28:2,16 42:20 43:5,19 45:11 52:8 56:6,8 60:19 61:18 99:2 121:3,6 132:20 138:17 145:22 146:3 149:22 156:4,7,13,16 157:3 158:2,10 159:11,16,19,22 160:1,4,5 161:2 161:14 163:13,22 165:19 166:14,19 167:10 170:1 174:13 175:13 182:11 192:22 201:4 207:9 217:8 221:1,4 228:13,16 228:19 242:10,14 244:16 251:16 253:11 258:4 260:19 265:14,19 266:19 290:15 294:4 295:2 297:12 332:20,22 333:7,8,9,11,17 334:9 357:16 358:6,8 384:11,13 385:3,4,5 386:6 391:22 408:18 409:8 410:5 411:2 411:11,21 412:1,1			

strive 282:14	201:7,10 211:11	sub 359:5	466:15 475:21
striving 282:16	211:19 213:15	subcommittee	501:1
strong 14:15 59:5	215:12 219:13	428:14	submits 440:1
71:7 83:4 91:2	220:17 223:21,22	subcommittees	submitted 36:7
96:2 259:18	236:17 263:4	427:17	69:5 81:1 83:17
304:19 338:3	270:11,20 271:22	subgroups 479:15	107:14 152:20
341:13 352:6	273:18,21 298:21	subject 22:21 23:2	157:19 189:13
374:4 376:8	325:15 327:22	29:15 33:12 42:22	302:22 354:11
stronger 41:1 83:4	339:10 340:1,10	55:16 123:7 189:4	submitting 66:8
211:20 339:21	351:18 352:18	204:14 302:19	68:8 73:17 86:1
364:10	354:1,16,17	316:11 365:13	204:9 205:6
strongly 44:8	355:20 358:10,19	409:9 410:2	309:18 321:2
48:22 50:20 71:21	360:13 397:5	438:11,16 461:17	325:6 355:3
71:22 108:1 118:8	439:21 451:7,22	476:11 478:7	466:16 493:13
138:16 139:19,20	475:1 488:20	subjective 212:3	suboxone 67:13
197:14 322:12	492:8 494:4	212:16	subpar 295:10
326:11 333:18	study 124:13	subjects 389:19	356:11
358:17 381:9	128:16 170:13	sublingual 41:15	subpopulation
438:22	186:5 188:9	270:14 277:13	452:8
structure 29:22	202:17 204:18	278:3,4 280:13	subset 464:5
71:14 86:7 121:14	211:6 212:9	317:9,12,19	subsidiary 268:16
273:10 448:1	220:16 225:19	318:12,22 319:3	substance 29:3,14
468:17 488:5	226:16 236:22	320:1	29:16 31:3,6 32:9
structured 443:17	237:1 265:17	submission 63:13	32:18 34:5 61:17
structures 146:3	279:11 282:22	72:3 107:17	68:1 81:17,21
struggling 156:16	283:4,8 285:9,21	123:14 167:18	82:1 93:11 105:9
160:5 424:6	287:2 299:4 301:7	169:10,18 196:12	105:22 106:1,2,8
stuart 6:14 61:19	301:11 335:18	205:1 337:12	106:15,18 212:11
77:19,20	336:18 358:1	493:14	273:1 322:9,11
stuck 109:12	359:4,8,15 389:18	submit 25:19 27:5	461:11
studied 31:19	398:8,12 451:9	36:14 52:22 71:19	substances 28:9
32:10 135:16	474:15,22 475:2	71:22 79:17	29:13 31:7,10
178:12 217:15	studying 292:21	111:12 114:21	32:1,19 33:9 56:2
259:9 264:19	stuff 127:9 229:12	115:5 118:18	69:1 82:3 89:18
435:15	243:17,22 248:16	122:5 124:17	93:21 99:19
studies 42:7 49:10	249:11 276:12	125:2 165:7	205:16,19 219:8
51:9 78:18,20	288:11 290:3,9,12	196:21 216:1	241:16 296:2
93:4,8 94:8 96:10	290:22 291:12	229:6 274:7	314:2,11,14 382:2
104:19 110:14	292:21 293:1	292:15 309:20	433:9 459:15
126:3,6 139:1	392:21 449:10	314:10 320:7	substandard
140:1 168:16	stumbling 97:5	325:17 344:14	131:21 295:10
169:3 171:22	stunning 83:2	354:17 395:16	382:22 477:16
175:2 183:5,8	sturge 457:6	412:18 434:16	substantial 32:2
184:6,16 185:10		446:22 456:14	106:12 136:15

157:1 246:16 247:12 300:15 substantiate 381:21 substantiation 268:14 substantive 326:5 subversion 175:15 succeed 170:9 successes 412:1 successful 365:2 368:20 402:18 417:6 430:18 successfully 364:22 367:19 successor 63:7 sudden 401:9 suddenly 403:1 sue 12:12 240:18 240:21 281:21 282:6,9,10 287:10 297:15 suffer 129:22 suffered 449:8 suffering 338:16 341:8 415:4 458:3 suffers 374:21 457:22 suffice 468:8 sufficient 73:5 77:15 330:3 360:11 389:8 suggest 185:5 429:22 433:4 473:9 suggested 117:5 120:6 121:12 193:19 402:20 474:20 suggesting 182:6 184:15 407:6 475:8 suggestion 122:2	suggestions 120:5 suggests 84:20 116:13 120:17 301:8,22 323:9 324:8 455:13,22 suicidal 174:18 373:20 374:22 suicide 56:19 57:19 245:2 373:18 374:18 375:14 484:20 suicides 376:5 suit 240:22 316:8 suitability 163:3 suitable 100:8 134:9 487:14 sulak 261:14 sum 480:16 summarize 302:2 summarized 315:8 summary 68:5 134:22 143:22 183:12 191:9 195:17 219:6 317:17 332:5 440:13 456:14 summer 373:7 394:6 superimposed 387:15 supermarket 153:9 supervision 33:5 139:4 346:22 supplement 6:21 32:5,9,14 44:15 47:11 51:21 65:4 71:13,15 72:3 73:6,11,20 77:10 77:12 79:4,6,10 83:12 102:7 108:18 116:1,7 118:3 159:15	171:5 188:19 217:22 272:15 273:4 306:18 313:7 325:3 357:4 357:6 358:22 364:19 395:10,20 403:19 406:1 410:16 415:10,21 428:16 433:10 435:2 436:17 438:3,3,5 439:2 440:22 441:13,18 441:21 442:7 478:17 496:21 497:22 supplemental 433:14 supplements 10:18 30:14 33:11 34:7 44:12 48:11 48:14 52:18 53:20 65:1 71:2 76:5,8 77:6 78:15 84:12 98:12,22 101:15 111:21 112:8,16 112:21 113:7,14 116:2,5,8 117:15 117:17 118:5,6,13 120:8,20 128:16 128:22 151:12 154:4 162:2 188:4 188:17,18 189:1 200:14,18 205:17 214:10 269:10 272:19 295:21 304:15 313:2 315:12 323:5,21 324:1 327:7 337:8 337:14 350:8 352:11 353:8 355:3 361:3 365:10 396:9,13 398:17,18 399:16 407:12 414:21	416:7 435:6,14 436:1 438:8,12,15 440:16,18 441:2,2 441:17 442:3 450:16 477:7 supplier 198:2 suppliers 97:19 154:1 490:3 supplies 302:15,19 supply 31:2 32:22 46:10 48:3 66:8 89:2 101:10,12 216:15 267:1 286:14 287:1 305:6 311:3,5 322:16,22 326:21 344:20 404:11 408:14 487:5,6 489:14,15 support 30:12 34:6 50:20 53:14 60:9 65:4 68:9 76:12 78:12,15 79:9,15,20 80:4 80:21 84:7,22 86:7 88:9 89:4 94:13 103:2 104:2 113:9 121:21 131:14 136:18 139:18 162:22 186:21 195:14 268:13 338:3 341:13 362:19 363:5,13,15 364:4 410:13,14 411:2 429:3 439:18 445:20 456:8 457:13 463:21 467:6 supported 247:6 327:22 456:21 supporting 50:15 125:16 170:12 252:21 294:6
---	---	---	---

394:15 482:3 supportive 79:1 128:4 supports 50:11 71:8 85:20 108:21 325:3 476:20 supposed 206:18 254:13 suppositories 41:16 suppresses 492:15 supreme 244:17 sure 25:5 30:18 89:20 90:6 91:2 91:16 114:1 115:2 115:7 158:8 214:18 231:1 233:6 238:10 276:1,4 282:1 286:5 307:19 312:19 336:5 343:13 344:3,22 346:3 349:1 360:12 404:20 459:7 481:10 493:15 499:5 surely 63:8 surface 42:8 126:11 203:17 338:18 489:3 490:14 494:15 surgery 458:18 surgical 495:8 surpassed 482:10 surplus 288:18 289:11 surprise 391:6 surprised 206:14 238:9 249:12 276:2,13 surprising 270:8 270:19 386:21 surprisingly 71:7 248:21 385:22	surrounding 48:18 155:3 466:14 surveillance 3:15 22:13 87:11 192:19,21 193:1 194:14 195:2 196:12 198:8 218:3 451:19 survey 125:4 154:9 158:1 159:10 161:1 162:5,11 164:8,12 164:16 188:7 189:7 247:14,15 251:5 387:10 453:8 455:12 483:10 surveyed 386:1 453:6 surveys 451:17 454:6 survive 377:6 surviving 473:4 susan 5:10 14:16 53:6,10 378:13,18 383:18 susceptible 382:14 suspect 198:19 sustainable 365:18 sweet 457:17 sweetheart 243:15 swept 62:4 swift 42:11 swiftly 38:2 155:7 437:20 swimming 438:1 swine 86:12 switch 223:20 symbol 273:14 symbols 479:19 sympathy 241:20	symphony 440:10 symptom 208:15 symptoms 131:1 224:3 271:13 275:17 318:1 385:11,14,17,21 387:4 388:1,3 389:13,16 493:7 synchronized 322:14 syndrome 140:16 140:17,18 173:11 203:1 338:17,18 447:16 457:6 489:5,21 491:6 494:14,19,22 syndros 30:7 synergetic 487:15 synergies 306:12 synergistic 306:14 308:2 syngap 8:9 129:20 syngap1 130:20 131:1 132:4 synthesis 93:12 synthesize 262:10 synthesized 313:6 synthesizing 315:20 316:6 synthetic 30:7 164:13,13 189:21 190:7,20 191:7,18 206:13 209:5 314:13 315:17 431:12 synthetically 210:10 311:21 312:9 syrops 207:12 system 25:7 54:5 71:10 72:1 78:13 78:13,20 79:9,21 79:22 92:21 93:15 94:14 151:19,21	197:19 198:1 204:21 205:7 259:7 261:4 262:1 262:2,2,3,7,16 263:3,9 270:1 300:3 301:20 438:13 441:20 482:2 485:4,5,8 488:17 systematic 157:19 213:18 439:18 systemic 236:14 systems 54:2 179:11 235:12 262:17,18 263:1,3 269:7 292:5 340:16 362:18 363:7 409:17 437:10 474:11 476:12 478:10
t			
t 18:2,2 19:1,1 table 20:21 148:18 190:1,22 318:22 464:5 tablet 63:2 114:7 318:12,21 319:1,3 319:7,11 tablets 63:4 tackling 140:3 tacrolimus 180:16 180:21 181:2 tailor 452:10 tailored 348:8 take 39:2,2,6 41:6 43:20 58:11 72:19 73:12 90:1 112:17 118:18 120:2 121:10 147:22 168:9 172:13 175:7 183:1 208:21 222:15 227:2,4 230:5 232:11,17,19			

234:4,13 235:2 236:9 246:4 247:16 248:9 249:14 252:3 254:14,14 257:9 262:6 281:1,15,17 291:3 295:3 337:14 339:7 343:18 344:14 358:21 372:17,21 376:14 389:10 399:13 401:10 402:20 403:7,21 407:7 418:1 422:20 430:1 437:9 467:15 468:20,21 469:2,4 469:8,13,21 488:9 takeaway 413:19 takeaways 247:18 386:21 taken 62:17 85:4 139:4 177:8 248:7 250:8 352:21 353:12 392:1 408:21 432:8 502:3,9 503:9 takes 149:4 265:4 403:9 takoma 261:8 talk 40:16 171:10 177:11 178:14 179:6 188:6 228:2 233:12 242:4 258:16 295:14 298:2 334:11 345:16 357:5 390:3 420:12 421:12 447:17,20 496:7 497:4,10 talked 171:22 177:5 185:15,16 309:22 310:13 348:17,19 352:10	389:7 424:7 470:9 474:15 498:6 499:15 talking 29:18 62:3 114:19 127:10 198:16 210:5 245:6 258:11 279:19 290:20 300:20 312:7 335:19,20,21 361:18 398:6 399:1 449:4 497:1 tall 187:15 tame 383:8 tampon 487:22 488:7,9 490:9,14 491:8,9 494:15,18 495:2 tampons 487:4,17 488:10 489:3 490:11,12,19,22 491:14 492:21 493:7 494:11 495:7 tandem 408:12 411:3 tangible 126:20 tape 127:17 283:3 tapping 195:19 target 92:21 146:13 394:3 452:10 targeted 130:19 130:20 387:3 452:9 targeting 93:19 94:14 389:16 targets 269:22 270:8 task 119:19 211:16 tasked 322:7 taskforce 85:8 395:4	taste 151:5 328:2 328:8,10 taught 92:1 259:10 tax 52:6 54:16 377:19 412:10 taxed 412:11 team 197:6 269:18 328:21 348:5 technical 134:1,10 134:20 168:11 172:12 325:13 328:3,11 381:4 425:15 426:7,18 427:8 444:2,9 445:7 495:14 techniques 152:4 technology 50:14 87:16 267:5,7 303:8 427:2 471:17,20 474:9 teen 260:6 telephone 247:15 tell 39:9 56:11 58:1 91:15 127:1 243:15 255:12 260:3 282:7 291:10,14 332:18 340:1 374:15,19 494:11 telling 39:1 92:12 179:12 246:13 334:18 344:19 346:7 tells 63:7 335:15 temperature 449:21 temple 265:18 temporary 70:8 411:9 ten 122:11 248:19 483:12 tend 114:3,17 474:12	tends 494:5 tens 347:21 348:1 tenth 412:22 term 68:17,19 78:18 130:21 139:10,16 156:18 157:2 163:6 182:14 183:7 186:18 208:14,15 213:19 396:15 448:15,18,22 489:17 terminology 417:10,11 terms 33:17 85:2 166:20 182:21 186:17 192:2 205:5 213:18 239:20 246:1 251:11 258:5 271:14,20 303:17 307:12,16 310:3,6 349:7 396:2 420:14,16 422:13 422:15 423:22 443:5 terpene 151:2,3 372:7 428:12 terpenes 9:10 84:4 148:14 150:11,20 151:4,14,15,18,20 152:1,6,9,17,19 165:17 210:13 308:3 318:22 350:14 486:1 terrain 32:20 territory 396:6,22 test 97:21 133:14 134:12 226:19,22 236:11 237:1 247:8 306:3 312:1 315:1 316:2 333:22 349:13 351:2,8,10,13
--	---	--	---

360:7 379:8 381:8 428:9 433:1 444:17 testament 418:12 tested 97:20 109:14 215:16 222:3 237:14,18 238:5 239:1,21 251:15 294:13 297:8 315:14 319:8,13 340:7 345:14 348:15 369:11 370:16 464:6 465:19 489:20 testicular 174:11 testify 256:18 277:19 testifying 279:13 460:5 testimonials 257:14 testimonies 377:18 391:4 471:12 testimony 68:10 378:18 381:18 472:1 493:14 testing 11:17 49:17 60:11 92:4 96:15 109:18 121:16,19,21 132:21,21 133:6 133:10,15 134:6,9 134:20 135:4 142:1 145:1,8,17 174:20 204:10 209:11 213:9,16 219:18 222:1,8 234:14,20 235:11 237:21 265:9 266:20 278:13 283:12,14,15,17 283:18 290:8,22	303:14 304:11,17 306:7 311:16 314:22 319:9,16 329:22 330:2,16 330:22 331:20,21 331:21 332:4 351:17,21 362:18 363:18,20 364:1,3 364:6 370:5 371:8 371:10,20 372:5 375:15 378:20 379:1,11,12,16 380:6,7,14,21 381:5 382:15 383:1,9,14 391:10 392:5,15 393:6 394:11 414:9 416:16,17,18,18 424:13,22 427:17 428:10 438:21 442:19,20 443:14 444:2,6,10,14 446:10 462:20 463:22 464:1,3,11 465:20,22 479:6,8 480:3 490:15,18 tests 67:17 99:11 213:10 237:20 246:20 266:21 318:20 339:16 424:12 446:13 458:14 493:22 tetra 13:3 298:12 298:16,18 302:9 302:15 tetrahydrocanna... 27:15 texas 263:21,22 264:18 265:22 294:11 373:7 457:2 479:1 text 36:13 textbook 422:8	textile 52:8 thank 26:14,15 36:16,19,21 37:17 39:21,22 42:12,13 42:21 45:4,5 47:15,16 50:3,4 52:20 53:4,5,9 55:1,15 56:3,12 56:13,14 58:15,17 58:19 61:4,8,9 63:14,15,18 65:21 66:10 68:16 69:10 69:15 70:13,14,14 72:7,10,16,21 74:8 75:19,21 77:18 79:15 81:2 81:4 83:5,6,10 85:12 86:2,8,17 87:12,13 89:12,20 91:4,5 92:12,14 92:17 94:20 95:12 98:7,14 100:20 101:17,18 104:8,9 104:10,16 106:22 107:1 110:11,15 110:16 111:1,2,3 113:15 115:3,13 115:15,19 118:20 118:21 119:3 122:4 124:11,12 125:5,6 127:22 129:13,15,18,18 132:7,8 135:5,7 137:2,12 142:12 144:8,14,15 147:2 147:3 150:5 153:2 155:13,14 156:5 157:13,15 158:19 158:20,22 160:21 161:5,7,11 163:19 164:5 166:3,4,10 169:11 172:9,11 172:16,21 173:4 176:1,2,9 181:11	181:12,14,19 185:12 187:6,7,10 187:20 192:4,5 196:19 197:22 198:10 200:8 204:3,4,7 209:15 209:17 214:13 216:5,7 220:5 225:22 226:1 227:7 235:2,4,8 240:8,10 245:10 245:12 252:5,13 252:14,17 257:16 258:18,19,20 263:13,16,18 268:2,3,4,8 273:14 274:6,9,12 279:11,13 280:1,7 281:12,13,18 282:8 287:8,10 293:15 298:1,3,4 302:21 303:2,4 307:5 310:10,17 315:15 316:18,19 317:2 320:17,19 321:7,8 326:3 328:16,21 332:14 332:15 337:10,20 337:21 341:17 342:2,3 347:5,6 353:2,3 356:12,14 361:5,6,8,11 364:8 365:11,21 365:22 372:15,16 372:22 373:3,5 377:22 378:2,11 378:14 383:17,18 384:4 389:22 390:16,17,19 394:17,20,21 395:2 400:4,5,7 405:4 406:12,13 412:19,20 413:1,8 419:2,4 425:5,6,7
--	---	---	--

<p>425:10,10,12 429:5,7,8 434:4,5 434:17,18,19 440:20 442:9,10 446:21 450:20,22 456:7,16,17 461:21 462:2,6 466:10,17,18,19 466:21 471:5,7 475:15 476:1 481:6,16 486:8,17 486:21 489:12 491:4 492:6 493:15 495:11,12 495:13 496:12,13 496:14 500:17,20 501:2,4 thankful 50:22 thankfully 191:3 thanking 496:9,9 496:10,11 thanks 70:12 89:14 95:10 137:11 158:18 161:4 200:7 216:3 233:17 293:14 310:9 352:8 475:14,22 481:12 495:16 thanksgiving 92:2 459:18 that's 422:14 the 27:15 28:15,21 30:8 31:18 32:8 32:11,13 33:6 57:1 61:1 62:8,10 62:20 63:3,5 67:11 69:1,3 72:4 80:19 84:5,7 92:5 102:22 150:18 173:16,21 174:6 174:22 175:10 176:1 177:16 179:10 182:6</p>	<p>183:6,12,18 184:6 184:7 186:12 189:10,20 190:5 190:17,18 191:15 191:16 194:17,17 209:14 211:1,3,8 211:12 212:13,18 213:4,7,10,12 214:5,16,22 215:3 215:17 217:2,8 221:20 224:6 228:12,15,18,19 229:10,19 230:2,7 230:21 231:22 232:19,22 234:8 234:20 237:14 239:13,14,19 240:4,6 254:20 271:12 274:1 275:5 293:22 299:13,15,16,17 299:19 301:11 303:17 305:13,19 308:5,7 309:22 327:1,14 329:4 330:3 335:8,10 340:22 341:1,4,5 345:15 350:16 360:9 361:21 363:3 368:3 377:16 382:8 390:5,6,8,13 393:20,22 397:10 397:13 408:20 411:6,19 424:11 424:16 425:4 449:16 450:10 452:22 453:4 455:4,5,6,19 459:15 465:11,13 465:19,20 467:12 467:19 468:2,4,7 468:9,10,12,14,16 468:19,22 469:1,5</p>	<p>469:7,10,18,20 470:19,21 473:18 473:18 474:12,13 484:12 485:2 487:13,16 498:12 thca 291:21 292:8 487:13 thecannabisindu... 107:18 theme 176:17 371:15 theory 411:10 therabis 14:5 357:4 therapeutic 29:21 30:10 35:16 39:15 51:7 63:20 64:19 64:22 65:9,20 180:1 184:11 264:3 268:22 285:14 380:10 462:12 492:17 therapies 35:19 67:9 130:15,19 132:6 385:13,18 387:1 401:3 therapist 59:5 therapy 130:20 thereof 188:10 369:21 thing 40:16 56:5 115:4 163:11 184:5 215:11 241:6 243:14 244:10 247:22 248:3 249:18 254:15 266:14 278:10 290:8 309:21 321:13 344:3 346:9,10 348:22 351:7 388:10,11 404:8 414:3 453:15 468:19</p>	<p>things 75:14 87:1 102:20 141:21 142:1,7 149:8 150:14,20 152:6 155:13 177:11 179:6 180:6 181:5 181:5 209:20 212:6 215:2 217:14 220:2 221:5 222:9 224:17 225:10,19 233:21 234:10 243:7 246:20 250:20 254:4,7 280:22 285:3,22 288:12,16 293:4 308:13,14 309:22 335:21 336:17 354:5 373:15 391:12 396:11 399:21 404:21 405:22 419:17 424:7,20 430:8 459:4 470:7 498:14 think 38:8 56:10 62:20 80:3 89:21 90:4,14,15,19 95:3,5 103:9 114:11 115:14 118:11 128:18 129:5,8 142:10 148:6,17 157:16 164:2 176:4 178:21 179:15 185:11 196:8 197:1,19 199:4 200:6 209:21 212:20 218:20 219:1,12,14 226:5 233:2 238:21,22 240:3 244:3 248:18 249:3,7 252:2 253:19</p>
--	---	--	---

254:6 256:1,10,22 267:11 287:11,19 290:18 291:2 298:8 312:6 313:18 314:12 321:12 327:10 336:3,9,11 337:2 337:4,19 343:1 350:5,10,14,17 351:4 352:17,22 387:12 391:12 395:3,12,15,22 396:4,17 397:16 398:2,3,15,21 399:4,18,22 400:3 401:13 404:8 405:5 441:5,8 442:1,5 447:10 452:14 455:7 486:3,5 487:10 thinking 32:19 37:20 55:22 90:11 165:11 199:15 217:22 374:17 390:4 491:13 thinner 339:20 thinning 124:7 third 109:4 116:14 132:18 183:22 192:18 199:7 202:15 222:11 248:1 250:18 305:5 325:18 342:20 345:21 348:12 349:16 351:13 363:18 370:17 377:8 380:21 383:13 394:2 401:4 410:17 414:7 446:8 453:2 479:6 490:2 thorough 134:10	thought 104:12 274:21 387:11,14 412:21 421:12,22 422:11 424:21 447:18 459:1 473:2 thoughts 89:16 91:9 277:13 278:10 352:15 374:22 399:15 thousand 125:4 241:4 289:7 395:11 405:15 thousands 54:13 54:13 205:13 207:7 259:5 338:15 347:12 threat 46:10,13 60:20 threatening 92:22 338:6,16 401:2 three 31:12 39:8 47:2 63:3 76:7,17 83:18 85:6 93:9 117:3 166:22 167:6,8 190:2,17 191:6 203:10 224:17 237:16 242:18,22 247:18 249:3,21 250:12 260:8 261:6 277:2 277:7 279:8 283:15 295:18 298:19 302:10 304:16 315:16 323:14 326:9 335:6 355:11 362:15 375:6 393:16 394:7 395:14 407:5,6,13 411:1 441:10 449:4 458:15,16 470:7,10 472:22 489:14	threefold 452:19 threshold 85:21 271:4,6,9 305:19 thresholds 412:7 threw 432:18 thrilled 485:20 thrive 45:1 52:18 throcmorton 4:8 21:15,15 throw 232:12 thuy 14:10 366:1 366:2 tied 147:22 tier 49:17 tiffany 135:8,8 tightly 314:11 tilburg 166:5 tim 22:12 time 1:15 24:3,18 24:20,21 25:2,3,9 25:11,13,18 28:1 36:16 38:13 42:18 45:4 53:9 62:7 69:16 74:8 84:20 90:4 98:15 101:13 107:20 108:21 110:6 117:2 122:1 123:5 131:3 136:6 140:4 142:5 149:21 150:11 168:9 171:9 187:16,17 209:15 212:1 215:7,16 221:1 232:5 234:20 241:19 246:8,12 252:17 261:1 275:13 281:17 288:7 290:7 293:4,14 296:19 300:16 301:14 305:17 317:15 320:17 325:8 340:21 355:4,4,18 356:13	361:5 365:11 372:17 381:3 389:22 397:17 398:16 406:18 409:7 413:2 418:1 418:1 419:3 421:13 423:22 424:4,11 426:1 436:15 439:13 453:5,8 456:22 457:22 458:19 459:5 460:17 461:22 468:15 485:2 491:8 496:14 499:14 timeframe 117:6 timeline 409:3 timely 307:2 times 43:7 51:7,8 54:11 183:9 190:16 242:19 274:22 277:3,7 278:7 299:16,18 469:17 timing 229:2 timothy 3:14 tincture 308:17 tinctures 96:20 114:11 tip 203:18 tiredness 492:12 tissue 203:5 tissues 169:14 270:2 titan 145:18 title 78:19 titled 26:16 83:7 447:8 titrate 41:10 149:7 titration 285:8,10 301:18 389:4 titus 6:14 77:19,20 77:21 79:20 80:15 81:2
--	--	--	--

tobacco 41:21 44:3 82:16 409:13 412:9,12 416:11 451:8 452:1,3 454:3 470:2,5 today 23:4 24:19 25:16 26:16 36:15 36:17 40:6,16 42:2,12 43:6 64:17 72:14 74:9 79:16 107:8,20 116:2 122:14 123:16 125:10,13 125:15,19 127:18 129:10 147:8 153:7,20 157:14 161:8,12 163:20 164:3,22 166:1,11 174:21 176:18 178:13 182:5 192:13 200:11 202:1 210:5,13 228:2 233:13 247:19 259:15,19 273:15 274:13 276:1 278:14 279:12 286:9 294:9,9 305:14 308:3,19 310:7 311:13 312:7,10 312:22 314:6 315:3 317:3 324:12 326:16 334:11 336:12 337:11 348:18,20 349:6,18 350:11 354:3 357:5 358:4 358:14 360:4 361:11,13 362:15 363:9,19 365:14 379:10,14 382:4 384:4 400:8 402:16 413:9 416:16,22 417:20	418:12 419:10 420:13 424:8 429:21 430:4,8,10 430:15 440:2 451:8 457:1 458:20 461:13 462:7,18,22 466:22 468:8 470:10 472:1,6 476:5,14,22 484:20 486:22 488:20 492:2,3 495:18 496:19 498:6 499:15 500:11 501:3 today's 20:9,10 22:18,18 23:15 24:6 27:1,4 72:18 81:9 328:22 381:17 383:4 457:7 459:16 told 37:5 39:3 57:8 129:21 206:19 247:21 248:5,7,17 249:4 250:17 251:7,12 251:20 373:21 374:2 401:14 402:6 431:14 449:9 483:13 495:21 tolerability 186:18 298:21 389:12 tolerance 228:12 301:8 302:1 tolerate 183:20 tolerated 51:11 79:13 217:10 320:2 359:17 439:22 477:2 492:9,22 tomorrow 42:3 484:20	tools 48:22 133:18 302:13 436:9 439:3 495:8 top 49:16 53:18 203:17 237:19 249:3,5 251:19 283:8 304:9 452:13 topic 26:20 36:18 149:1 246:15 417:20 421:12 topical 34:12 41:14 75:14 154:4 278:7 313:10 447:7 489:1 tops 285:18 tory 4:17 39:22 40:3 total 211:4 238:6 250:8 256:8 314:19 359:12 372:10,11,11 393:22 453:17 489:22,22 totally 405:2 touch 227:5 touched 216:22 218:20 288:11 305:14 tough 187:16 321:14 toughest 43:7 tour 242:14,15 town 374:1,2 toxic 60:10 99:19 180:17 193:21 203:3 339:9 489:5 489:21 491:6 494:13,19,22 toxicities 183:14 toxicity 51:13 141:10 270:10 340:9,11 492:10	toxicology 57:12 61:12 185:10 197:5 204:15 269:8 325:15 398:2,6,17 399:8 toxicoses 65:20 toxins 60:1 102:21 380:10 459:15 toys 426:13 trace 84:4 275:5 331:12 341:1 449:16 traceability 102:3 134:7 146:22 363:8 370:13 371:21 408:16 traces 487:13,19 track 93:6 218:8 266:21 331:12 tracking 408:11 tract 270:3 491:12 trade 102:1 115:22 153:8 395:9 435:1 476:5 476:7 481:2 traditional 123:10 164:18 264:6,7 320:12,14 traditionally 441:18 trafficker 292:3 tragedies 58:2 tragic 38:19 trained 485:7 training 87:10 132:20 134:3 334:4 463:18 465:6,8 trains 240:18 trajectory 223:16 transcribed 22:19 23:5 transcriber 503:1
--	---	---	---

transcribers 25:4	318:6 438:16	225:19 268:13	truth 125:22
transcript 23:6	475:10 488:1	270:11 284:4,15	175:15 235:20
503:3,5	treating 29:21	286:13 298:19,20	478:20
transdermal	102:9 143:1 222:5	299:9 316:2 318:1	truthful 53:21
41:14	249:20 263:7	318:4 326:15	try 36:7 132:10
transfers 411:13	297:17 339:16	333:16 334:7,14	150:6 209:20
transformed 96:8	389:16	360:19 401:17	295:11 317:9
transient 202:20	treatment 30:5,8	460:2 461:17	333:12,17 377:12
320:5	39:16 51:12 93:1	492:5,18,21 493:2	384:18 418:2
transition 212:7	135:22 136:3,18	tried 154:10 248:5	trying 75:17
transparency 50:2	138:21 220:13	458:2 498:21	141:19 147:19
89:11 102:2	221:6 222:21,22	trigger 277:1	182:15 185:22
231:10 235:20	223:6,7 264:13	304:5 306:3	246:16 248:1
305:6 364:13,21	317:12 374:9	trimmed 59:13	249:18 283:4
381:16	387:19 388:3	tripartite 407:7	288:6 290:5,7
transparent 89:4	403:15 458:11	truckloads 292:1	294:10 296:11
94:12 370:9 426:8	473:22	true 9:10 133:8	297:6 327:9
446:18	treatments 130:18	150:10 151:14,20	336:13 350:16
transparently	458:5 472:7	151:21 152:9	374:4 388:15
477:6	475:18	160:15 173:18	390:8 422:10
transplant 472:19	treats 29:13 170:5	210:12 241:6	437:1 459:1
transplantation	171:4	251:17 265:3	498:17
180:19	trembling 209:3	267:21 296:15	ts 143:5 144:8
transport 424:17	tremendous 80:5	313:17 358:6,6,7	tsa 82:10
transportation	205:8 245:5	383:9 405:18	tsc 142:17,18
427:19 428:13	267:13 338:20	406:5 502:6 503:5	143:2,4 144:1,9
trauma 234:16	343:4	truer 33:19	tss 494:10
travel 456:22	tremor 385:11	trueterpenes.com	ttb 151:13
traveled 457:1	387:1	152:13	tuberous 8:20
treat 35:13,19	trend 300:1	truly 43:19 59:16	142:15,17
92:21 94:10	trial 51:12 136:17	72:20 74:8 361:10	tumor 398:11
105:10 130:6	142:21 143:18	380:16	tumors 260:7
171:5 248:1,21	179:4 201:2 275:3	trump 38:20	turn 46:20 97:8
249:18 264:21	275:6,7 278:1	trust 73:9,13 88:4	208:6
267:12,13 323:20	282:19 286:18	89:1 116:20 236:3	turned 377:8
324:22 338:21	293:8 298:20	296:18 304:6	458:22
339:6 374:20	299:3 300:13	364:21 365:9	turnouts 482:10
415:19 455:19	301:16 318:4,5,19	436:14 446:4	turns 25:13
468:1 470:18	320:6 359:11	486:10	tv 498:16
471:1 473:22	360:16,17	trusted 97:6	tweeting 36:13
474:17	trials 51:18 93:22	130:17 426:6	twenty 250:5
treatable 473:14	94:2 99:18 123:6	trusting 60:17	335:7 484:19,20
treated 147:2	126:1 128:17	trustworthy 88:12	484:20
168:18 261:7,17	136:11 222:1		

<p>twice 277:8 458:7</p> <p>two 37:2 38:21 51:3 57:16 60:8 62:21 63:3 85:6 91:18 93:7 99:1 105:6 112:17 115:5 120:21 140:16 145:18 155:17 160:9 172:21 173:3 197:4 201:21 208:19,20 213:9 221:20 238:19 241:7 260:7 268:5 269:21 275:8,10 275:12 277:2 278:7 279:8 294:3 295:17 296:10 301:4 320:3 321:17 329:14 336:19 338:16 341:5 342:16 343:8,12 354:4 382:12 391:21 392:17,20,20,21 407:11 409:10 447:15 457:9,11 469:13 470:5 472:20 473:3 484:19,20,20 489:20 494:21 498:7</p> <p>type 29:17 89:11 159:5 160:18 171:1 174:10 218:1,5 219:2 280:17 289:18 323:11 358:19 389:4 402:2,11 453:14 454:13 455:2 464:21 465:16,20</p> <p>types 141:21 156:10 164:17</p>	<p>165:12 218:17 237:3 258:2 289:4 300:2 309:3 322:3 350:18 414:21 415:6 416:4,8,12 417:12 426:16 452:20 458:16</p> <p>typewriting 502:5</p> <p>typical 416:3</p> <p>typically 51:21 184:10 215:3 223:10 272:11 441:10</p> <p>typo 448:18</p> <hr/> <p style="text-align: center;">u</p> <hr/> <p>u.s. 1:16 2:4,9,13 2:17,21 3:5,9,13 3:17,21 4:5,11 5:5 46:11,15 47:17,19 49:11 52:5,11 67:2 78:7 80:16 87:21 94:1 116:14 116:15 126:1,4 133:2 157:7 175:4 188:12 244:16 283:14 289:6 311:4,10 331:11 332:19 362:11 383:17 384:14 386:2 395:16 407:21 423:4 428:5 432:5,5,10 484:18 485:14</p> <p>uk 293:7 347:17 487:1</p> <p>ulcerations 495:4 495:10</p> <p>ultimately 64:4 309:7</p> <p>unable 27:4 143:19</p> <p>unacceptable 133:11</p>	<p>unanswered 34:9 414:14</p> <p>unapproved 35:9 35:15 64:17 76:22 140:8 341:10</p> <p>unaware 404:10 404:12</p> <p>unbelievable 430:12 460:11</p> <p>unborn 242:6</p> <p>unc 26:8,9</p> <p>uncertainty 43:21</p> <p>uncharacteristic 193:14</p> <p>uncharted 396:6</p> <p>unclear 181:8</p> <p>uncommon 188:20</p> <p>uncontrolled 400:13 401:7,22</p> <p>uncovered 246:9</p> <p>undergo 96:15</p> <p>undergone 314:22</p> <p>underground 346:14</p> <p>underlining 385:2</p> <p>underlying 139:11</p> <p>understand 56:21 57:21 97:15 108:9 130:2 131:16 153:20 162:6,11 164:19,20 165:1,4 178:1 203:20 204:2 225:1,12 246:17 276:16 296:9 309:12 333:4 349:19,22 386:12 387:6 388:15 401:21 404:19 408:3,4 432:6 449:20 457:3</p> <p>understandably 154:16</p>	<p>understanding 50:17 72:20 81:16 90:17 162:14 203:16 272:2 327:3 353:20 386:19 389:4 456:1</p> <p>understands 73:8 111:14 117:8</p> <p>understood 56:20 80:13 233:6 303:19 410:20</p> <p>undertaken 492:20</p> <p>undertaking 271:22 333:16 493:2,5 494:7</p> <p>underway 93:8</p> <p>underwent 458:14</p> <p>undesired 306:8,9</p> <p>undue 84:21</p> <p>unduly 431:9</p> <p>uneducated 353:18</p> <p>unethical 59:11</p> <p>unexpected 143:11</p> <p>unexplained 401:9</p> <p>unfettered 54:22</p> <p>unfortunately 61:20 101:11 221:19 229:5 255:10 281:16 312:12 401:3</p> <p>uniform 88:2,17 163:5 165:21 265:5 266:8,17 267:16 425:5</p> <p>uniformity 156:2 159:4 264:11 265:6 266:6</p> <p>unify 414:1,6</p>
---	---	---	---

uninformed 353:18	274:16 357:22 423:7	upload 91:14 313:4	116:2,3,5 117:17 118:8,13 128:2
unintended 176:18 449:17	unknown 139:12 139:13 229:9	upregulation 202:12	136:7,9,12,18 143:3 146:1
unique 34:8 87:20 118:1 120:3 157:17 192:1 219:15 221:19 271:20 324:7,7 339:7 366:19 401:14 408:5	410:8 419:2 451:17 459:14	ups 77:3 upwards 108:20	153:21 154:6,11 162:20 167:21 168:15 169:10,21 170:11,18 172:15 174:8 179:22 182:14 185:2 201:12,18 204:19 213:19 214:9 221:14 222:20 224:21 230:20 245:4 247:20 248:15,18,21,22 249:2,6 250:15 254:17 255:18 257:14 260:9 261:10 264:20 266:19 276:10 280:9,10,12,22 284:15,17,22 285:6 294:18 295:10 305:12 315:12 323:16 324:16,18 326:14 330:13 345:10,13 345:19 351:15,17 352:11 354:1 355:22 370:22 373:13 382:1 389:20 390:4 392:5,16 397:2 398:14 399:1,5 400:1,2 414:8 415:3 416:2 424:12 429:21 430:9,10 433:12 433:16 435:6,14 436:3,9 439:22 443:1 444:14 445:19 446:20 448:11 449:17
uniquely 90:15	unknowns 177:12 340:5 382:5	urge 94:11 116:3 118:8 122:18 139:20 144:3 155:7 163:17 244:13 286:9,10 354:7 468:3 470:20 471:3	
unit 92:4 279:4	unlawful 113:8	urgency 385:2 484:16	
united 1:1 28:16 42:20 43:19 45:11 52:7 99:2 138:16 156:4,7 157:3 175:13 207:9 253:11 294:4 297:12 333:17 334:9 357:16 358:6,8 384:11,13 385:3 386:6 409:8 426:5 444:22 467:8 481:20 484:1 486:11	unnecessary 94:4 332:13	urges 112:3 440:13	
uniquely 90:15	unofficial 353:13	urging 284:6	
unit 92:4 279:4	unparalleled 432:1	urinary 262:19	
united 1:1 28:16 42:20 43:19 45:11 52:7 99:2 138:16 156:4,7 157:3 175:13 207:9 253:11 294:4 297:12 333:17 334:9 357:16 358:6,8 384:11,13 385:3 386:6 409:8 426:5 444:22 467:8 481:20 484:1 486:11	unprecedented 119:10,20 431:6	urine 213:9	
units 57:19	unproven 459:6	usable 266:18	
universal 110:1 266:18 479:16	unrealized 410:8	usage 156:21 157:6 172:5 368:4 433:16	
universally 303:19	unreasonable 77:17	usda 155:12 322:7 322:13 342:16 391:16 408:12 411:3 412:6	
universities 47:8	unregulated 138:20 209:6 316:11 382:1,8 402:15 459:7,17 467:20	use 28:3,5,16 33:10 34:6 35:18 39:3,9 48:10 49:22 54:3 56:2 57:18 61:18 64:3 64:3,5,8,9,20 65:1 65:12 66:1 67:19 68:2,4 73:3,10,19 82:4 85:20 86:3,5 97:13 100:19 102:7,9 104:22 105:2,10 108:18 112:2,18 113:15	
university 4:18 10:8,10,13,15,19 10:21 11:3,5 40:1 40:5 50:8 171:21 176:17 179:21 180:16 181:21 187:22 192:9,10 192:15 195:10 200:12 204:14 210:1 213:1 216:8 216:20 264:18 265:19 274:14,15	unsafe 69:8 349:12 356:12 431:10 468:2 470:19		
	unscheduled 210:8		
	unsubstantiated 35:16 268:19		
	unsuspecting 238:16		
	untargeted 394:10		
	untested 136:7,8 459:6		
	unwillingness 399:10		
	updated 97:13 364:14 427:1		
	upheld 257:1 355:1		

450:8,15 452:1,3 452:4,7 453:2,12 453:19 454:3,3,5 454:10 455:4 464:14,17,21 465:1,3,9 467:11 470:8,14 471:18 479:6 482:19 483:7,10,11,11 487:7 489:2 490:7 492:3 useful 47:12 80:22 86:19 115:5 118:14 152:20 309:19 310:5 386:20 387:12 434:11 456:12 user 206:5 451:10 users 41:4 116:14 127:12 173:16 215:15 222:20 375:4 377:6,6 426:22 453:7 454:3 456:2 491:9 uses 31:14 34:19 73:16 82:7 133:22 258:11 262:9 270:9 324:21 325:5 351:20 352:15 375:7 402:14 407:12 408:1 431:3 436:5 449:11 487:14 usp 98:13,14,19 100:5,16 315:10 365:10 450:13 usp's 99:3 usually 56:2 113:21 206:8 277:7 455:4 utah 290:15 479:1 utility 167:6 387:6 utilize 45:15 47:1 388:2	utilized 369:4 427:3 445:8 utilizing 71:9 183:1 291:3 292:12 utmost 44:16 v v 188:6 vacuum 37:22 221:22 477:14 vaginal 488:8,12 488:15,18 489:2,4 491:12 492:19 493:9,18,21 494:1 494:4,5,8,16,16 vaginally 488:14 vague 130:9 valenti 16:16 471:8,9,13 475:16 valentina 17:6 486:20,22 valid 134:6 validate 133:17 236:18 305:13,20 validated 50:15 99:11 133:14 237:10 273:9 302:14,16 303:13 305:11 311:17 312:1 316:2 319:7 348:15 351:8,14 351:16,22 362:18 392:6 462:20 463:22 validation 305:5 354:17 394:11 valproate 143:10 359:21,22 405:21 valuable 25:3 45:20 365:11 value 30:10 45:17 50:11 98:16 182:7 186:20 238:1 328:2	values 190:11 191:2,2 238:20 354:21 vandrey 11:2 209:18,19 210:22 214:18 215:7,14 215:19 216:4 246:11 vanguard 15:7 406:14 vape 124:8 204:19 249:7 454:1 vapes 416:11 vaping 191:7,16 205:21,22 206:1 206:16 249:8 454:18 vapor 299:1,10,11 299:18 vaporization 211:20 vaporized 212:17 282:15 300:8 vaporizer 41:2 variability 70:2 142:10 143:21 177:6 191:11 315:18 350:18 404:10 variable 138:12 142:2 237:17 variables 123:18 177:9 333:20 variance 292:7 variances 305:3 371:9 variation 454:19 456:2 variations 260:3 285:12 varied 234:15 356:9 465:12 varies 238:20 309:13 452:8	464:22 varieties 228:13 228:20 282:20 variety 126:22 177:1,18 180:18 196:18 227:17 230:4 287:4 362:14 484:6 various 42:2 64:12 71:1 138:21 189:11 200:18 202:1,9 203:7 241:12 259:10 306:13 322:3 371:3,9 389:12 404:4 418:4 442:16 464:7,10 478:8 vary 29:17 177:7 177:9 272:6 354:2 453:1 varying 76:21 vast 42:8 76:20 434:7 437:6 vastly 467:20 vaught 5:6 50:6,7 50:7 53:2 vcu 231:17 vega 12:14,15 274:11,12,13 279:18,21 280:2,4 280:6,13 281:1 vegetable 205:11 vendors 189:12 410:22 venues 156:10 verbal 83:15 verbally 282:7 verified 322:22 325:19 verify 143:20 479:7 version 30:8 341:21 407:20
--	--	---	--

versions 272:10	304:1,6,18 430:5	voltage 488:1	154:19,20 161:11
versus 148:10	491:14	volume 268:18,18	163:11,19 164:3
185:17 188:22	viewed 61:22	voluntarily	166:1 170:9 176:3
191:12 233:4,10	viewpoint 79:1	121:19 370:4	176:7 177:11,20
291:20 292:8	viewpoints 321:16	voluntary 166:13	180:6 207:13
407:11 452:22	views 40:6 61:21	167:4 272:14	209:19,21 212:6
455:5,5	66:1 476:15	400:17	213:8,14 225:20
vertical 319:17	vigorous 96:15	volunteer 492:5	231:8 233:19
vertically 332:21	vigorously 132:11	492:21	244:19 255:18
333:1 366:7 370:8	violate 35:7 121:8	volunteered 374:7	277:19 279:3
vested 365:15	410:18,19	volunteers 215:13	281:9 288:11
vet 96:5	violation 35:16	488:21 492:10	289:16 290:8,9,10
veteran 67:3	85:2 241:15	vomiting 193:15	291:22 294:8
288:1 433:17	342:15	vote 482:9,10	295:14 297:7
veterans 260:10	violence 242:20,20	voters 482:11,13	298:1 302:21
282:20 452:18	violent 373:16	vouch 62:16	303:21 304:8,8
482:16 484:19	viral 102:18	vu 14:10 366:1,2,2	306:12 323:15,19
veterinarian	virginia 4:22 9:16	vulnerable 116:17	325:22 336:19
193:18	10:21 42:17,20	223:16 340:7	346:3,3,17 347:2
veterinarians 64:3	43:8 53:15 56:6	360:18 468:2	349:1 351:7 352:4
64:6	204:14	470:19 477:17	359:2 384:3
veterinary 2:20	virtual 471:20	479:15	388:10 391:2
3:8,16 6:3 22:14	virtually 478:4	vyripharm 12:9	405:13 422:12
63:17,19 65:1,6	479:16	263:20 264:2	423:18,21 431:11
65:12 66:12 167:7	viscosity 182:13	265:3 266:14	448:12 450:8,12
197:6 199:14	visibility 84:10	267:4,18	483:15 496:17
357:22	vision 160:10	w	498:14 500:22
vets 288:6	457:12 461:12	wait 295:13	wanted 164:19
viability 65:14	472:3 474:4,9	386:16 485:21	165:1 184:11
163:6	475:13	waiting 169:2	193:4 197:2
viable 83:20 85:10	visit 152:12 169:7	176:4	206:18 236:18
vibrant 82:18	visiting 5:19 59:2	waiver 60:11	257:6 284:3
vice 87:16 92:18	visual 471:20	wake 60:13	376:16 406:22
98:11 321:11	vital 87:22	walgreen's 174:21	451:10 452:19,22
328:19 353:6	vitamin 79:11	walk 147:14	453:2 455:1,17
vicente 15:11	126:8,17,17,18	226:17 472:17	475:3 496:7
476:4	128:10 415:10	walker 11:4	wanting 187:3
vicodin 250:20	vitamins 486:2	192:15 216:6,7	207:13
victims 5:15 11:19	vitro 492:17 494:4	walking 96:18	wants 240:21
56:15,18 240:16	vocal 38:14	walks 207:18	242:14 297:22
242:1 375:14	voice 426:9 482:20	walls 494:16	374:15
videotape 23:2	483:3	want 42:21 55:12	war 67:3 105:20
view 74:12 78:9	voices 486:16	57:21 67:21 90:18	173:9 377:13,14
137:3 182:20		90:22 132:8	433:18,20 484:19

warehouses 46:1	255:6 256:7	432:8 448:10	wellbeing 87:22
warfarin 179:16	257:13 284:21	481:7 490:17	259:13 318:18
179:16,18,18	285:10,17 291:16	491:20 492:8,15	320:7,21 321:5,6
180:1 339:19	295:8 312:21	494:3	321:7 400:20
warner 13:6	338:22 339:4,12	weaker 339:21	wellness 51:21
warning 35:8 57:2	347:20 349:2	wean 460:8	72:15 73:1 78:16
57:10 58:10 139:5	356:2 375:4	weapon 377:16	80:1 209:2 268:10
201:4 272:14	388:18 389:5	weaponized	431:3 433:16
291:10 376:22	396:3,4 410:19	376:18	went 92:9 172:17
439:3 479:15	415:1 417:6,7,7	webcast 22:19	180:3 207:22
warnings 174:18	432:19 442:8	23:8 501:3	225:22 237:7
174:20 409:15	448:3,7 482:1	weber 457:6	274:15 281:16,19
415:3,6	487:18 496:4,6	website 23:7,10	295:15 372:19
warns 174:8	498:1 499:12	107:15,18 109:19	448:3 457:22
warrant 192:1	ways 35:7 39:18	110:11 152:12	werline 16:8
wars 433:21	39:19 71:1 90:11	169:7 206:2 207:2	456:18,20,21
washers 246:21	143:17 167:1	237:20 343:15	wertz 11:7
washing 239:8	249:9 325:9	469:16	west 65:19 130:12
246:21	385:21 416:13	websites 206:3	159:5 290:4 383:8
washington	474:14 494:21	236:7	wheat 147:12
115:21 253:2	we've 33:20 47:2	weed 374:5	wheel 414:12
261:15 481:17	49:22 74:17 87:9	weeds 141:15	where'd 247:17
waste 45:22 232:9	87:10 100:7	week 23:11 96:19	wherewithal
232:11,18 233:19	129:10 158:12	159:9 173:14	416:21
428:1	162:5,7 175:5	277:7 359:7	white 1:17 231:4
watched 459:21	177:5,13 211:11	weeks 48:6 208:19	366:8
watching 125:13	211:18 213:15	223:14 448:14	who've 254:9
129:22	214:18 216:11	449:4 457:17	wholeheartedly
water 319:1 372:9	238:5 240:19	467:16	44:14
427:22 428:5	242:3 243:7 253:8	weerts 220:8,9	wholesale 53:12
467:16,20 488:1	253:9 273:20	226:7,10,12,15	wholly 171:4
waters 383:6	278:14 284:7	weight 28:22	whoopi 174:22
waving 23:18	288:7 289:18	189:2 224:2 240:4	wi 496:11 498:15
38:10 375:12	292:20 311:9	340:13 368:3	wide 143:22
waxes 234:8	314:10 326:15	394:1 465:15	146:10 164:21
way 25:1 36:8	338:12 339:10,12	468:13 469:3	270:7,15,21 305:2
37:13 62:14 77:7	342:10 344:8	485:11	337:15 340:18
128:19 129:2	347:21,22 348:6	welcome 18:4	437:10 439:1
141:9 152:10	348:12 349:15	49:21 155:10	484:6
167:1 183:12	354:3 357:12	166:6 169:7 347:2	widely 119:14
212:15 216:2	358:4 379:13	429:22	221:16 238:20
219:3 231:15	391:3 395:12	welcoming 26:11	354:2 405:8
243:9 244:5 249:5	401:14 405:21	weldon 8:8 129:17	417:13
249:6 253:22	422:17 424:7	129:18,19	

wider 260:16	173:22 223:15	110:1 195:8	worried 142:6
widespread 33:10	224:11,13 225:1	235:14 253:8	worries 458:8
79:14 126:11	271:21 340:8	274:21 419:14,15	495:16
157:6 172:5	375:20	466:7 472:18	worry 231:21,22
241:21	women's 95:17	worker 60:6	232:1 278:2
wife 243:13	493:12	workers 60:7	280:14 292:9
447:12 457:15	wonder 459:21	working 21:6,9,14	worse 125:18
458:12,22	wondered 185:17	21:18 35:2 103:19	183:15 223:18
wild 65:19 130:12	wonderful 282:10	127:6 145:3	388:4 406:7
159:5 290:4 383:8	wondering 68:18	155:12 156:1	worsen 459:16
wildfire 122:13	89:15 103:15	173:17 203:9,22	worsening 404:6
wildflower 6:11	113:16 157:18	211:16 288:13	worst 472:19
72:14,22 73:8,22	248:10 399:14	289:19 293:9	worth 436:6
william 6:20 83:8	wondrous 54:21	296:10 315:10	worthy 435:18
166:5,5	243:8	325:8 363:4,10	wounds 278:8
william's 166:5	wonky 212:6	377:20 394:2	wow 276:4,5,16
williams 8:11	woods 92:9	409:1 426:15	276:17
132:12,13,13	words 190:11	427:19 428:5	wrap 412:14
willing 52:22 61:2	239:15 326:14	429:20 463:16	446:15,16 455:15
101:11 482:5	441:4	464:9 466:9	455:22 486:7
willingness 48:21	work 40:8 44:17	488:16 489:9	490:22 492:7
wilmington 311:2	48:21 58:4 59:22	493:10	500:13
wilson 135:8	87:11 97:18	workload 205:8	wright 6:16 81:5,7
wind 66:19	100:10,16 127:8	412:3	81:8
window 184:12	130:18 162:5	works 127:4	write 277:18
winning 377:13	179:8 187:3	144:22 260:15,15	writing 83:17
wisconsin 10:8	209:22 218:16	276:14 471:19	162:21 277:17
176:17	219:16 227:17,20	488:14 499:3	396:15
wisdom 259:14	236:12 244:9	world 26:7 39:20	written 68:9 79:17
wise 307:2	247:18 263:22	46:11 49:2 54:6	80:10 107:15,17
wish 174:9 377:21	265:2 276:13	82:19 84:12	111:12 118:18,19
411:11	286:10 288:8,20	104:20 171:5	120:5 123:14
withdrawal 170:7	289:10,20 290:2	182:22 186:21	144:7,10 158:3,17
223:4,9,13,18	292:8 294:16	218:1 253:1 286:4	164:1,5 169:5
witness 377:15	296:13 322:5	293:7 295:19	242:5 274:7 325:7
witnessed 59:11	352:5 358:7	311:5 313:20	326:5 357:6
275:22	359:20 360:6	377:8,10 386:3	397:20 479:18
wmi 6:11 72:11	394:5 425:20	403:1 405:6 426:5	493:13 500:17
woefully 60:4	428:22 431:21	430:18 442:16	wrong 59:17
wollongong 213:1	432:7 433:4 457:1	459:16 476:22	60:20 130:7
woman 149:3	467:8 470:1,1,3	484:19 497:18	243:16 252:2
208:21	497:20 498:2	499:9,10,11	295:14 433:4
women 7:9 53:13	worked 48:6	world's 46:10	448:3 477:13
53:14 95:16	57:15 59:7 61:6	87:18	498:14

wrote 61:20 127:1 127:3 422:7	274:19 282:22 283:9 288:3 290:19 292:21 296:10 307:1 311:9 339:11 342:15 367:12 391:21 392:21 394:13 395:14 406:18 413:15,22 418:17 425:18 429:19 430:19 435:12 441:10 447:15 472:2,20 472:22 476:15 477:4 480:20 483:13 485:18,21 489:14 500:6	zoe 8:4 122:7,8 zone 304:19 zynerba 13:13 328:19,21
y		
yael 12:2 252:15 yanked 406:6 yeah 55:10 74:20 75:16 86:21 104:5 125:3 149:22 165:6 187:15 198:17 226:11 310:8,12 326:17 326:17 352:9 378:8 413:4 434:17 446:17 497:5,9 year 28:17 43:13 52:5 59:8 77:11 94:7 105:4 108:22 140:21 161:16 162:9,10 208:21 220:15 222:22 226:16 227:4 228:18 236:21 240:19,20 241:7 246:5,22 260:7 288:1 289:8 314:18 317:4 335:17 355:11 374:11 403:7 447:12 458:22 472:14,15 473:3 491:10 499:21 years 47:3 50:13 60:8 62:5 63:6 67:5 68:7 84:16 85:6 93:9 117:3 119:8 122:11 126:15 141:15 173:7 174:2 179:9 182:1 188:5 201:8 206:3 216:11,15 235:14 236:13 244:2,8 245:18 259:11,14 268:13	yeast 372:10 396:11 490:1 yellow 25:9 454:4 yesterday 98:5 107:14 357:21 430:8 york 221:6 242:18 333:9,9 419:19 421:3 478:16 youn 15:12 451:1 451:2 young 174:9 206:16 207:5 260:6 401:6 younger 373:16 373:17 452:15 484:8 youth 16:15 55:3 55:6,7 377:7 467:1,5,14 468:9 470:4,8,14 471:4 483:10 yucky 448:7	
	z	
	zealand 347:17 zero 239:3 318:8	