

*FDA/FTC WORKSHOP ON A COMPETITIVE
MARKETPLACE FOR BIOSIMILARS*

March 9, 2020

*A Matter of Record
(301) 890-4188*

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

FOOD AND DRUG ADMINISTRATION

FDA/FTC WORKSHOP ON A COMPETITIVE
MARKETPLACE FOR BIOSIMILARS

Monday, March 9, 2020

9:05 a.m. to 4:18 p.m.

FDA White Oak Campus
White Oak Conference Center
10903 New Hampshire Avenue
Silver Spring, Maryland

	C O N T E N T S	
2	AGENDA ITEM	PAGE
3	Welcome	
4	Eva Temkin	6
5	Opening Remarks	
6	Stephen Hahn	11
7	Tara Koslov	23
8	FDA Licensure Process and U.S.	
9	Biosimilar Markets	
10	Eva Temkin	33
11	Christine Simmon	39
12	Molly Burich	
13	Surya Singh	
14	Moderated Panel Discussion	44
15	Meredyth Andrus	
16	FDA and FTC Approaches to Help Ensure	
17	Truthful and Non-Misleading Advertising and	
18	Promotional Communications	
19	Dominic Cirincione	80
20	Richard Cleland	91
21	Moderated Panel Discussion	98
22	Lowell Schiller	

	C O N T E N T S (continued)	
	AGENDA ITEM	PAGE
1		
2		
3	FDA Draft Guidance for Industry:	
4	Promotional Labeling and Advertising	
5	Considerations for Prescription	
6	Biological Reference and Biosimilar	
7	Products Questions and Answers	
8	Elizabeth Pepinsky	101
9	Dominic Cirincione	114
10	Moderated Panel Discussion	120
11	Catherine Gray	
12	What's at Stake? The Benefits of Competition	
13	Murray Aitken	125
14	Inma Hernandez	141
15	Alex Brill	156
16	Andreas Schick	
17	David Schmidt	
18	Moderated Panel Discussion	167
19	Alison Falb	
20		
21		
22		

1	C O N T E N T S (continued)	
2	AGENDA ITEM	PAGE
3	Improving Stakeholder Engagement:	
4	Education and Understanding	
5	Cheryl Koehn	177
6	Sameer Awsare	185
7	Michele Andwele	191
8	Hillel Cohen	197
9	Moderated Panel Discussion	206
10	Sarah Ikenberry	
11	Elizabeth Jex	
12	Biosimilar Disparagement as an Antivirus or	
13	Consumer Protection Cause of Action	
14	Michael Carrier	214
15	Rebecca Tushnet	218
16	Moderated Panel Discussion	225
17	Randall Weinstein	
18	Richard Cleland	
19		
20		
21		
22		

1	C O N T E N T S (continued)	
2	AGENDA ITEM	PAGE
3	Open Public Comment	255
4	Sarah Ikenberry	
5	Eva Temkin	
6	Catherine Gray	
7	Antara Dutta	
8	Armine Black	
9	Closing Remarks	
10	Catherine Gray	328
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		

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

2 (9:02 a.m.)

3 Welcome - Eva Temkin

4 MS. TEMKIN: Good morning. I'm told that
5 we're already two minutes behind, so I'm going to
6 jump in and get started.

7 Welcome to the FDA/FTC Workshop on
8 Competitive Marketplace for Biosimilars. I'm Eva
9 Temkin. I'm the acting director for policy in
10 CDER's Office of Therapeutic Biologics and
11 Biosimilars, and I am thrilled to be here to kick
12 off what I'm sure will be an exciting and
13 informative day.

14 The purpose of our workshop today is to
15 discuss FDA and FTC's collaborative efforts to
16 support appropriate adoption of biosimilars,
17 discouraging false and misleading communications
18 about biosimilars, and deterring anticompetitive
19 behaviors in the biologic product marketplace.

20 From my perspective, to improve patient
21 access to life-saving therapies, we need to look at
22 some key factors that we're going to touch on

1 during our time today.

2 First, there has to be availability of
3 biosimilars, that is developers make choices to
4 develop and seek approval of biosimilars; second,
5 there has to be awareness of biosimilar products
6 and their promise for patients and from healthcare
7 provider communities; and third, we need adoption.
8 License holders need to bring biosimilars to market
9 and people need to use them.

10 Navigating these three steps successfully
11 requires a competitive marketplace and fair
12 business practices. Done right, it can ultimately
13 result in access for more patients to important
14 biologic therapies.

15 Before we begin, I also want to make a few
16 administrative announcements. First, please
17 silence any cell phones or other mobile devices, as
18 they may interfere with the audio in the room
19 today.

20 Second, we ask that all attendees sign in at
21 the registration tables outside the meeting room.
22 We are a sold-out event, so if you did not

1 preregister to attend but are in this room, you
2 might want to head to Room 1504. That's our
3 overflow room today. We will be streaming live
4 audio and video to this room.

5 Third, this Workshop is bringing together
6 several speakers from FDA, FTC, and stakeholders
7 who may use different terminology and bring
8 different perspectives. Please note that views,
9 thoughts, and opinions expressed throughout the day
10 by any individual are not attributable to any other
11 participant.

12 This is the most glamorous part of my day.
13 The restrooms are located in the lobby past the
14 coffee area to the right and down the hallway. And
15 finally, copies of today's presentations are
16 available upon request.

17 Contact information is also available at the
18 registration table out in the hall. For media
19 inquiries, our press officer today is Jim McKinney.
20 If any members of the media are here today, please
21 sign in, and if you have questions or are
22 interested in speaking about this workshop, please

1 contact Jim.

2 There are no rules of evidence for this
3 workshop today, but there are some general
4 procedural rules that I will read very quickly in
5 the hopes of moving things along. Attendees should
6 not interrupt the presentations at any of the
7 planned panels, which will not be taking questions
8 from the audience. There will be an open public
9 comment period at the end of the day once the panel
10 presentations have concluded.

11 This workshop is subject to FDA policy and
12 procedures for electronic media coverage.
13 Representatives of the electronic media are
14 permitted, subject to certain limitations, to
15 videotape, film, or otherwise record today's
16 proceedings.

17 This workshop will also be transcribed, and
18 copies of the transcript can be ordered through the
19 docket or accessed on FDA's website approximately
20 30 days after the workshop. And on that note, I
21 would ask that all of the speakers and panel
22 participants make sure to speak into a microphone

1 because the transcriptionist needs us to do that so
2 that the transcription can be accurate.

3 For the open public comment period of our
4 day today, we have approximately 17 speakers
5 registered to speak, and each one of them will be
6 allotted 4 minutes to present.

7 At this point in time, I believe all of the
8 oral presentation time has been allotted to
9 preregistered speakers. If that changes, though, a
10 preregistered speaker doesn't attend or something
11 opens up, there may be an opportunity for
12 additional oral presentations at the end of the
13 workshop. Please sign up at the registration table
14 outside the meeting room if you're interested in
15 doing that by 10 o'clock.

16 We also encourage you to submit to the
17 docket. You can see the Federal Register notice
18 for details on how to submit comments to the
19 docket. And I would say from my perspective, we
20 always review written comments. They're very very
21 helpful, so I really encourage folks to do that.
22 Please submit written comments by April 9, 2020.

1 This workshop is being webcast live, however, the
2 webcast is not interactive, so viewers cannot
3 comment or ask questions.

4 With that, it is my great pleasure to
5 introduce FDA Commissioner Hahn. Dr. Hahn came to
6 FDA in December of last year after serving as the
7 chief medical executive at the University of Texas
8 MD Anderson Cancer Center.

9 In just a few short months after coming to
10 FDA, Dr. Hahn has helped bring the FDA and FTC
11 joint statement to life, reinforcing the agency's
12 commitments to taking key steps to reduce gaming of
13 current FDA requirements and coordinating with the
14 Federal Trade Commission to address anticompetitive
15 behavior. Dr. Hahn and Tara Koslov, FTC's chief of
16 staff, will be providing opening remarks for
17 today's workshop. Thank you.

18 (Applause.)

19 Opening Remarks - Stephen Hahn

20 DR. HAHN: Good morning, and thank you, Eva,
21 for that kind introduction. I'm really pleased to
22 see so many of you all joining us today, both

1 virtually and in person. This is a really
2 important topic, and I'm especially delighted to
3 welcome to White Oak -- it's far away from downtown
4 D.C., so I appreciate your being here -- Tara
5 Koslov, who's the chief of staff of our partner
6 agency, the Federal Trade Commission.

7 I just want to stop and take a moment here.
8 This is an incredibly important topic. We'll spend
9 a lot of time today talking about it. But I do
10 want to spend a moment to acknowledge those who've
11 lost their lives to the coronavirus outbreak. We
12 very much care about what happens around the world
13 to folks who have been exposed to this and just
14 want to take a moment to acknowledge that.

15 The other thing I'd like to do is to
16 acknowledge the many people at FDA, CDC, HHS, and
17 around the U.S. government who have worked
18 tirelessly, and I can assure you of that, 24/7, to
19 address this outbreak. They are true American
20 heroes in trying to help us address this across the
21 country and the world.

22 The focus of today's meeting is an important

1 one, to discuss the FDA's and FTC's collaborative
2 efforts concerning the biologics marketplace in
3 biosimilars. For those of us who believe in the
4 marketplace, it's really important that the free
5 market work well, and that includes making sure, as
6 my predecessor Dr. Gottlieb had said before, that
7 there are no shenanigans. It's a really important
8 concept, and work together trying to address that
9 issue.

10 We believe that getting more biosimilars,
11 and hopefully interchangeables, on the market will
12 offer great potential and have a positive effect on
13 the American public, both from an availability
14 point of view but also from a cost point of view.

15 Last month, as you know, we signed a joint
16 statement on our collaboration, which outlined our
17 shared goals and objectives and discussed how our
18 agencies will work together to support competitive
19 markets for biological products. This truly is an
20 example of the U.S. government in a transagency
21 fashion working together. It also described key
22 steps we intend to take to address false or

1 misleading communication by biological product
2 manufacturers. This is not meant to be an us
3 versus them situation, but just so that everyone is
4 on the same level working field and moving forward
5 to provide as much transparent information as
6 possible to developers and the American public.

7 We've also released a draft guidance for
8 industry called Promotional Labeling and
9 Advertising Considerations for Prescription
10 Biological Reference and Biosimilar Products:
11 Questions and Answers. That's a mouthful but
12 really important information contained in that
13 draft guidance. We're expecting to get comments on
14 that, and we'll work with our partners around that,
15 and today we're holding this workshop, the next
16 important step in our collaboration.

17 What the partnership of our two agencies
18 means is that our combined extensive resources and
19 efforts in this area can have a dual focus on both
20 the scientific and the legal fronts. This means we
21 will do everything possible to support a robust
22 market place for biological products, including the

1 adoption of both biosimilar and interchangeable
2 products.

3 On the scientific end, and we are very much
4 a scientific organization at FDA, we are working to
5 support innovation and advance the scientific
6 development of these groundbreaking products.
7 We're also engaged in very close participation, our
8 partnership with FTC, in activities designed to
9 help ensure that healthcare professionals and
10 patients receive truthful and non-misleading
11 information about biological products and to deter
12 anticompetitive behaviors in the marketplace
13 related to them.

14 I came to this job as a provider of cancer
15 care. I can't tell you how important it is that we
16 communicate with patients and providers about this
17 and give them the most accurate information. That
18 will go a long way to ensuring that these products
19 are available to the American public and providers.
20 What these activities have in common is the goal of
21 helping to reduce costs and enhance patient access
22 to these important and potentially life-saving

1 products.

2 The development of biologics offers us one
3 of the best examples we have today of the potential
4 offered by unprecedented advances in medical
5 science. What we're seeing across the world, and
6 particularly in the United States, is
7 unprecedented, and we are very much interested in
8 bringing science innovation to the patient bedside
9 for providers and patients alike.

10 These products, which may be produced
11 through biotechnology in a living system, are used
12 to diagnose, prevent, treat, and cure diseases and
13 medical conditions. We've seen enormous progress
14 in this field in a relatively short period of time.
15 We're all working to catch up with that amazing
16 acceleration of innovation, and these products are
17 increasingly playing a central role in the
18 treatment of the many serious and life-threatening
19 diseases. In fact, in some situations, these are
20 the only products available to treat patients with
21 life-threatening situations.

22 So there's an urgent unmet medical need for

1 us to do as much as we can in this sphere, and that
2 will likely continue to grow, and we certainly hope
3 it does grow. Last year, we approved
4 10 biosimilars. That makes a total since 2015 of
5 26 for 9 different related reference products; and
6 in the early months of 2020, we have continued to
7 see strong momentum. Congress recognized this
8 promise 10 years ago, and to support it, passed the
9 Biologics Competition and Innovation Act.

10 Just as a brief moment here, we know from
11 the generic space, the prescription side, the drug
12 side, that the more generics we have
13 available -- and I'm making a relationship between
14 generics and biosimilars, and I realize the
15 translation isn't a hundred percent correct. But
16 we know when we introduce generics on the drug side
17 that we significantly reduce costs, so let me give
18 you a few facts about this.

19 If one generic is introduced to a reference
20 product, on average, that reduces the price of that
21 product by about 35-36 percent. If we introduce up
22 to 6 generics in a product space, that can reduce

1 the price of those products by as much as
2 95 percent. We're hoping to get the same sort of
3 scale and approach in the biosimilar and certainly
4 in the interchangeable space. The more we can do
5 in this area, the better it's going to be for
6 competition and choice for the American people.

7 We think, and our estimates are, that over
8 the last decade, competition in the generic space
9 has saved Americans in the healthcare system more
10 than a trillion dollars, and we need to get working
11 to have this occur in the biosimilar space and
12 interchangeable space as well.

13 Biologics account for a disproportionate
14 amount of the overall spending of prescription
15 drugs. They're 2 percent of the total of
16 prescription drugs but account for, by our
17 estimates, 40 percent of the cost of prescription
18 drugs.

19 Where we are right now is where we were
20 before in the prescription drug side of the house
21 and, again, the more we do work on the biosimilar
22 interchangeable side, the better it's going to be

1 for the American public, again, with choice and
2 competition. We've taken Congress' goal to heart
3 and are doing everything, particularly with our
4 great partners at FTC, to increase accessibility
5 and help Americans realize the promise of
6 biosimilars.

7 We're already making some significant
8 strides, but we have more work to do, and we
9 realize that, and we're always looking for ways to
10 improve. We've improved the efficiency of the
11 biosimilar and interchangeable product development
12 approval process.

13 Across the agency we're looking at this.
14 How do we make it more efficient? How do we make
15 it easier for developers to provide the information
16 to us? How do we on our end make it easier for our
17 reviewers so that the number of review cycles goes
18 down and the process and the timeline for approval
19 goes down as well?

20 We are maintaining our gold standard of
21 safety and efficacy, but we definitely want to
22 maximize efficiency and want to provide as much

1 regulatory clarity for developers as possible.
2 We're also doing our best to try to strengthen
3 effective communications with the American public,
4 providers, and with innovators.

5 The last point has special relevance for our
6 partnership with FTC, and I want to focus on that
7 for a moment. We know that a free market, as I
8 mentioned before, and enhanced competition supports
9 increased innovation, so it has the virtuous effect
10 of not only helping in terms of decreasing prices
11 as we've seen on the generic side, but also
12 stimulating further innovation. But for it to be a
13 free market and a fair market, it has to absolutely
14 be free.

15 Unfortunately, since the earliest stages of
16 the development of the biologics market, there have
17 been obstacles to increase competition. That's not
18 okay. We've seen efforts by manufacturers to delay
19 competition for biosimilar products and we've seen
20 the publication of materials that seem designed to
21 create uncertainty about biosimilars and discourage
22 patients and healthcare providers from using them.

1 These behaviors have the potential to put
2 innovation at risk, erode public confidence in the
3 product, weaken efforts to lower healthcare costs
4 through competition, and ultimately undermine
5 advances in healthcare, as potential treatments and
6 cures are unavailable or go unrealized. At FDA, as
7 at FTC, we are very committed to empowering the
8 American consumer and the American provider, and we
9 must do more in that area.

10 To counter these activities, we've taken a
11 number of actions from the creation of the
12 biosimilar product development program to a public
13 education campaign that you all know about.

14 Our collaboration with the FTC is the next
15 step in our efforts to end these types of
16 counter-productive activities; and, Tara, I want to
17 thank you and Commissioner Simons for the terrific
18 work that you've done in partnership with us. It
19 will help and support and ensure an environment in
20 which biosimilars can fulfill their promise and
21 reach the patients who need them because the market
22 is a competitive and fair one.

1 The FDA, as I mentioned, is a science-based
2 organization and data-driven, and our work is
3 premised on the understanding that decisions must
4 be based on good data and sound science. In this
5 way, we can promote innovation and support the
6 development of new treatments and cures. But this
7 activity must be conducted on a fair playing field
8 that the patients and our public and our providers
9 depend upon.

10 Our collaboration with FTC, as I've
11 mentioned, is designed to help ensure this, and I
12 very much want to congratulate FTC in all they've
13 done. Today's meeting, as I mentioned, is that
14 next step and, again, really appreciate the
15 partnership with FTC.

16 So on that note, it's my great pleasure to
17 introduce the chief of staff of FTC, Tara Koslov.
18 Ms. Koslov has served as Chairman Simon's chief of
19 staff since he was sworn in as chairman of FTC on
20 May 1, 2018. She has worked on healthcare
21 competition matters throughout her 23-year career
22 at FTC. That's really impressive staying power.

1 Thank you for your service to the American
2 people, including on biologics and biosimilars.
3 Just in our brief conversation, I know you feel so
4 passionate about this subject. Prior to her
5 position as chief of staff, Ms. Koslov was acting
6 director of the Office of Policy Planning. She is
7 a graduate of Harvard Law and Brown University.

8 Ladies and gentlemen, Tara Koslov. Thank
9 you.

10 (Applause.)

11 Opening Remarks - Tara Koslov

12 MS. KOSLOV: Good morning, everyone. I'm
13 delighted to join Commissioner Hahn in welcoming
14 you all here today, and on behalf of FTC, Chairman
15 Simon, he truly regrets not being able to be here
16 with us today, which is why you get me instead.
17 But as Commissioner Hahn mentioned, I have long
18 worked on these issues, and I am indeed passionate
19 about them. So I'm pleased to be here representing
20 my agency.

21 Let me begin with a few thank yous. This
22 workshop is part of the decades-long collaboration

1 between the Federal Trade Commission and the FDA to
2 promote competitive markets for pharmaceuticals.
3 Today, our focus is on biologics markets and what
4 can be done to spark competition for these
5 innovative new treatments.

6 I would like to thank former FDA
7 Commissioner Scott Gottlieb for initiating this
8 joint agency effort and Commissioner Hahn for
9 continuing it. I would also like to thank the FDA
10 for hosting this workshop and the many FDA and FTC
11 staff who made this workshop happen. An incredible
12 amount of work went into planning and executing
13 this event. As someone who has done plenty of
14 events at the FTC, I know exactly what goes into
15 putting together something like this, and I'm very
16 grateful for everyone's efforts.

17 Biologics, as we all know, our innovative
18 treatments for serious and life-threatening
19 diseases like cancer, diabetes, and Crohn's
20 disease. Often biologics are the only effective
21 treatments for these diseases, but biologics can be
22 very expensive, some costing tens of thousands and

1 others costing millions of dollars. Total U.S.
2 spending on biologics is growing rapidly and
3 reached \$125.5 billion in 2018.

4 I'm going to provide the FTC's perspective
5 as a competition and consumer protection
6 enforcement agency. As many in this room already
7 know, the FTC has a broad mission to protect
8 consumers and promote competition by preventing
9 anticompetitive, deceptive, and unfair business
10 practices.

11 Because of the critical role competition
12 plays in reducing prices and fostering innovation,
13 the FTC has long been interested in promoting
14 competition in pharmaceutical markets.

15 One way the FTC does this is by conducting
16 industry studies. More than 40 years ago, for
17 example, the FTC published a report on state laws
18 that prevented pharmacists from substituting
19 generics for branded drugs.

20 The FTC concluded that these laws imposed
21 substantial unwarranted costs on consumers by
22 unduly restricting price competition between

1 generic and branded drugs. These findings helped
2 pave the way for now familiar state laws that allow
3 automatic substitution of a generic for the brand.

4 Similarly, a 2002 commission study on
5 generic drug entry recommended the brand name
6 companies and generic applicants, settling patent
7 litigation under the provisions of the Hatch-Waxman
8 Act, should be required to submit those settlements
9 to the FTC.

10 This recommendation was incorporated into
11 the Medicare Modernization Act of 2003 and is now
12 the primary means by which the FTC learns about
13 potentially anticompetitive patent settlements
14 between brand and generic drug manufacturers.
15 Following the 2018 amendments to the Medicare
16 Modernization Act, the FTC now also obtains and
17 reviews patent settlement agreements involving
18 biologics and biosimilars.

19 Another way the FTC promotes competition in
20 pharmaceutical markets is by vigorously combating
21 anticompetitive conduct. Notably, the commission
22 has a long record of successful enforcement actions

1 against brand and generic drug manufacturers
2 seeking to gain the Hatch-Waxman process by
3 entering into anticompetitive reverse payment
4 agreements.

5 The agency's victories include a landmark
6 decision by the Supreme Court in *FTC v. Actavis*,
7 holding that such agreements can create antitrust
8 liability. We've also seen favorable
9 interpretations of activists in other federal
10 courts and sweeping settlements that prevent major
11 manufacturers from entering into anticompetitive
12 reverse payment agreements.

13 Perhaps as a result of these successes, the
14 number of potentially anticompetitive reverse
15 payment agreements has dropped precipitously.

16 The FTC's experience with pharmaceuticals
17 also extends to the biologics industry. In fact,
18 the FTC brought its first enforcement action
19 involving a biologic almost 30 years ago. More
20 recently, the FTC provided technical assistance as
21 Congress developed the abbreviated pathway for
22 approval of biosimilars.

1 In 2008 when Congress was weighing options
2 for an abbreviated pathway, the House Committee on
3 Energy and Commerce requested, and the FTC
4 provided, lessons learned from Hatch-Waxman to help
5 structure the new pathway, and in 2009, the FTC
6 testified before Congress about a follow-on
7 biologic drug competition to inform the debate on
8 the legislation that became the abbreviated
9 pathway.

10 As an aside, the commissioner who provided
11 that testimony at the time was actually the
12 commissioner I was working for at the time as her
13 attorney advisor, which shows you how far back my
14 involvement goes in these issues. So it's kind of
15 nice to come full circle.

16 Competition between reference biologics and
17 biosimilars is just as important as competition
18 between brand and generic small molecule drugs.
19 Biosimilars, which are as safe and effective as
20 their reference biologics, hold the promise of
21 reducing price, and therefore increasing access to
22 these treatments. This is because when given a

1 choice between two highly similar products,
2 well-informed consumers typically choose the less
3 expensive option.

4 This competition in turn drives prices down,
5 but competition only works when consumers have
6 reliable and truthful information. In some
7 instances, statements from reference biologic
8 manufacturers and the groups they fund may mislead
9 patients and physicians into believing the
10 biosimilar is not as safe or as effective as the
11 reference biologic. Such deception might violate
12 both consumer protection laws and antitrust laws.

13 On the consumer protection front, while the
14 FTC generally supports comparative advertising,
15 that advertising must be truthful and not
16 misleading. Advertising that creates an impression
17 of clinically meaningful differences between a
18 reference biologic and its biosimilar is likely
19 false or misleading, and therefore would constitute
20 an unfair or deceptive practice.

21 Similarly from an antitrust perspective,
22 maintaining or growing share by deceiving patients

1 and physicians about competitors offerings is not
2 competition on the merits. It also erects
3 artificial barriers to entry and creates costs for
4 biosimilar manufacturers who have to counter the
5 deception. Such deception, therefore, likely would
6 constitute an unfair method of competition.

7 The FTC is committed to taking appropriate
8 enforcement action against false or misleading
9 communications involving biologics and biosimilars,
10 but the FTC's enforcement priorities in this
11 industry extend beyond deceptive conduct. The FTC
12 will also seek to deter behavior that impedes
13 access to samples needed to develop generics and
14 biosimilars.

15 For example, just this past January, the FTC
16 brought its first case alleging a restrictive
17 distribution scheme that anticompetitively blocked
18 competition for a small molecule drug. The FTC
19 will also continue to review patent settlement
20 agreements involving biologics and biosimilars for,
21 among other things, anticompetitive reverse payment
22 agreements.

1 In closing, I want to reiterate the
2 importance of the more than 65-year history of
3 collaboration between the FTC and the FDA. I
4 believe this collaboration has benefited American
5 consumers in untold ways, but most concretely by
6 making safe and effective treatments more widely
7 available and at a lower price.

8 On behalf of Chairman Simon and the FTC, I
9 thank the FDA for its critical support of the FTC's
10 investigations and industry studies, and we look
11 forward to continuing this legacy of collaboration.
12 Thank you all for your time this morning. I'm sure
13 you will all have a very productive and engaging
14 day. Thanks.

15 (Applause.)

16 MS. ANDRUS: Good morning. My name is
17 Meredyth Andrus. I'm an attorney in the healthcare
18 division of the Bureau of Competition at the
19 Federal Trade Commission. This first panel we put
20 together are some experts in the field to discuss
21 the development and licensure of biologics and
22 biosimilars and the post-approval uptake process.

1 I'm going to let all of the panelists
2 introduce themselves. The way we will conduct this
3 panel is there will be two brief presentations by
4 Christine and by Eva, and then we will go through a
5 series of questions and answers that we have
6 prepared. So without further ado, let's jump in
7 and let's do some introductions first.

8 Surya?

9 DR. SINGH: Hi. Thank you for having me.
10 I'm Surya Singh. I'm an independent consultant, an
11 internist by training, and former chief medical
12 officer of the Specialty Pharmacy at CVS/Aetna.
13 I've been interested in these issues for a long
14 time, so thanks again.

15 MS. BURICH: Hi. Molly Burich, director of
16 public policy at Boehringer Ingelheim.

17 MS. SIMMON: Hi. Christine Simmon,
18 executive director of the Biosimilars Council,
19 which is a division of the Association of
20 Accessible Medicines, which represents generics and
21 biosimilar manufacturers.

22 MS. TEMKIN: Hi. Again, Eva Temkin. I am

1 the policy director for the Office of Therapeutic
2 Biologics and Biosimilars.

3 MS. ANDRUS: Why don't we start with Eva,
4 who will kick it off for us with a short
5 presentation.

6 Presentation - Eva Temkin

7 MS. TEMKIN: Sure, with the goal of making
8 all of you sick of me before 10 a.m.

9 I have a short presentation that I'm going
10 to walk through. I started with this slide because
11 I thought it was an interesting perspective. We
12 often hear, as we just did, parallels drawn between
13 the promise of biosimilars and that of generic
14 drugs, and many of the challenges, I think, may be
15 parallel to including allegations of
16 anticompetitive behavior and what to do about them,
17 which is why we're all here today.

18 To kick it off, though, I want to talk a
19 little bit about terminology and regulatory
20 framework just so that we can all be in the same
21 place. What this slide lays out is essentially we
22 have two pathways for bringing biological products

1 to market,, 351(a) of the Public Health Service
2 Act, which is for stand-alone or reference
3 biologics, which are approved based on a
4 demonstration that the proposed product is safe,
5 pure, and potent, also known as safe and effective
6 in some camps. Then we have the 351(k) pathway,
7 which is the abbreviated pathway to licensure for
8 biosimilar and interchangeable products.

9 Now, these pathways, again, parallel what
10 happens in the small molecule world, but they're
11 different by design. Heterogeneity across all
12 biological products is expected. That's why we
13 have the standard that we have for biosimilarity.

14 What is that standard? Well, I've put up
15 the definition, and I know there are a lot of words
16 on this slide, but I really want to focus on and
17 highlight actually what's at the bottom.

18 When we're talking about biosimilars, we're
19 talking about products that have been demonstrated
20 to be highly similar to the reference products and
21 to have no clinically meaningful differences from
22 those reference products. This is not a

1 re-establishment of safety and effectiveness; it's
2 a demonstration of the relationship between the
3 proposed product and the reference product.

4 Once approved, we have a biosimilar product,
5 and the labeling will include relevant data and
6 information from the reference product labeling;
7 although notably, biosimilar product labeling may
8 differ from reference product labeling for a
9 variety of reasons, and we can talk about that a
10 little bit more if it is useful for the discussion.

11 As an example, I think it's helpful to note
12 that a biosimilar applicant can seek licensure for
13 fewer than all of the indications for which a
14 reference product is approved, so that's an example
15 of where the labeling may differ.

16 The approved biosimilar is expected to be
17 safe and effective just like the reference product
18 in patients who are treatment experienced, that is
19 in treatment with a reference product, or treatment
20 naive, that is they haven't yet been treated with
21 any product or with the reference product at all.

22 What does this demonstration mean? I wanted

1 to touch briefly on the data requirements. For
2 demonstrating biosimilarity, we have a fair bit of
3 guidance out in the world on this, and I'm happy to
4 talk about it at great length, but I will endeavor
5 to do so in one slide and one minute, essentially.

6 Essentially, we have a stepwise approach to
7 generating data to support a demonstration of both
8 similarity, and what the picture does is attempt to
9 demonstrate that the analytical similarity data,
10 the comparative analytical data that we're looking
11 at in a biosimilar application, is really the
12 foundation of the analysis and the demonstration of
13 biosimilarity.

14 At each step, we take stock and we evaluate
15 what residual uncertainty might be remaining, and
16 we move on to the next step of data generation. So
17 ultimately, the nature and scope of clinical
18 studies will depend on the extent of residual
19 uncertainty that remains after analytical
20 assessment and to the extent, relevant animal
21 studies.

22 Generally, we consider all of these pieces

1 of data together in the totality of evidence
2 approach to evaluating the biosimilarity, but we
3 generate the data typically stepwise in this way.

4 Then we have interchangeability. 351(k) has
5 both biosimilarity and interchangeability in it.
6 An interchangeable product is defined actually in
7 Section 351(i) of the Public Health Service Act as
8 a product that can be substituted for the reference
9 product without the intervention of the healthcare
10 provider, and I think we'll talk a lot, both in
11 this panel and over the course of the day, about
12 what that means and the importance of
13 interchangeability.

14 I wanted to make sure that we included a
15 little bit about the additional data requirements
16 that we typically look for -- well, that we hope to
17 typically look for. We don't have licensed
18 interchangeables at this point.

19 We do have final guidance on demonstrating
20 interchangeability, which is where this can all be
21 found, but essentially it's still a totality of the
22 evidence approach.

1 We're still talking about stepwise data
2 generation, but we do require for an
3 interchangeable, the statute requires that the
4 proposed product be demonstrated, that it will be
5 expected to have the same clinical result as the
6 reference product in any given patient, and that
7 there won't be an increased risk either in safety
8 or in reduced effectiveness from switching back and
9 forth between the reference product and the
10 proposed interchangeable.

11 So that's a lot of words about regulatory
12 standards. I wanted to close by circling back to
13 how enthusiastic we are about biosimilars and
14 interchangeables and how excited we are about the
15 potential for these products to really enhance
16 patient access.

17 We at the FDA have and continue to play a
18 critical role in facilitating access to biosimilars
19 and hopefully interchangeables some time in the
20 soon future. We have 76 development programs
21 referencing 38 reference products, and we're
22 feeling pretty good about the promise of

1 biosimilars as we go into this exciting day.

2 Presentation - Christine Simmon

3 MS. SIMMON: Great. Thank you, Eva, and
4 good morning to everyone. I actually want to start
5 with my second slide because it's a Monday, so that
6 fits.

7 I think, as was mentioned this morning,
8 there are now 26 biosimilars approved by the FDA,
9 which is very exciting. I think we should all take
10 a moment to bask in that. Twenty-six. Many of us
11 have sat in this room, many, many, many, many
12 times, at ADCOM meetings and public workshops
13 around biosimilars, and here we are with 26
14 approved.

15 This slide indicates the 15 that are on the
16 market. Think about the 26 that are approved.
17 There's the five-year anniversary of the FDA's
18 approval of Sandoz's Zarxio just this week or last
19 week maybe. The most recent biosimilar to reach
20 the market a couple of weeks ago is the third,
21 Herceptin, which I think, as Commissioner Hahn
22 mentioned this morning, with greater competition

1 and multiple products in the marketplace, you start
2 to see increased access and savings for patients,
3 which is of course all of our mission here.

4 So that's very exciting. Yet, if 15 of the
5 26 approved are marketed, that obviously means that
6 there are 11 --

7 (Brief pause.)

8 MS. SIMMON: Well, what it will show, when
9 we see it, are the 11 that are not yet
10 approved -- excuse me, not yet marketed.

11 I think as we talk about biosimilars here in
12 2020, we have every reason to be optimistic. But
13 there's a difference between being an optimist and
14 being a cockeyed optimist. I think that we do have
15 to be mindful of the challenges that we still
16 face -- where we can have a slide, and I promise
17 you a different slide --

18 (Laughter.)

19 MS. SIMMON: -- that has 11 that are not on
20 the market. So let's try to go backwards.

21 (Technical difficulty.)

22 MS. TEMKIN: This is not FDA trying to avoid

1 talking about the biosimilars that have not been
2 marketed; I promise.

3 MS. SIMMON: I'm going to put the really
4 optimistic slide up, and that's the one that made
5 it. This is the middle slide of three, and the
6 prior slide talks about the challenges that we're
7 going to talk about somewhat today.

8 There are some challenges, obviously, around
9 biosimilars, and we want to focus on those so that
10 we can reach the point of cockeyed optimism. You
11 think about these in a couple of different
12 categories, the challenges around development and
13 then the challenges to a viable and competitive
14 biosimilars market.

15 Ha! There they are, the ones not yet
16 marketed, but we've so moved on from that, but
17 thank you.

18 (Laughter.).

19 MS. SIMMON: The challenges around
20 biosimilar development, you can think of those
21 around the clinical studies, particularly the
22 bridging and the confirmatory studies in phase 3.

1 All these are very costly studies and very
2 necessary to achieve the FDA designation of "no
3 clinically meaningful differences."

4 But as you look at the cost to develop
5 biosimilars, and ways to work on the bridging, and
6 think about what's really necessary in terms of
7 clinical studies -- which I do think the FDA is
8 looking at hard and has been helpful and somewhat
9 flexible in their guidance, particularly in the
10 insulin guidance which came out, which was very
11 helpful in its flexibility -- these are things we
12 want to continue to examine.

13 Obviously patent abuses and patent thickets,
14 these are critically important to combat in order
15 to get biosimilars to the market and through the
16 development process. When you look at the market
17 itself, exclusionary contracting practices has been
18 a lot in the news of late. This is, again,
19 something that's stymieing the ability of a
20 biosimilar to get on the formulary and get to the
21 market.

22 Similarly, the rebate trap, I think we're

1 all familiar with that. We're familiar with the
2 lawsuits that have been filed around that. I know
3 today we'll be talking about misinformation. I
4 think misinformation is a really broad category.

5 You can have explicit misinformation, which
6 the agency, FDA, is addressing, and FTC, in their
7 guidance document around communication, but also
8 implicit misinformation, which we at the
9 Biosimilars Council would argue includes current
10 policies around naming and even the very existence
11 of the interchangeability designation, which of
12 course is part of the statute but is also unique to
13 the United States.

14 Finally, reimbursement and formulary
15 replacement issues we may not get to today but,
16 again, are very important. Really, more under the
17 purview of the Centers for Medicare and Medicaid
18 Services, they did, in their most recent draft call
19 letter, seek to potentially address this through
20 the potential for a preferred and non-preferred
21 tiering system in the specialty category, which
22 would be useful for biosimilars.

1 So again, optimism, somewhere between
2 cautious and cockeyed. I think that we have a lot
3 of good things to discuss, so I look forward to the
4 questions. Thank you.

5 Panel Discussion - Meredyth Andrus

6 MS. ANDRUS: Thank you, Eva and Christine.

7 The first question we have involves the
8 development of biosimilars. Every single year, for
9 the past four or five years, there have been
10 increasing numbers of approved biosimilars, but
11 there still are questions and uncertainty.

12 Are there any areas where the FDA could
13 provide additional guidance that would be helpful
14 to manufacturers, to consumers, and to healthcare
15 providers?

16 MS. TEMKIN: I can jump in for a second.
17 Some of you have probably heard me talk about a
18 white board that I have in my office, which has a
19 list of policy development projects and guidance
20 development projects that we hope to undertake, and
21 that that list is constantly shifting in priority.
22 But what we do know -- and I point to the

1 biosimilars action plan that the agency put out in
2 the summer of 2018, I guess.

3 The whole point here is to provide
4 additional clarity and certainty and to help with
5 efficiency in biosimilar development to support
6 biosimilar development. That biosimilar action
7 plan includes FTC collaboration and a lot of this
8 work that we're doing, but it also includes areas
9 of additional guidance, and reviewing our
10 regulations, and modernizing those, and a lot of
11 big ticket projects that we have been undertaking
12 and continue to undertake.

13 All of that by way of background, it's super
14 useful from my perspective to hear what folks need,
15 what industry needs, and what people in the world
16 outside of the agency are thinking as priorities
17 for additional clarity, so we certainly would
18 appreciate hearing those thoughts. I'm sure we'll
19 hear some of them during the open comment period as
20 well.

21 MS. ANDRUS: The United States is the only
22 major jurisdiction worldwide with an

1 interchangeable designation for biosimilars. As
2 demonstrated with the recent draft insulin
3 immunogenicity guidance, FDA has significant
4 flexibility in interpreting the statute as well as
5 the authority to issue product class-specific
6 guidance.

7 Two questions: Does the designation still
8 hold value here in the United States, and does FDA
9 have a role to play in determining that?

10 MS. BURICH: I'll start on that. I think
11 the answer to does the designation of
12 interchangeability hold value in the U.S., the
13 answer is yes, although it depends on the product
14 and it depends on whether the product is, in fact,
15 physician administered, a medical benefit product,
16 or a pharmacy benefit product.

17 The reason why that's meaningful is, as Eva
18 noted earlier, the primary draw of
19 interchangeability is that automatic substitution
20 that can occur at the pharmacy level. In other
21 words, if you don't have that pharmacy interaction,
22 whether retail or specialty, interchangeability

1 doesn't have a whole lot of significance if there
2 isn't that pharmacist interaction.

3 As Christine's slides noted, the number of
4 approved products, all 15 of those products, are
5 medical-benefit, physician-administered products.
6 I think that's an important piece of context around
7 why interchangeability continues to be talked
8 about, but we haven't seen it yet. It's really, in
9 part, because of the type of products that
10 interchangeability is relevant to. And while we
11 have several approved self-administered
12 biosimilars, we have none that are launched and
13 won't be launched for the next couple of years.

14 So we still have some time until we see an
15 interchangeable potentially come to market and
16 until we see the products where interchangeability
17 has value in terms of that pharmacist interaction.
18 We still have a little ways to go until we get
19 there.

20 MS. SIMMON: I would just add, again, that
21 it is important and helpful to have
22 product-specific guidance on interchangeability, as

1 we did see in the case of insulin. Also, we look
2 forward to FDA making more of a determination
3 around what the name of an interchangeable product
4 will be. It's really not clear. We know that
5 transition insulins won't have a suffix, so it
6 could be that there might be special considerations
7 for interchangeables, and we'll want to hear more
8 about that.

9 On the point Molly made, interchangeability
10 is more important, in some ways, at the retail
11 pharmacy setting and when it becomes part of the
12 Part D benefit and you see it more frequently. We
13 have heard from pharmacists that they might not be
14 comfortable doing the switching if the name is
15 going to be something that's going to be different
16 and confusing for them and their patients.

17 Of course there are state laws. We've made
18 a lot of progress in amending the state laws to
19 account for interchangeable biosimilars, but there
20 may be some state laws that still have to be
21 addressed.

22 DR. SINGH: One quick comment about the

1 products that have launched already in terms of the
2 complexity of the competition, I think in the case
3 of infliximab, where you have actually both medical
4 and pharmacy adjudicated and the presence of both
5 benefits being used, it introduces a whole other
6 area, again, of a marketplace complexity.

7 The deals that get arranged and the
8 influence of rebate bundling, competition, and the
9 application of formulary that can be run
10 cross-benefit is very splintered to the marketplace
11 right now and different by health plan and PBM.

12 So you have that presence as well as the
13 medical benefit side, and that makes it even more
14 complicated, which I'll return to when we come to
15 the latter questions.

16 MS. ANDRUS: There are, as we saw, 26
17 approved biosimilars in the United States, but only
18 15 are actively marketed. What might explain why
19 the other 11 are not actively marketed?

20 DR. SINGH: I can start, and I'm sure others
21 have comments about this, too, because it's sort of
22 a central theme.

1 Thinking back to the slides that Christine
2 showed, and she articulated this well, I think I'll
3 just elaborate a little bit. The first one, before
4 I get to some of the purely marketplace commercial
5 issues, is the idea of the patent thickets. I
6 think there's a paper in JAMA last year -- and this
7 is publicly available information, so I'll quote a
8 couple of statistics.

9 Adalimumab as an example has over a hundred
10 patents. Eighty-nine percent of them were filed
11 after the original launch of that medication. So
12 you just think about that and think about the
13 barrier to having a biosimilar for that particular
14 medication, or any others into the marketplace,
15 it's certainly a lot more complicated to wade
16 through that patent thicket, if you will, to use
17 that terminology that's taken over the market.

18 The second and third are really interrelated
19 about the other 11 and why they haven't launched.
20 They're both commercial and contracting issues.
21 One is that the same manufacturers, or sometimes
22 marketplace arrangements between manufacturers, are

1 involved in both the innovator, if you will, the
2 originator biologic, and the biosimilar.

3 So the contracting, especially the big
4 consolidated procurers of drugs on the specialty
5 pharmacy side of the market and the way that the
6 contracting happens, there's a relationship between
7 the contracting for those new biosimilars and the
8 originator biologic that are very hard to
9 disentangle.

10 That bleeds into the third issue of what was
11 called before -- I think part of what was
12 underneath the rebate trap, and you may want to
13 elaborate on that, is that the rebates in that
14 particular category may be driven by a bunch of
15 different factors.

16 It's different on the medical benefit side,
17 again, and the pharmacy benefit side. You'll hear
18 all of us, I think, agree that the issues in
19 contracting and procurement are pretty unique on
20 the medical benefit side where the market is much
21 more splintered.

22 If you have a few major entities doing

1 contracting on behalf of a lot of covered lives on
2 the pharmacy benefit side, the bundling of
3 rebates, if you will, across categories, where
4 there are interdependencies, is much more common
5 than when you have individual practices or
6 hospitals and health systems doing the contracting
7 on the medical benefit side. So that's the other
8 major issue.

9 But getting back to the question of why have
10 some of these other 11 not launched, I think what
11 I've observed and then heard in a variety of
12 different forms in the market is that some of the
13 manufacturers are taking a bit of a wait-and-see
14 approach, especially in what's going to happen with
15 the rebate trap or changes structurally, and the
16 way that rebates are both contracted and then
17 ultimately invoiced and administered in the market.
18 It's a dynamic issue.

19 There was obviously a lot of talk about
20 removing the anti-kickback protection for rebates
21 last year and Medicare, and I think a lot of the
22 manufacturers are just watching the changes that

1 may happen structurally very closely before they
2 make a decision.

3 MS. SIMMON: Surya, you made a lot of great
4 points, and I think that's exactly right. A lot of
5 these issues are clearly around the rebate traps,
6 the exclusionary contracting, and the cost of
7 litigation. I would add on to that a couple of
8 things.

9 With respect to litigation, we want to
10 commend the FDA for its recent changes to the
11 Purple Book, making it more easily searchable
12 electronically. That's a huge benefit for
13 biosimilar manufacturers and others.

14 Of course what would help even more, and we
15 know this is outside the agency's purview, is to
16 require patents to be listed for biologics and
17 reference products in the Purple Book. We support
18 legislation. There's a bill that's been introduced
19 by Senator Susan Collins around this called the
20 Biologic Patent Transparency Act -- it rolls right
21 off the tongue -- and to ensure that this happens
22 to foster the potential for development.

1 Let's say you're a biosimilar manufacturer
2 and you get to see patents listed in the Purple
3 Book. Once you've cleaned up your coffee from
4 spitting it out when you saw the number of patents
5 listed, you start to contemplate litigating them.
6 It's about \$3 million to get through this
7 litigation, which is a large expense for biosimilar
8 manufacturers.

9 Think about that Humira, for example, was
10 first approved in 2002, and there are 5 biosimilars
11 approved for it, but none are on the market. We
12 know that there will be a bunch coming onto the
13 market but only due to the ability to enter into
14 patent settlement agreements with AbbVie.

15 Because of patent settlement agreements,
16 which in this case are very pro-competitive, these
17 biosimilars will get to the market 11 years earlier
18 than might otherwise be possible. This is alluded
19 to in the introductory remarks. The FTC of course
20 has been very active and has done a lot to ensure
21 that patent settlement agreements are
22 pro-competitive.

1 So hopefully we can put to rest the misnomer
2 of pay-for-delay and think of them as they really
3 exist, and how much it will help the patients who
4 might not otherwise receive Humira until 2034
5 without these settlement agreements.

6 We continue to work to make sure that
7 biosimilar manufacturers have the ability to enter
8 into these settlements and also to use inter partes
9 review, which is an administrative process to
10 challenge patents that are constantly under threat.
11 There are those who seek to exclude pharmaceutical
12 products from the ability to pursue inter partes
13 review and settle these patent issues or address
14 them administratively, which can be more efficient
15 and less expensive than going through litigation.

16 These are some of the issues I just wanted
17 to bring to light as to answer the broad-based
18 question of why they're not all on the market, in
19 addition of course to the rebate issues as Surya
20 pointed out.

21 MS. ANDRUS: Thanks.

22 Are there any significant differences in

1 uptake rates between biosimilars that are approved
2 to treat ongoing or chronic conditions and
3 biosimilars approved to treat acute conditions, and
4 what might account for that if there are?

5 DR. SINGH: Yes, I can start here also. I
6 think the distinction between the acuity or
7 chronicity of the underlying condition is helpful,
8 but it draws back into focus the very specific
9 conditions and the benefit under which they're
10 adjudicated commonly that were on the list that
11 Christine presented. I think that distinction has
12 more impact on what adoption has looked like so far
13 than the acuity or the chronicity of the underlying
14 condition.

15 Just very specifically, now that we have
16 bevacizumab, trastuzumab, and rituximab biosimilars
17 on the market, as soon as we have enough data to be
18 able to really examine what the uptake curves and
19 the adoption curves have looked like for those
20 medications, we'll be able to validate what I'm
21 saying.

22 I think in the example of the white and red

1 cell growth factor biosimilars, the adoption curves
2 versus infliximab, where I was saying it's been
3 more complicated because of this dual benefit
4 approach, that there's a lot of that particular
5 category for -- just to broaden it a little
6 bit -- both GI and RA, issues or conditions,
7 rheumatologic and gastroenterologic conditions,
8 that the drug treats.

9 The management of it, from both the
10 utilization management or formulary management
11 standpoint, has been more complicated because of
12 that dual benefit approach; whereas on acute or for
13 a finite period of time, administered medications
14 purely under medical, again back to the health
15 system and provider procurement of the medication,
16 we see a better degree of steeper uptake curve.

17 So I think that's what we're going to see
18 with bevacizumab, trastuzumab, and rituximab once
19 the data is available, but that's kind of how I
20 frame it.

21 MS. SIMMON: I think that's right. You can
22 sort of put some names to it. You can see that

1 systems like Kaiser and smaller health systems that
2 have integrated delivery networks are going to have
3 greater uptick for all the products. Large
4 academic medical centers like Mayo and Johns
5 Hopkins are not having such rapid uptick of
6 biosimilars.

7 So it does speak to the financial component
8 that's at play in these systems, which speaks to
9 the perniciousness of getting to all the factors
10 that are influencing biosimilar utilization and
11 uptake.

12 DR. SINGH: I just wanted to make one other
13 following comment because you've raised a point,
14 and I'm not sure if there's another place to say
15 this. So I just want to make sure that I put it
16 out there.

17 I think the idea of misinformation or
18 misleading information influencing prescribers
19 decisions about biosimilars, I think we've sailed
20 past that. There's a lot of survey data to support
21 this but anecdotally also. A lot of leaders of
22 large multidisciplinary practices, Kaiser included

1 but large oncology practices, rheumatology
2 practices, et cetera, there's no reluctance anymore
3 to speak of to use biosimilars. Really, the market
4 is being driven by economics, and I think that's
5 what's going to dictate the adoption curves that we
6 see.

7 MS. ANDRUS: So if there's no lingering
8 reluctance on the part of the physicians and
9 there's no real difference between acuity and
10 chronicity, are there any unique characteristics in
11 any of the therapeutic categories where biosimilars
12 have been approved and launched that have slowed
13 uptake?

14 MS. BURICH: I think the points that have
15 been raised are really important. I think that in
16 the same way is it acute versus chronic, is it
17 immunology versus oncology, I think what we see is
18 the mix of products, the benefits they're covered
19 under, and it's sort of all of these factors that
20 are coming together that are making -- while we're
21 seeing significant strides in the number of
22 approved products and the number of launched

1 products, we still know that uptake in a lot of
2 areas is lower than we want it to be, both from a
3 overall outlook of the sustainable nature of the
4 biosimilar market, but also just to generate
5 savings at a time when drug pricing is in such
6 focus within the U.S.

7 So I'm sort of in a similar boat as the
8 other panelists, which is that I think it's maybe
9 less about the specifics of the products and more
10 about where the existing launched products sit
11 within our system and what some of those dynamics
12 are. I think that is what is proving to be an
13 important piece that we haven't quite connected all
14 the dots to, to get the market moving consistently
15 across all the products.

16 MS. ANDRUS: Do providers have varying
17 incentives to use biosimilars or to use the
18 reference product? Generally speaking, what role
19 do insurers play in moving share to a biosimilar,
20 and what is the impact of most biosimilars and
21 biologics that are dispensed not in a pharmacy
22 setting but rather in hospitals, and clinics, and

1 doctors offices, through a medical benefit plan?

2 DR. SINGH: I can start on this also. The
3 first question in there, I think that provider
4 incentives do vary a lot, so let me just take a
5 step back and give a little bit of a macro picture
6 using some of the specific classes and agents where
7 we have biosimilars in the market already,
8 particularly infliximab.

9 Again, I'll start with the point that when
10 it's purely, or at least let's say 90 percent,
11 adjudicated under the medical benefits, it's a very
12 different picture than when there's a lot of
13 pharmacy benefit involvement.

14 At the inception of white-cell growth
15 factor, the introduction of biosimilars for both
16 filgrastim and pegfilgrastim now, much more of it
17 on a percent basis, if you look at the most recent
18 publicly available reports from IQVIA and others, I
19 think they illustrate the point that there's been
20 more shift towards some white-cell growth factor
21 going through the pharmacy benefit and being
22 adjudicated as a pharmacy drug, then medical over

1 time over the last five years.

2 As that's happened, and then we watch what's
3 happened with infliximab, you start to get to the
4 point that the provider incentives -- there's a lot
5 in the word "incentives" there. There's the
6 economic incentive. There's also the ease of
7 administering the same agent and inventorying the
8 same agent in your practice for all patients that
9 you see.

10 The complication has been the action of the
11 other stakeholder group that you mentioned in the
12 second question, is insurers. Insurers have
13 increasingly used their leverage, basically, to be
14 able to say we're only going to allow pharmacy
15 adjudication of some drugs, and we're either going
16 to, quote/unquote, "white bag" or we are going to
17 supply through our affiliated specialty pharmacy or
18 our network specialty pharmacy's drug to a
19 practice.

20 That further complicates this issue of the
21 provider incentive because now the provider, if you
22 put yourself in their shoes, is stuck saying I have

1 this inventory of drug that I contracted the best
2 rate possible. I'd like to give it to all
3 patients, but I can't use it for everyone. I'm
4 required to accept drug from a specialty pharmacy
5 and administer to patients and bill just for my
6 services rather than billing for the drug.

7 So the provider incentives vary a lot, and
8 the complications on their business and how they do
9 their drug inventory and all that can't be
10 basically overstated. I mean, it's a huge issue
11 for many of these practices.

12 The last thing I'll say before I give others
13 a chance to comment about the insurer role, there's
14 both the supply chain aspect and then this idea
15 that they're not going to allow providers to
16 contract and bill them for whatever version of
17 drug, the incumbent or the biosimilar, the original
18 biologic or the biosimilar.

19 There's that issue, and they will,
20 quote/unquote, again, "deliver or white bag" drug
21 to the practice, and that's more a common practice
22 now than it was five years ago for sure. I can't

1 give you a percentage because it's definitely
2 different region by region.

3 The other issue for insurers is this whole
4 idea of fail first and being able to use
5 utilization management and prior authorization,
6 which is much more streamlined than it was, but
7 much more omnipresent I guess on the medical
8 benefit than it used to be.

9 PA is used on the medical benefit a multiple
10 of where it was five years ago. It's always been
11 used extensively, as I think everyone is probably
12 aware, on specialty pharmacy drugs on the pharmacy
13 benefit, but it's much more common on the medical
14 benefit now as well. So insurers are really using
15 that as a way to drive their preferred product
16 strategy.

17 MS. TEMKIN: Can I ask a little bit of a
18 follow-up question? I'm going off script, so
19 forgive me.

20 Just to tie it back to some of the
21 discussion about interchangeability and where that
22 fits in, how does the avenue of interchangeability

1 versus biosimilarity impact some of the incentive
2 structures, if it does?

3 MS. BURICH: I think it's a really important
4 question. I think this is why I think your
5 question is quite apropos on why this medical
6 benefit versus pharmacy benefit is such a
7 significant difference, and therefore impacts the
8 overall flow of incentives and everything else.

9 I think when you think about an
10 interchangeability designation, your physician does
11 not have the same financial skin in the game as
12 they do on the medical benefit side because, again,
13 interchangeability is very likely tied to products
14 that have that pharmacy interaction, so that
15 inherently changes the incentive structure because
16 physicians aren't inventorying and managing the
17 cost of those drugs.

18 DR. SINGH: I'm going to paraphrase what you
19 said. I think that was really good. I think
20 substitutability, substitution, as a result of
21 having interchangeable designation for a practice,
22 when they have all the issues that I was just

1 talking about with inventory and so on, they've
2 already chosen what they're going to procure and
3 gotten best price on what they're going to procure
4 and stick in their inventory.

5 Forget the white bagging that gets sent to
6 them on a patient-specific basis to get
7 administered. They've already chosen, and they're
8 going to prescribe that specific agent. So
9 interchangeability basically does nothing in that
10 case.

11 Under the medical benefit, when you've
12 chosen what you're going to inventory, and you're
13 the big practice, and you have 40 sites to manage,
14 and everybody got shipped out the same version of
15 pegfilgrastim now, and it's a biosimilar, that's
16 what they're going to prescribe. It's in their
17 EMR, it's in the protocols, et cetera.

18 Flip it over to the pharmacy benefit side,
19 and now interchangeable really matters because it's
20 specialty pharmacy. If I'm the specialty pharmacy,
21 it's only going to ship out what is my preferred
22 product, and I can only do that if the pharmacist

1 in my specialty pharmacy has the right to
2 substitute. They get the right to substitute,
3 without having to go back to the provider to, to
4 the prescriber, if they have the interchangeable
5 designation.

6 So on the pharmacy benefit with drugs, it
7 really matters. You'll see, I think, a completely
8 different uptake curve, adoption curve, on the
9 pharmacy benefit because of interchangeable
10 designation. It'll make virtually no difference on
11 the medical benefit side.

12 MS. SIMMON: Just before I move on, I think
13 we'd be remiss if we didn't talk about some of the
14 legislative proposals out there around provider
15 incentives. There is a bill to increase the
16 reimbursement for providers in Part B from ASP plus
17 6, the average sales price plus 6 percent of the
18 reference biologic ASP; to increase that by
19 2 percent to ASP plus 8. We know the ASP plus 6,
20 some of the folks are I think wonky in the audience
21 and know that sequestration impacts that, so it's
22 not a true plus 6.

1 This is interesting and useful, but I think
2 ultimately a limited opportunity to try to increase
3 provider incentives. What we support -- many of us
4 here at the table support, that might have a longer
5 term benefit -- is the opportunity to do a shared
6 savings program.

7 This practice, which is known as gainsharing
8 in Europe and has had success there, would allow
9 the provider, and in some cases could be extended
10 to the patient, to share in the savings that a
11 biosimilar provides to the Medicare program. So
12 taxpayers, providers, and patients could benefit
13 from the shared savings, which would also increase
14 utilization and uptake of biosimilars.

15 These are some opportunities, and shared
16 savings is something that can be done
17 administratively right now by the administration
18 via CMS and could also be a legislative proposal
19 and has been introduced as an amendment to current
20 legislation and introduced today. I think we're
21 expecting a bill to be dropped today on that.

22 So these are some, again, opportunities

1 outside the FDA-FTC purview or our ability, but
2 that could have a significant impact.

3 MS. ANDRUS: What educational efforts to
4 support biosimilars have worked well? What
5 educational efforts are needed to counteract
6 misinformation being published about biosimilars?

7 MS. BURICH: I'll start. The materials that
8 the commissioner referenced earlier have been
9 tremendously helpful and important for all
10 stakeholders, physicians, and patients.

11 I think the materials that have been
12 developed by the agency are very palatable. They
13 take complex concepts from A to Z, from biologics
14 all the way to biosimilars and interchangeables,
15 and really try to break it down in a way, depending
16 on where you sit in the chain of using a product,
17 that you can consume that information in a way
18 that's reasonable.

19 While I hate to add to the list of the
20 FDA -- and I'm looking at Sarah and Eva -- I think
21 that we do need more education from the FDA. I
22 think the education that's been developed thus far

1 was tremendously helpful.

2 It also brings a validity and an
3 impartiality coming from the FDA, and I think we
4 need to see that specifically around some of the
5 topics we've already talked about, the
6 interchangeables, what they are, what they aren't,
7 where they fit in terms of the product specifics as
8 we've talked about on this panel, and also where
9 physician-led switching can and should play an
10 important role for products that don't and will not
11 have an interchangeable designation for all the
12 reasons that we've talked about today.

13 I think that we've seen a tremendous amount
14 of resources that the FDA has put out, and we would
15 love to see a few more that are focused on a few
16 emerging areas because they are so important to
17 have that voice and those tools from a trusted and
18 reliable source like the FDA.

19 MS. ANDRUS: So we're down to our last
20 couple of minutes, but I wanted to throw out one
21 question about what we can learn, lessons learned
22 both from the generic industry, our experience

1 there, and what, if anything, we can learn about
2 the European experience with biosimilars.

3 MS. SIMMON: Real quickly, I'll touch on the
4 parallels to the generic experience. I think we do
5 see some parallels, but there are significant
6 differences. When generics were introduced in
7 1984, there was slow uptake.

8 I just saw something with one of my
9 documents from 2006, back before I needed to wear
10 glasses to read them. I was talking at a
11 conference saying generics were 56 percent of the
12 drugs dispensed, so now generics are 90 percent of
13 the drugs dispensed.

14 Will we see that with biosimilars? That's
15 not completely likely, but the uptake did take some
16 time. There was misinformation. There were the
17 same efforts to mire generics in patent litigation,
18 and that goes on today.

19 So it's sort of the same playbook. Change
20 can be hard. And while we all applaud and
21 appreciate innovation, what comes with that is that
22 some companies go to great lengths to protect their

1 ability to charge monopoly prices and prevent
2 competition. So we will continue to, I think, make
3 progress in the biosimilars area, and I think we
4 have already made progress so far, but we'll
5 continue that.

6 I think the substitution interchangeability
7 issue remains one of the thorniest because generics
8 were always designed to be substitutable and
9 interchangeable. So that's a difference that we'll
10 have to continue to work to overcome.

11 MS. BURICH: I would just say from a
12 European experience, I think what's probably most
13 important is that while the European pathway across
14 the countries of Europe has existed longer than the
15 United States pathway, the countries across the EU
16 really took a very active role, in a lot of
17 different ways, to drive a robust and sustainable
18 biosimilar market.

19 You have countries who are implementing
20 shared savings or gainsharing programs, doing
21 robust educational dialogue between physicians and
22 patients, and setting up incentives across the

1 supply chain. And again, while the systems that
2 exist over in Europe look very different than the
3 systems we have here, there are some important
4 lessons around market preparedness that we can and
5 should be implementing now to get this market
6 moving in a very positive direction to really
7 generate those savings and improve access.

8 MS. TEMKIN: I would just add from my
9 slightly different lens on all of this -- and I was
10 not here during the early days of the generics.
11 Don't worry; I was doing something else.

12 I think the people that are working in the
13 agency on biosimilars and on these issues have had
14 a takeaway of the importance of educational
15 outreach and the importance of engaging market
16 questions and incentives so that we can understand
17 and do the best that we can to try to build a
18 similarly robust structure for our different
19 products.

20 DR. SINGH: I guess my one quick
21 comment -- taking a step back to the macro issue of
22 trying to use biosimilar introduction and all this

1 competition to be able to create some headroom,
2 basically, to pay for all of the new innovative
3 treatments within your premium dollar with your
4 insurance plan -- I have a lot of hope.

5 I guess parallel to the generics industry,
6 even though we've harped on and had this refrain
7 about the difference between the benefits, and even
8 on the medical side, more competition is better,
9 it's going to help us drive prices down. It gives
10 you a better ability. Even though it's splintered
11 in different health systems, you can procure
12 differently to drive prices down. So I have a lot
13 of enthusiasm that we're going to achieve the
14 long-term goals and create that headroom that I was
15 just talking about.

16 MS. ANDRUS: Thank you very much. We thank
17 our panel, and our next panel will begin at 10:30.

18 (Applause.)

19 (Whereupon, at 10:16 a.m., a recess was
20 taken.)

21 MR. SCHILLER: Well, good morning. We're
22 going to begin the panel now on FDA and FTC

1 Approaches to Help Ensure Truthful and
2 Non-Misleading Advertising and Promotional
3 Communications. I'm Lowell Schiller, and I'm the
4 principal associate commissioner for policy here at
5 FDA.

6 As we've been discussing this morning,
7 biosimilars can offer significant benefits in terms
8 of competition and patient access. But for those
9 benefits to be fully realized, it's critical that
10 patients, healthcare providers, and others in the
11 healthcare system have an accurate understanding of
12 what biosimilars are and aren't and how they fit
13 into the overall armamentarium of therapeutic
14 options.

15 That's why as FDA has been implementing our
16 biosimilars program, we've made education and
17 engagement a critical part of our efforts. We also
18 recognize that sometimes incorrect or misleading
19 information may be disseminated about drug
20 products, including biosimilars, and that
21 misinformation can have negative consequences for
22 the public adoption of biosimilars, for the public

1 health, or both.

2 For example, if a biosimilar manufacturer
3 falsely states that its product is identical to the
4 reference product when in fact it's not, that can
5 mislead patients, providers, and others. On the
6 flip side, we've seen troubling examples of
7 biological reference product manufacturers
8 disseminating information that could frighten
9 patients and healthcare providers away from using
10 biosimilars.

11 For example, we've seen communications that
12 could sow seeds of doubt by suggesting to patients
13 and healthcare providers that biosimilars are less
14 safe or less effective than their reference
15 products, or that there may be clinically
16 meaningful differences between a biosimilar and its
17 reference product when in fact a biosimilar cannot
18 be licensed or marketed unless it's first been
19 established that there are no clinically meaningful
20 differences from the reference product.

21 Some of these communications may avoid
22 making overtly false statements, but even material

1 without an overtly false statement can be
2 misleading. For example, if it selectively deploys
3 a series of statements, which may be true in
4 isolation and perhaps omits other important
5 information, it's possible for the overall message
6 to be misleading and potentially harmful to the
7 public health.

8 We've seen this trick before. After the
9 Hatch-Waxman amendments passed in 1984 and American
10 patients were starting to learn about and accept
11 generic drugs, some manufacturers of branded drugs
12 disseminated materials to scare patients from using
13 generics, for example, by creating the false
14 impression that these drugs were less safe, or
15 weren't therapeutically equivalent, or were
16 inadequate in other ways. Some of the
17 communications we're seeing today about biosimilars
18 use the same old play from the same old playbook.

19 In looking at what's happened on the generic
20 side, the good news is that patients and healthcare
21 providers have come to learn the value of generic
22 drugs, and the adoption rate has been overwhelming,

1 as we've heard. I believe we're also on a path to
2 a more vibrant biosimilars market, and part of how
3 we get there is by encouraging truthful and
4 non-misleading communications and by addressing
5 misinformation in the marketplace.

6 We can do that in several ways. One is
7 through our own education efforts. Another is by
8 making our expectation clear that manufacturers cut
9 the shenanigans. We have a system of balancing
10 innovation and competition that has worked very
11 well for many years. The system incentivizes
12 innovation through patents and market exclusivity,
13 but with the expectation that after a limited
14 period of time, there will be a real opportunity
15 for follow-on competition to take hold.

16 Brand manufacturers obviously have financial
17 incentives to try to stave off follow-on entry, but
18 when they do so through deception or regulatory
19 gainsmanship, it undermines our system for
20 balancing innovation and competition, and
21 ultimately we risk undermining the promise of
22 biosimilars.

1 In some cases, other forms of government
2 intervention may be appropriate. If a
3 communication about a biosimilar crosses the line
4 and presents information that's false or
5 misleading, it may be appropriate for the
6 government to act. Both FDA and FTC have certain
7 tools and authorities to encourage truthful and
8 non-misleading communications about drug products,
9 including prescription biological reference
10 products and biosimilar products.

11 Our panelists today will be providing an
12 overview. Now, speaking today we have Dominic
13 Cirincione, who's a regulatory counsel in FDA's
14 Office of Prescription Drug Promotion or OPDP. He
15 regularly provides advice and regulatory counseling
16 on policy and compliance matters to both OPDP
17 reviewers and OPDP management.

18 Our other speaker is Richard Cleland, who's
19 assistant director of the Division of Advertising
20 Practices within FTC's Bureau of Consumer
21 Protection. He joined the Division of Advertising
22 Practices in 1991. His primary area of expertise

1 is in the advertising and marketing of
2 health-related products and services, obviously
3 relevant today.

4 So without further ado, Dom, do you want to
5 take it?

6 Presentation - Dominic Cirincione

7 MR. CIRINCIONE: Yes, thank you.

8 Well, good morning, everyone. As Lowell
9 said, my name is Dominic Cirincione. I've been
10 since 2017 a regulatory counsel with the Office of
11 Prescription Drug Promotion, and today I'm here to
12 present how FDA, and more specifically OPDP, helps
13 ensure truthful and non-misleading advertising and
14 promotional communications about prescription drug
15 products.

16 OPDP'S overarching mission is to protect the
17 public health by helping to ensure prescription
18 drug product information is truthful and
19 non-misleading and includes a fair balance of both
20 benefit information and risk information.
21 Prescription drug information includes promotional
22 communications as in prescription drug advertising

1 or promotional labeling made by or on behalf of a
2 drug manufacturer, packer, or distributor.

3 Generally, FDA and OPDP accomplishes this
4 through a comprehensive program, which includes
5 surveillance, compliance, education, and
6 communication with the public. Our compliance
7 tools include issuing warning or untitled letters
8 to manufacturers in regard to their disseminated
9 promotional materials that violate the Food, Drug,
10 and Cosmetic Act, and implementing regulations
11 concerning the promotion of prescription drug
12 products, particularly where the violation poses a
13 risk to public health.

14 FDA's authority over promotional
15 communications about a prescription drug made on
16 behalf of a drug's manufacturer, packer, or
17 distributor comes from the Federal Food, Drug, and
18 Cosmetic Act, or FD&C or FDCA.

19 More specifically, two primary or key
20 provisions on which FDA frequently relies are
21 Section 502(a) of the Food, Drug, and Cosmetic Act,
22 which relates to false or misleading labeling,

1 including promotional labeling, and Section 502(n)
2 of the FDCA, which relates to prescription drug
3 advertising.

4 FDA has also promulgated a number of
5 regulations related to both drug labeling and
6 prescription drug advertising in Parts 201 and 202
7 of Title 21 of the Code of Federal Regulations or
8 CFR. FDA and OPDP rely upon these statutes and
9 regulations throughout the course of our work.

10 OPDP helps to ensure truthful and
11 non-misleading promotional communications about
12 prescription drug products through a variety of
13 tools. As noted on our previous slide, that
14 includes a robust surveillance and communication
15 program with the public, and part of that
16 communication plan with the public includes OPDP's
17 response to industry's voluntary request for
18 comment on specific draft promotional materials.

19 This process allows OPDP to provide feedback
20 on draft promotional communications if the
21 manufacturer chooses to request it. This process
22 also allows for OPDP to engage with the

1 manufacturer on specific Communications prior to
2 their use in the public domain.

3 FDA and OPDP also provide guidance for
4 industry in areas related to promotional
5 communications. The guidance such as the most
6 recent guidance, the Q&A on biosimilar reference
7 product communications, provides the public with
8 FDA's current thinking on particular subject
9 matters, and many of these guidance documents are
10 informed, in part, by OPDP's social science
11 research program.

12 OPDP's research program is designed to
13 investigate applied and theoretical issues of
14 relevance to direct to consumer, or DTC, and
15 professional promotional prescription drug
16 materials.

17 OPDP's research supports the FDA's goal of
18 science-based policy while maintaining our
19 commitment to protect public health. And as
20 always, we invite the public to visit OPDP's
21 website to learn more about our social science
22 research program to determine more about the

1 studies that are being conducted and to review the
2 new research and progress.

3 OPDP also employs a robust surveillance and
4 compliance program to monitor compliance with
5 applicable FDA-administered laws and regulations.
6 For example, OPDP regularly attends conferences and
7 other events to observe industry promotion, as well
8 as reviewing the many promotional materials
9 submitted to the FDA by firms in accordance with
10 the postmarketing reporting requirements.

11 OPDP also reviews and investigates
12 complaints from healthcare professionals,
13 consumers, and competitors regarding violative
14 promotional materials in the public domain. And
15 while I'm on the topic of surveillance, I did want
16 to remind the audience and the public that OPDP's
17 BadAd program may also be used to report
18 potentially false or misleading prescription drug
19 promotion to FDA and to OPDP.

20 You may send an email to badad@fda.gov or by
21 calling the toll-free number, 1-855-RXB-ADAD.
22 Reports can be kept anonymous, however, we would

1 encourage reporters to leave their contact
2 information in case we need to follow up and
3 receive more information.

4 If as a result of our surveillance
5 activities we see an apparent violation of the
6 Food, Drug, and Cosmetic Act or implementing
7 regulations regarding promotional labeling or
8 advertising for a prescription drug, particularly
9 ones that pose a risk to public health, most
10 commonly we will send a warning or an untitled
11 letter to provide notice of the observation of the
12 apparent violation and then seek compliance.

13 The vast majority of our concerns are
14 typically addressed in this way, but if these
15 efforts to obtain compliance are not successful,
16 FDA can work with the Department of Justice to
17 pursue enforcement actions to address violations of
18 the Food, Drug, and Cosmetic act. These can
19 include, for example, seizures and injunctions.

20 To help you better understand FDA's role in
21 helping to ensure compliance with the Food, Drug,
22 and Cosmetic Act and implementing regs concerning

1 the promotion of prescription drug products, we
2 thought it would be helpful to provide you with
3 some of the more common issues FDA, and more
4 specifically OPDP, observes across all prescription
5 drug advertising and promotional labeling that
6 could render a presentation false or misleading.

7 While the issues I'm about to discuss do not
8 constitute an exhaustive list, FDA will most
9 commonly send a warning or an untitled letter to
10 provide notice of our observation of these kinds of
11 apparent issues and seek compliance.

12 Before I continue, I do want to remind the
13 audience that the agency's warning letters and
14 untitled letters are publicly available on the FDA
15 website, and each letter is also typically
16 accompanied by the violative piece, and the
17 application of FDA's authorities in this space is
18 necessarily fact specific. So the details of a
19 particular piece, including both its content and
20 the matter of the presentation, are important.

21 The first common issue OPDP often sees in
22 prescription drug advertising and promotional

1 leveling is a mission of risk information.
2 Promotional materials that include claims regarding
3 a drug's efficacy must also include information
4 regarding the important risks associated with the
5 drug.

6 For example, imagine a sales aid for a drug
7 that has a black box warning. The sales aid has
8 multiple pages of information regarding the
9 efficacy of the drug, but the black box warning
10 isn't presented anywhere in the sales aid.

11 The lack of this important risk information
12 about the sales aid that has numerous claims
13 regarding the efficacy of the drug would be
14 misleading. It's an omission of risk. It's
15 important to also note that the regulation
16 regarding omission of risk applies to all
17 prescription drugs, not just those of black box
18 warnings.

19 The second common issue related to the first
20 is the minimization of risk information in
21 prescription drug promotional materials. Risk
22 information must be presented with a prominence and

1 readability reasonably comparable to the
2 presentation of the efficacy information. Many
3 factors can impact prominence and readability; for
4 example, the size, the style, and color of the font
5 and layout of the piece and use of white space.

6 Imagine, for example, that your own ad
7 presents efficacy claims in large bold font with
8 colorful graphics, but the risk information,
9 however, is buried at the bottom of the page in
10 very tiny font with no headings or no signals in
11 any way to alert the reader to the presence of that
12 important information. This format in which the
13 risk information is not presented with comparable
14 prominence to the efficacy claims minimizes the
15 risks of the drug.

16 The third issue we often see in promotional
17 materials is an overstatement of the effectiveness
18 of the drug. Promotional materials would be
19 considered false or misleading if, for example,
20 they; one, overstate or exaggerate the
21 effectiveness of the drug; two, make claims
22 regarding the efficacy of the drug that aren't

1 appropriately supported or; three misrepresent data
2 from clinical studies.

3 For instance, if during a sales call, a
4 sales representative is promoting a prescription
5 drug product and the sales representative presents
6 a flyer which contains the claim "it works in as
7 little as 3 days," however, according to the
8 package insert, the primary endpoint in the
9 clinical trials used to support the approval of the
10 drug was "relief after 10 days," and there is no
11 available data or evidence to support a shorter
12 duration of treatment. Therefore, the claim
13 misleadingly suggests the drug works faster than
14 what has been demonstrated.

15 A fourth common issue often seen in
16 prescription drug promotional materials is
17 misleading drug comparisons. Claims or
18 presentations in prescription drug promotional
19 materials that suggest that a drug is safer or more
20 effective than another drug would be considered
21 false or misleading if they are not appropriately
22 supported.

1 For example, imagine at a conference there
2 was a promotional booth for a prescription drug
3 product. A bar chart on a convention panel at the
4 booth compares study results from the prescription
5 drug's package insert and study results from its
6 main competitor's package insert and includes a
7 claim stating that it showed improvement in
8 significantly more patients than its competitor.

9 This comparison would be misleading because
10 comparing the response rates for two different
11 drugs in two different studies does not support a
12 conclusion that one drug is safer or more effective
13 than another because, for example, these studies
14 may have been conducted in different patient
15 populations or using different clinical study
16 designs and methodologies.

17 Just to round out my presentation here, we
18 provided a graphical representation of observed
19 violations noted in OPDP's warning and untitled
20 letters for the last five years, from 2015 to
21 present, and although false or misleading claims
22 about the risks of drug products, or complete

1 omissions or minimization of risk information, are
2 the largest share of our observed violations and
3 letters since 2015, FDA does still take very
4 seriously false or misleading benefit claims about
5 drug products, including comparative claims that
6 lack adequate substantiation.

7 In conclusion, I hope this presentation
8 highlights some of FDA and OPDP's work to help
9 ensure truthful and non-misleading advertising and
10 promotional communications from manufacturers,
11 packers, and distributors of prescription drug
12 products. On this slide, please do find our
13 contact information, and thank you very very much
14 for your time.

15 I'm going to pass it over to Mr. Rich
16 Cleland, assistant director for advertising
17 practices in FTC's Bureau of Consumer Protection.

18 Presentation - Richard Cleland

19 MR. CLELAND: Good morning. I hope you hate
20 the morning after daylight savings time as much as
21 I do.

22 (Laughter.)

1 MR. CLELAND: If I fall asleep, give me an
2 elbow or something. I saw a lot of people doing
3 this, this morning.

4 This is not my usual audience. I more talk
5 to dietary supplement companies and OTC drug
6 companies, but I don't deal a lot in the
7 prescription space.

8 So this morning, I thought I would provide
9 you with a quick tutorial on what enforcement might
10 look like with regard to promotional material that
11 is communication that falls outside of the FDA's
12 jurisdiction. This includes promotional
13 communications that don't refer to a manufacturer's
14 or distributor's drug by name, as well as
15 promotional communications made through what
16 amounts to surrogates for the drug company.

17 As a threshold matter, the FTC's
18 jurisdiction only extends to commercial speech, and
19 I know I've seen some stuff out there that I really
20 question whether it would meet that threshold. We
21 look at a number of factors to determine whether or
22 not something is commercial speech, the content of

1 the speech and whether it contained a message
2 promoting the demand for a product or service.

3 It could also be denigrating a competitor's
4 product as well, whether the speech refers to
5 specific products or services, whether the speech
6 included information about the attributes of a
7 product or service such as type, price, or quality,
8 including information about the health benefits
9 associated with the product; the means used to
10 publish the speech; traditionally is it paid
11 advertising, is it recognized, and would it be
12 recognized by consumers as advertising?

13 Then finally, the speaker's economic
14 interest in motivation in disseminating the speech.
15 In this regard, context matters. For example, a
16 peer-reviewed scientific article or a press release
17 may or may not be considered commercial speech
18 depending upon how its disseminated and how it's
19 used.

20 Now, looking specifically at advertising,
21 assuming we get over the commercial speech barrier,
22 the FTC enforces two sections of the FTC Act that

1 are relevant here, Section 5 and Section 12.

2 Section 5 prohibits unfair methods of competition
3 and unfair deceptive acts or practices in commerce.
4 Section 12 prohibits the false advertisement of a
5 food, drug, and service.

6 False advertisement is defined under
7 Section 12 as an advertisement that is misleading
8 in any material respect, including the failure to
9 display material information. The FTC has provided
10 some gloss over these general principles. We don't
11 have all the statutes as the FDA has, but we think
12 these two statutes give us some pretty good tools.

13 A company is responsible for both express
14 and implied claims. In express claims, as you
15 heard some reference to this morning, the statement
16 says what the message is. They run the gambit
17 between express claims, virtual express claims, to
18 statements that few consumers would even consider
19 to convey a particular message.

20 With regard to determining add meaning, the
21 FTC's position is that extrinsic evidence such as
22 copy testing an expert testimony is not necessary

1 to establish implied message where the implied
2 claim is reasonably apparent on the face of the
3 advertisement.

4 Advertisements are interpreted based on the
5 net impression of the advertisement from the
6 viewpoint of a reasonable person in the target
7 audience. For example, the net impression of an
8 advertisement may be different depending on whether
9 the advertisement is targeted at a person suffering
10 from diabetes or a physician treating diabetic
11 patients.

12 Reasonable consumers you have to understand
13 don't read everything in an advertisement. They
14 read the headlines. They may read some of the
15 text. It is rare that a footnote in an
16 advertisement will ever alter the net impression of
17 an advertisement.

18 A reasonable interpretation does not have to
19 be an interpretation that's accepted by a majority
20 of the viewers of that ad. If a significant number
21 of consumers would take a message away from an ad,
22 the advertiser is liable for any misrepresentations

1 or deceptive content in that ad.

2 I think this is an important point,
3 particularly in this area of biosimilars. When an
4 ad conveys more than one meaning and only one only
5 one of which is misleading, the advertiser is
6 liable for the misleading interpretation, even
7 though a non-misleading interpretation of that
8 advertisement is possible.

9 In this regard, consider the general
10 statement that a biosimilar product is not
11 interchangeable with this reference product. A
12 very knowledgeable consumer might understand that
13 to mean that to receive the biosimilar instead of
14 the reference product, the consumer may need a
15 prescription from the healthcare prescriber written
16 specifically for that biosimilar product. That
17 would be a correct interpretation of that phrase.

18 However, a consumer, like I think most
19 consumers out there, relying on the common meaning
20 of the word "interchangeable" might interpret that
21 to mean that an approved biosimilar could not be
22 prescribed in lieu of the reference product, and

1 that would be misleading.

2 Claims can essentially run afoul of the FTC
3 Act in three ways. It can be a false claim, it can
4 be an unsubstantiated claim, and it also can be
5 deceptive because it fails to disclose a material
6 fact.

7 Looking at some specific claims now that
8 I've observed, for example, there are clinically
9 meaningful differences between a reference product
10 and a biosimilar or that the products are not
11 similar. Biosimilars may be highly similar to
12 their reference products, but there's still a
13 chance that a patient may react differently; the
14 biosimilar product is less safe or effective than
15 the reference product or that the reference product
16 is safer or more effective than the biosimilar.

17 These statements could all be potentially
18 challenged as false, as unsubstantiated, and for
19 the failure to disclose material information. The
20 particular remedies that are available to the FTC,
21 we also have on occasion used warning letters where
22 we thought education was an appropriate first step,

1 but we also have enforcement tools that don't
2 require us to go through the Department of Justice,
3 which gives us a great deal of flexibility. We can
4 bring our actions. These are either
5 administratively or we can use our Section 13(b)
6 authority and file them directly in district court.
7 Thank you.

8 Panel Discussion - Lowell Schiller

9 MR. SCHILLER: Well, thank you both. I
10 think we have time maybe for one question, so let
11 me start with this. We've just heard about two
12 different frameworks, I think, hopefully
13 complementary frameworks, for helping to ensure
14 truthful and non-misleading communications. I'll
15 ask both of you.

16 How do you see the recently announced
17 collaboration between FDA and FTC helping to ensure
18 the protection of public health and fair
19 competition in the marketplace with respect to
20 prescription biosimilar products?

21 Dom, do you want to start?

22 MR. CIRINCIONE: Sure. I think the

1 collaboration will showcase how FDA and FTC both
2 support and protect public health and competition
3 in the marketplace for prescription biologic
4 products. Our organizations I think have serious
5 concerns about false or misleading statements about
6 prescription drug products and biologic products
7 and the negative impacts on public health and
8 competition.

9 I think with these shared goals in mind and
10 using our respective authorities, FDA and FTC will
11 help to ensure that healthcare professionals and
12 patients receive truthful and non-misleading
13 information about biosimilar products. It leveled
14 the playing field to support biosimilar uptake and
15 I think facilitated more competitive marketplace
16 for everyone involved.

17 MR. CLELAND: Let me take a 42-second shot
18 at this. We're going to talk more about
19 competition later on in the program today, but just
20 focusing for a second on the consumer protection
21 side, together I think we can cover the whole
22 waterfront. I think the FTC is here to try to deal

1 with manufacturers or others that are trying to
2 avoid the FDA jurisdiction by using promotions that
3 aren't subject to your authority, so I think
4 together we can cover the full waterfront.

5 MR. SCHILLER: On that note, let me thank
6 you both for very helpful presentations, and I'll
7 try to keep us as on time as we can be. Thank you.

8 (Applause.)

9 MS. GRAY: Good morning. My name is
10 Caty [ph] Gray, and I'm the supervisor for the
11 advertising and promotion policy staff in the
12 Office of Prescription Drug Promotion or OPDP, as
13 you heard from both Lowell and Dom. I share Rich's
14 dislike of the Monday after daylight savings time,
15 so thank you to you all for being here and joining
16 in this important conversation.

17 I'm joined by Betsy Pepinsky and Dom
18 Cirincione to discuss FDA's draft guidance for
19 industry titled Promotional Labeling and
20 Advertising Considerations for Prescription
21 Biologic Reference and Biosimilar Products
22 Questions and Answers.

1 As Lowell mentioned, Dom is a regulatory
2 counsel in OPDP. Betsy is also an attorney, and
3 she works as a health science policy analyst in our
4 group, primarily focused on guidance and policy
5 development regarding prescription drug promotion.
6 I'm delighted that both of these experts are here
7 to speak on this important topic, and I'm going to
8 turn it over to Betsy to get us started.

9 Presentation - Elizabeth Pepinsky

10 MS. PEPINSKY: Thanks for that introduction,
11 and good morning. As Caty said, Dominic and I are
12 here to discuss the draft guidance that published
13 just in February of this year on Promotional
14 Labeling and Advertising Considerations for
15 Prescription Biological Reference and Biosimilar
16 Products Questions and Answers.

17 FDA issued the draft guidance to answer
18 questions that firms may have when developing
19 FDA-regulated promotional materials for their
20 reference products and biosimilar products and to
21 help ensure that these materials are truthful and
22 non-misleading. This draft guidance represents one

1 piece of the broader effort to address false or
2 misleading communications about biological
3 reference and biosimilar products and the negative
4 impacts of such communications on public health and
5 competition.

6 The draft guidance was issued by CDER's
7 Office of Prescription Drug Promotion in
8 consultation with CDER's Office of Therapeutic
9 Biologics and Biosimilars and in cooperation with
10 the Center for Biologics Evaluation and Research.

11 Again, OPDP's overarching mission is to
12 protect the public health by helping to ensure that
13 prescription drug information is truthful and
14 non-misleading and includes a fair balance of
15 benefit and risk information. Generally, FDA and
16 OPDP accomplish this comprehensive program, which
17 includes surveillance, compliance, education, and
18 communication to the public.

19 Starting with a bit of background on why FDA
20 issued this draft guidance, as the number of
21 biosimilars increases, we have started to see
22 promotional materials for some of these products

1 and get questions from firms on promotional issues
2 related to biosimilars and reference products. We
3 are especially concerned about promotional claims
4 and presentations that make false or misleading
5 comparisons between a reference product and a
6 biosimilar in a way that misrepresents the safety
7 or effectiveness of either of these products.

8 The goal for this draft guidance is to
9 discuss considerations to help ensure that
10 FDA-regulated advertising and promotional labeling
11 for reference products and biosimilars are truthful
12 and non-misleading.

13 The guidance covers promotional issues
14 involving both reference products and biosimilars,
15 but some questions are focused only on biosimilar
16 product promotion, and the guidance does not
17 discuss considerations unique to promotional
18 materials for interchangeable biosimilars.

19 In terms of the general requirements for the
20 content of FDA-regulated promotional materials for
21 reference products and biosimilar products, FDA
22 regulates promotional labeling and advertisements

1 by or on behalf of manufacturers, packers, and
2 distributors for prescription drugs, including
3 those that are biological reference and biosimilar
4 products.

5 Under the FD&C Act in implementing
6 regulations, these promotional materials must be
7 truthful and non-misleading, convey information
8 about a drug's efficacy and its risks in a balanced
9 manner, and reveal material facts about the drug.
10 All these requirements apply to promotional
11 materials for reference products and biosimilar
12 products licensed under Section 351 of the Public
13 Health Service Act, the same as they would apply to
14 any other FDA-regulated promotional materials for
15 prescription drugs.

16 When concerning promotional presentations,
17 whether a promotional presentation is truthful and
18 non-misleading involves a fact-specific
19 determination that takes into account such factors
20 as how the information is presented, the type and
21 the quality of the data relied on to support the
22 presentation, and the contextual and disclosure

1 considerations.

2 The draft guidance is intended to help firms
3 understand how to support and present information
4 in promotional materials for their biosimilars and
5 their reference products in a truthful and
6 non-misleading way.

7 How should firms identify reference products
8 and biosimilar products in promotional materials?
9 A biological product may be identified by its
10 proprietary name, proper name, or core name in
11 promotional materials, depending on the context in
12 which the product is being described.

13 When developing promotional materials for
14 their products, firms should carefully evaluate the
15 information presented in their materials to ensure
16 that in each instance a product is addressed, the
17 materials correctly and specifically identify the
18 product to which the information applies.

19 Clearly and correctly identifying the
20 relevant biological product or products in
21 promotional materials can help prevent
22 presentations that are inaccurate because they

1 attribute data or information to the wrong product.
2 It can also help the audience identify which
3 product or products are the subject of a particular
4 promotional presentation.

5 For instance, if a biosimilar's FDA approved
6 labeling uses the core name of the reference
7 product followed by the word "products" to convey
8 that a risk applies to both the biosimilar and the
9 reference product, it would be appropriate for
10 similar presentations about this risk and
11 promotional materials for the biosimilar to use
12 this nomenclature.

13 As another example, if promotional materials
14 include information from a study that used a
15 non-U.S. licensed comparator biologic or otherwise
16 mentioned such products, the non-U.S. licensed
17 comparator should be accurately identified as such
18 in the materials.

19 Questions 3 and 4 of the draft guidance are
20 focused on promotional considerations for
21 biosimilars and they address questions regarding
22 the inclusion of study data and information in

1 promotional materials for these products.

2 In its guidance entitled Labeling for
3 Biosimilar Products, FDA recommends that a
4 biosimilar's FDA-approved labeling incorporate
5 relevant data and information from the reference
6 product's FDA-approved labeling, and this includes
7 incorporating clinical data that supported FDA's
8 finding of safety and effectiveness for the
9 reference product in the biosimilars labeling.

10 If a firm wants to provide information from
11 studies that supported the licensure of the
12 reference product in promotional materials for its
13 biosimilar when this information is included in
14 both the reference product labeling and the
15 biosimilar labeling, the firm should refer to the
16 biosimilars labeling for this information.

17 For example, in the case where a biosimilar
18 is licensed for fewer than all conditions of use
19 for which the reference product is licensed, the
20 biosimilar's labeling generally will include
21 information from studies on the reference product
22 that is relevant to those conditions of use for

1 which the biosimilar is licensed. The firm
2 developing promotional materials for its
3 biosimilars should look to the biosimilar's
4 labeling for this information.

5 FDA has also recommended that the
6 FDA-approved labeling for a biosimilar generally
7 not include data and information from the studies
8 conducted to support a demonstration of
9 biosimilarity between the reference product and the
10 biosimilar.

11 We have heard that firms are interested in
12 communicating data and information from these
13 studies to healthcare providers and other
14 interested parties, however, and have questions on
15 whether and how this kind of information can be
16 presented in promotional materials for their
17 biosimilar.

18 If a biosimilar's FDA-approved labeling does
19 not include information from studies conducted to
20 support a demonstration of biosimilarity between
21 the reference product and the biosimilar,
22 promotional presentations of such information

1 should be consistent with the biosimilar's
2 FDA-approved labeling and be truthful and
3 non-misleading as described in FDA's guidance on
4 medical product communications that are consistent
5 with the FDA required labeling, which is referred
6 to as the CFL guidance in the draft guidance.

7 This guidance describes FDA's thinking when
8 examining a the consistency of a product
9 communication with the product's FDA-approved
10 labeling. It discusses how FDA determines whether
11 a communication is consistent with the product's
12 FDA-approved labeling and provides general
13 recommendations for conveying this type of
14 information in promotional materials in a truthful
15 and non-misleading way.

16 When information from the studies that
17 supported a demonstration of biosimilarity is not
18 included in the biosimilar's FDA-approved labeling,
19 firms should apply the principles outlined in the
20 CFL guidance if they include information from these
21 studies in promotional materials for their
22 biosimilars.

1 As generally discussed in the FDA-FTC joint
2 statement, ensuring that advertising and
3 promotional communications subject to FDA
4 regulation are truthful and non-misleading can help
5 to protect and promote public health by enabling
6 patients and healthcare providers to make decisions
7 based on the accurate information.

8 FDA is concerned that false or misleading
9 comparisons between reference products and
10 biosimilars in FDA-regulated promotional materials
11 can undermine public confidence in these products
12 and negatively affect public health.

13 What should firms consider when comparing
14 reference and biosimilar products in their
15 promotional materials? FDA's licensure of a
16 biosimilar means that the agency has determined
17 that a biosimilar is highly similar to the
18 reference product notwithstanding minor differences
19 in clinically and active components and that there
20 are no clinically meaningful differences in terms
21 of safety, purity, or potency.

22 FDA recommends that firms carefully evaluate

1 presentations that compare reference products and
2 biosimilars and avoid presentations that represent
3 or suggest that a biosimilar is not highly similar
4 to the reference product or that a clinically
5 meaningful difference in terms of safety, purity,
6 or potency exists between the products.

7 Although assessment of each promotional
8 presentation involves a fact-specific
9 determination, such presentations, including those
10 suggesting that the reference product is safer or
11 more effective than the biosimilar or that a
12 biosimilar is safer or more effective than its
13 reference product, are likely to be false or
14 misleading.

15 For example, a presentation suggesting that
16 a biosimilar is superior to its reference product,
17 based on a difference that is not clinically
18 meaningful between the rates of occurrence of a
19 particular adverse reaction observed in a study
20 that supported the demonstration of biosimilarity
21 between the two products, would be misleading.

22 It's also possible that individual

1 statements of accurate information could contribute
2 to a misleading presentation when provided in the
3 comparative context.

4 For example, in the case of a biosimilar
5 that is licensed for fewer indications than the
6 reference product, presentations that create the
7 net impression that the biosimilar is, in general,
8 less safe or less effective than the reference
9 product, simply because the biosimilar is licensed
10 for fewer indications than the reference product,
11 would be misleading.

12 Also, presentations suggesting that a
13 biosimilar is less safe or less effective than the
14 reference product in a particular indication,
15 because the biosimilar's licensure for that
16 indication was based, in part, on extrapolation,
17 would be misleading.

18 Promotional presentations about a
19 biosimilar's licensure, a biosimilar to a reference
20 product should accurately describe the biosimilar
21 product. For example, promotional materials for a
22 biosimilar that FDA has not licensed as

1 interchangeable should avoid creating the
2 impression that the biosimilar has been licensed as
3 interchangeable with the reference product because
4 this would not be accurate. Promotional materials
5 for a reference product should avoid creating the
6 impression that a biosimilar is less safe or less
7 effective than the reference product because the
8 biosimilar has not been licensed as interchangeable
9 with the reference product.

10 A biosimilar is not required to be identical
11 to the reference product in order to be licensed,
12 rather licensure as a biosimilar means that the
13 biosimilar has been found to be highly similar to
14 the reference product notwithstanding minor
15 differences in clinically and active components and
16 that there are no clinically meaningful differences
17 between the biosimilar and the reference product in
18 terms of safety, purity, or potency.

19 Therefore, representations or suggestions
20 that a finding of biosimilarity means that FDA
21 determined that the reference product and the
22 biosimilar are identical to one another generally

1 would not be accurate, but promotional materials
2 for a reference product should avoid presentation
3 suggesting that the biosimilar is not as safe or
4 effective as the reference product because it is
5 not or may not be identical to the reference
6 product.

7 I'll now turn it over to Dom to discuss the
8 examples talked about in the draft guidance.

9 Presentation - Dominic Cirincione

10 MR. CIRINCIONE: Great. Thank you, Betsy.
11 Thank you very much.

12 (Pause.)

13 MR. CIRINCIONE: Well, I'll just keep going.

14 Question 7 in the draft guidance provides
15 three longer examples to help illustrate some of
16 the general considerations discussed within it.

17 For the purposes of these examples, we used a

18 fictional biosimilar called NEXSYMEO and a

19 fictional reference product called JUNEXANT.

20 NEXSYMEO and JUNEXANT are both replicamab products.

21 The first example describes a scenario in
22 which a firm provides the route of administration

1 dosage form and strength of the biosimilar NEXSYMEO
2 in promotional materials for NEXSYMEO, and it
3 includes a claim that NEXSYMEO has the same route
4 of administration, dosage form, and strength of the
5 reference product.

6 FDA would not expect to object to this kind
7 of a presentation because it is supported by
8 NEXSYMEO's licensure as a biosimilar to JUNEXANT,
9 which is based, in part, on information showing
10 that NEXSYMEO has the same route of administration,
11 dosage form, and strength as JUNEXANT.

12 In the same materials, the firm includes a
13 claim that NEXSYMEO can be considered for patients
14 who are new to replicamab product therapy for the
15 treatment of a licensed indication and for patients
16 currently being treated with JUNEXANT for the same
17 indication.

18 The claim is supported by information
19 submitted as part of NEXSYMEO's application for
20 licensure as a biosimilar to JUNEXANT, including
21 data from a comparative clinical study that
22 included patients who underwent a single transition

1 from JUNEXANT to NEXSYMEO and patients who were new
2 to replicamab product therapy, which supported a
3 demonstration of no clinically meaningful
4 differences between NEXSYMEO and JUNEXANT. FDA,
5 again, would also not expect to object to this kind
6 of presentation.

7 The second example describes another
8 scenario in which FDA would not expect to object to
9 the presentation described. In this example, as
10 part of NEXSYMEO's application for licensure as a
11 biosimilar to JUNEXANT, FDA evaluated a comparative
12 clinical study that included patients treated with
13 a non-U.S. licensed comparator product to support a
14 demonstration of no clinically meaningful
15 differences between NEXSYMEO and JUNEXANT.

16 NEXSYMEO's firm wants to present data that
17 is not included in NEXSYMEO's FDA-approved labeling
18 about outcomes observed in that study. So the firm
19 develops a presentation that is consistent with the
20 recommendations in the CFL guidance, which Betsy
21 mentioned earlier, including recommendations on
22 appropriate scientific and statistical support.

1 The firm clearly and prominently provides
2 contextual information about the study design, the
3 methodology, the role the study played in the
4 biosimilarity evaluation, relevant data on
5 NEXSYMEO's FDA-approved labeling, and any material
6 limitations in that data. The firm also accurately
7 describes the comparator used in the study as a
8 non-U.S. licensed product. FDA, again, would not
9 expect to object to this kind of presentation.

10 Example 3 illustrates a presentation that
11 FDA would consider misleading, however, in this
12 scenario, promotional materials for JUNEXANT state
13 that in a clinical study, patients on JUNEXANT
14 experience a numerically higher overall response
15 rate than patients on NEXSYMEO JUNEXANT.

16 The basis for the statement is a comparative
17 clinical study that supported a demonstration of no
18 clinically meaningful differences in terms of
19 safety, purity, and potency between JUNEXANT and
20 NEXSYMEO.

21 Although this statement accurately conveys
22 the reference product's higher numeric overall

1 response rates observed in the study, the materials
2 do not disclose that this difference in response
3 rates was not statistically significant, and they
4 do not describe the study design or include any
5 other appropriate context.

6 By focusing on the numerical differences in
7 response rates, which was not statistically
8 significant, the presentation misleadingly implies
9 JUNEXANT is superior to NEXSYMEO. It also
10 misleadingly implies that there is a clinically
11 meaningful difference between the products when the
12 data presented in the promotional materials do not
13 support that conclusion.

14 How can firms request FDA review of draft
15 promotional materials? Well, FDA encourages firms
16 voluntarily to seek feedback on promotional
17 materials for reference products or biosimilar
18 products before their dissemination to follow the
19 current process for submitting draft promotional
20 materials to FDA for comment.

21 We remind firms that they are also subject
22 to the postmarketing requirements for submitting

1 promotional materials to FDA like all other
2 prescription drugs under Form 2253. Firms can
3 visit OPDP's website for more information on the
4 submission of promotional materials to FDA and for
5 general information on our regulation of
6 prescription drug and biological product,
7 advertising, and promotional labeling.

8 We remind firms that in addition to the
9 considerations specifically outlined in this
10 guidance, they should ensure that their
11 FDA-regulated promotional materials otherwise
12 satisfy all the applicable requirements from the
13 Food, Drug, and Cosmetic Act and FDA's implementing
14 regulations related to promotion for prescription
15 drug products.

16 Firms should also ensure that they comply
17 with the provisions obligating them to update the
18 FDA-approved labeling for their products to ensure
19 that the labeling is not false or misleading or for
20 any other reason.

21 This is a draft guidance, as you all are
22 aware, and as such, we are looking forward to

1 receiving and then reviewing the comments submitted
2 to the docket. As noted in the Federal Register
3 notice that announced the availability of the
4 guidance, in addition to the draft guidance itself
5 for comment, we also are seeking input on specific
6 promotional considerations for interchangeable
7 products as well.

8 Thank you very very much. I'll turn it back
9 over to Caty.

10 Panel Discussion - Catherine Gray

11 MS. GRAY: Thank you, Dom and Betsy. I
12 wanted to follow up with just a few questions for
13 you.

14 Dom, the draft guidance states that it does
15 not cover considerations you need for promotional
16 materials for interchangeable products. Does that
17 mean that the Q&A's in this guidance don't apply to
18 interchangeable products at all?

19 MR. CIRINCIONE: The guidance does not
20 address considerations unique to promotional
21 materials for interchangeables because FDA is still
22 contemplating what, if any, considerations are

1 unique to such promotional materials.

2 We are looking forward to the stakeholder
3 input regarding what, if any, interchangeable
4 specific promotional considerations exist and what
5 other considerations can help FDA-regulated
6 promotional materials convey truthful and
7 non-misleading information about interchangeables
8 for a variety or various audiences.

9 MS. GRAY: Thank you. I can echo Dom's
10 comments that we're looking forward to feedback
11 from our stakeholders on this topic as well.

12 MS. GRAY: Betsy, the examples throughout
13 the draft guidance suggest that an evaluation of
14 whether comparisons between reference products and
15 biosimilars are truthful and non-misleading can be
16 quite nuanced. Do you have any more advice on how
17 firms should approach these presentations and
18 promotional materials for the reference and
19 biosimilar products?

20 MS. PEPINSKY: Yes. FDA appreciates the
21 complexities around these types of presentations,
22 and as noted in the draft guidance, they do require

1 consideration of the specific facts. In general,
2 however, firms should keep in mind that whether
3 presentation is truthful and non-misleading
4 depends, among other things, not only on the
5 specific claims in isolation, but also the net
6 impression to which those claims contribute.

7 So we encourage firms to carefully consider
8 individual claims in a promotional piece, as well
9 as the presentation as a whole, considering the
10 overall impression it makes about the safety and
11 effectiveness of the product.

12 I would just note that we make the same
13 recommendation not only for firms evaluating
14 proposed comparisons between reference products and
15 biosimilars, but also for firms developing any
16 presentation in FDA-regulated promotional materials
17 for prescription drugs and biologics.

18 MS. GRAY: Thank you very much for your
19 attention to our panel. At this point, we're going
20 to wrap up for the morning session. I encourage
21 you to enjoy your lunch, and we will see you back
22 here at 12:15. Thank you very much for your

1 attention.

2 (Applause.)

3 (Whereupon, at 11:21 a.m., a lunch recess
4 was taken.)

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

1 A F T E R N O O N S E S S I O N

2 (12:15 p.m.)

3 MS. FALB: Thank you for your attention.

4 This panel is What's at Stake? The Benefits of
5 Competition. I want to let you know for this
6 structure, we've organized this panel into three
7 sections. There will be a presentation by one of
8 our panelists at the beginning of each section and
9 then some prepared questions and answers. The
10 sections we will cover our biosimilar markets
11 overview; the impact of biosimilar entry; and
12 barriers to biosimilar entry.

13 Before we get started, I would like to ask
14 the panelists to introduce themselves. I will go
15 first, and then we can continue to my left. My
16 name is Alison Falb, and I am a regulatory counsel
17 in CDER's Office of Therapeutic Biologics and
18 Biosimilars.

19 DR. HERNANDEZ: My name is Inma Hernandez,
20 and I am faculty at the University of Pittsburgh.

21 MR. BRILL: Hi, everybody. I'm Alex Brill,
22 and I'm a resident fellow at the American

1 Enterprise Institute.

2 MR. SCHMIDT: Good afternoon. I'm David
3 Schmidt. I'm an assistant director in the Bureau
4 of Economics at the Federal Trade Commission.

5 MR. SCHICK: Hello. I'm Andreas Schick.
6 I'm the director of economics at the FDA's Office
7 of Program and Strategic Analysis.

8 MR. AITKEN: Good afternoon. I'm Murray
9 Aitken. I'm executive director at the IQVIA
10 Institute.

11 MS. FALB: We're going to be starting with a
12 presentation of slides by Murray Aitken, so I think
13 we can pass you the clicker and hope for the best.

14 (Laughter.)

15 Presentation - Murray Aitken

16 MR. AITKEN: I'm going to spend a few
17 minutes just to frame out the overall biologics
18 market so that we can also understand biosimilars
19 in the context of the overall market and talk a
20 little bit about the market dynamics that we see
21 playing out based on IQVIA data and measurement of
22 the market, both on a dollar and a volume basis.

1 Just a comment about the data that I'll be
2 drawing from; this is data that we gather at IQVIA
3 from a variety of sources, including wholesalers
4 who track the flow of medicines, all types of
5 medicines, through the distribution system. We
6 also gather data from manufacturers who are direct
7 shipping their products.

8 We also gather data from retail pharmacies
9 for that part of the market. We also have access
10 to insurance claims data. So we tend to take a
11 360 degree-ish view of what's happening and
12 consolidate all of that to develop an overall
13 perspective of the market.

14 When we measure the size of a market in
15 dollar terms, we generally use what we call invoice
16 price, which is what we capture from wholesalers.
17 So you can think of it as list price, but it's
18 before the application of rebates and discounts,
19 which we know can be significant. However, we do
20 estimate the magnitude of the rebates and discounts
21 and other forms of price concessions that go on in
22 the marketplace.

1 So you'll see some of the charts where we
2 are using net prices, and when we say net, we're
3 looking at that from the perspective of
4 manufacturers, so the net amount that is received
5 by a manufacturer.

6 Let me summarize the points, and I've got
7 slides to support these. As we've already heard
8 today, biologics are a growing share of the overall
9 market, and certainly relative to small molecules,
10 we've got different dynamics playing out both on
11 what happens when a drug loses exclusivity front,
12 as well as the mix of new drugs coming out of the
13 pipeline through FDA approval and into the
14 marketplace.

15 When we look at the pipeline, particularly
16 the late-stage clinical development pipeline
17 products that are in phase 2 clinical testing or
18 later, it suggests that we're going to continue to
19 see the growth dynamic of biologics not only in
20 traditional biologic oriented therapy areas but in
21 other disease areas as well.

22 Biologics reach the market through multiple

1 channels and pay types, and this is where things
2 get complicated quickly as, again, you've heard
3 reference to this morning. I don't think we're
4 going to have enough time to go through all the
5 pieces of the market and all of the characteristics
6 and payment dynamics, but understanding at least a
7 relative size and importance of different parts of
8 the market we think is important in order to
9 understand not only what's happening in biologics,
10 but specifically in biosimilars as well.

11 We'll take a look at the dynamics that we
12 see play out in the small molecule part of the
13 market and then the large molecule or biologics
14 part of the market, and we look at this in a couple
15 of ways.

16 One is what share of the dollar value of the
17 market is subject to generic competition or
18 biosimilar competition for large molecules, and
19 then for that part of the market, what's the
20 relative volume dispensed or used as the generic or
21 biosimilar relative to the total use of those
22 molecules. Those are the two metrics that we use

1 to try to assess how the market is evolving.

2 Starting with the big picture, and this is
3 on an estimated net price basis, we've got a total
4 medicine market in nominal dollars of \$344 billion
5 in 2018. We're still polishing the 2019 numbers.
6 That total is up 21 percent since 2014. But you
7 can see in dark blue, the small molecule share has
8 fallen from 70 percent to 58 percent over this
9 5-year period, so all the growth is essentially
10 coming from the biologics part of the market at the
11 top, which has gone from about \$85 billion dollars
12 in 2014 to \$144 billion in 2018.

13 Again, that's a reflection of the shift in
14 science, the movement, the gradual movement towards
15 biologics in R&D, as well as the impact of the
16 entry of new competition when patents expire or
17 other forms of exclusivity expire.

18 If we just convert things to a real net per
19 capita basis -- we've made those adjustments to the
20 earlier numbers, adjusting for inflation and
21 adjusting for population growth -- the pattern is
22 similar, but I think it's also useful just to look

1 at the number at the top, \$1044 per person -- this
2 is in 2019 dollars, I believe -- that was spent on
3 all medicines of which \$435 was for biologics, up
4 from \$291 in 2014, and then the spending on small
5 molecules has fallen by about 12 percent.

6 So you've got a 50 percent growth in the top
7 of the chart and a 12 percent growth in the bottom
8 of the chart. That's why we're all here.

9 Just looking into the pipeline, the trend of
10 new drugs towards biologics will continue to grow.
11 Sometimes, frankly, it gets overstated. Right now,
12 about 40 percent of new drugs are biologic;
13 60 percent are small molecules. Not all innovative
14 targeted cancer treatments are biologics. There's
15 a good number of small molecules in there as well.

16 I do notice sometimes there's a little bit
17 of confusion as to what's biologic and what's small
18 molecule when it comes to innovative medicines, but
19 we show here a number of the therapy areas, again,
20 including ones that in the past have not been
21 particularly biologic oriented, and just show the
22 share of the late-stage pipeline in these disease

1 areas that is represented by
2 biologics or biotech products.

3 In terms of how these biologics reach the
4 market, and now I'm switching to an invoice price
5 level because, frankly, we don't have net prices at
6 the payer type or channel level, so we can only
7 estimate net prices at the overall market level.
8 On an invoice price basis, retail and mail
9 represents about 60 percent of the total biotech
10 market and 40 percent in non-retail.

11 On the right-hand side, we've got some of
12 the smaller segments of the market. So starting at
13 12 o'clock and moving clockwise, we've got the
14 retail and mail commercial payer market, which is
15 26 percent of the total; then we've got retail and
16 mail Medicare Part D market, an additional 17
17 percent; retail and mail Medicare Advantage, 5
18 percent; and then retail and mail managed Medicaid
19 at 8 percent; followed by retail and mail
20 fee-for-service Medicaid at 2 percent; and then
21 we've got 1 percent retail and mail cash.

22 Then continuing on, we've got the non-retail

1 part of the market, non-retail commercial hospitals
2 about 3 percent; commercial office site about
3 13 percent; and then non-retail Medicare
4 fee-for-service, 2 percent; followed by non-retail
5 Medicare Advantage, 11 percent; and non-retail
6 Medicaid and other, 12 percent.

7 As you see on the chart, these are
8 directional estimates. Frankly, I don't think
9 anyone has a good way of teasing out these
10 different parts of the markets, but I think it is
11 important and relevant to understand the different
12 segments of the market to the extent that there are
13 different incentives. There are different
14 reimbursement levels that play out in each of these
15 segments. I'm sure we'll talk about this as we get
16 to the discussion.

17 Just looking at the top 10 biologics that
18 are on the market as of September 2019, this is
19 invoice price sales. I just thought it was useful
20 to look at the cumulative invoice sales of these
21 drugs since they were launched and through
22 September of 2019. This is for the branded version

1 of the drugs if there's a biosimilar in the market.

2 As you can see, all the top 10 have
3 cumulative sales of more than \$40 billion. I also
4 just indicated the number of years since their
5 launch, which also speaks to these are pretty old
6 drugs by now.

7 I think we don't have quite enough
8 discussion about the extent to which there is a
9 next-generation treatment available in the case of
10 these molecules in particular and the extent to
11 which the dynamic of investing in and promoting a
12 next-generation of biologic, to the extent we're
13 going to see likely see more of that going forward
14 than we have in the in the past, where
15 manufacturers have not necessarily been
16 particularly motivated while they don't face
17 competition from biosimilars.

18 Just to wrap up in terms of what we see
19 happening, again, at the overall market level in
20 terms of the dynamics of generics and biosimilars,
21 this is our view of the small molecule market. The
22 bars are measuring the percentage of the small

1 molecule market that's accessible to one or more
2 generics by molecules, so we build this up molecule
3 by molecule. This is in quarterly view, and from
4 2014 to the fourth quarter of 2019 we're at 40
5 percent.

6 Basically, 40 percent of the value of the
7 small molecule market is subject to a generic, and
8 then the green bar at the top, when a generic is
9 available, it's dispensed in volume terms
10 96.5 percent of the other time. This is what we're
11 used to in terms of the small molecule market.

12 Here's the same view but now for biologics,
13 starting at q1 of 2013. So again, the bars show
14 what percentage of the value of the market is
15 subject to a biosimilar. You can see the
16 additional biosimilars entering the market. These
17 are not approvals; this is entering the market.
18 You can see that now 17.5 percent of the value of
19 the biologics market is now from molecules that
20 have one or more competitors as biosimilars.

21 The green line is tracking, again, the
22 volume share that the biosimilar has of the

1 molecule for which there is a biosimilar available,
2 and that of course goes up and down with the entry
3 of new biosimilars, so it resets the denominator.
4 But we're now at 20.2 percent of the volume of
5 biologics dispensed. When there's a biosimilar
6 available, it goes out as a biosimilar.

7 This is what we watch the most, I would say,
8 in terms of the impact and the uptake, at least
9 from a market dynamic perspective, a separate
10 discussion on pricing a course. But if we just
11 look forward a little bit, the dark blue bar here
12 and the green line are the same as on this chart,
13 just rescaled because we've introduced now the
14 biologic molecules for which a biosimilar has been
15 approved but not yet marketed, so that's the light
16 blue.

17 That includes adalimumab, etanercept, and
18 teriparatide, where there are biosimilars approved.
19 If you include those in the calculation, then we're
20 at 50 percent of the value of the biologics market
21 subject to biosimilars. Now, that won't actually
22 happen until 2023 or some time later, but it's a

1 sign of where we're going in terms of the overall
2 market place for biosimilars.

3 So with that, I will pause. Thank you.

4 MS. FALB: Thank you.

5 As we continue our conversation about the
6 biosimilars market, what aspects of that market are
7 most important to keep in mind, or would anyone on
8 the panel like to highlight?

9 MR. SCHMIDT: Sure. I'll take a first crack
10 at that. I'm going to adopt an unfamiliar position
11 for me, which is to caution against too much
12 pessimism. I think we see statistics like what
13 Murray put up, which are incredibly informative and
14 useful, but we shouldn't interpret it as evidence
15 that the biosimilars are a failure or are in some
16 way lagging way behind what these small molecule
17 generics have accomplished.

18 It's very early days for the biosimilars
19 right now, and it's also very early days for
20 economists and others to be analyzing these
21 markets. So we're still working on gathering good
22 data, and I know many of the people on this panel

1 are contributing to that and it's great to see.

2 But to get to the heart of the question, I
3 think what would be really useful would be able to
4 look at good comparison groups like how are
5 biosimilars doing relative to other drugs that are
6 paid for by the same types of payers in the same
7 dispensing settings and do we see a huge difference
8 there.

9 Is it something inherent about the payer
10 type or the dispensing setting that's causing the
11 innovator products to hold on to market share more
12 than they do for the stereotypic small molecule
13 drug dispensed at your local pharmacy?

14 I think, as of yet, we don't know the answer
15 to that, and I think some of these researchers are
16 pushing in that direction, and it's great to see.

17 But I think, obviously, it has been highlighted,
18 payer type is important, dispensing location is
19 important, and keeping that in perspective when
20 we're looking at some of this information I think
21 is incredibly important.

22 MR. BRILL: Just a quick addition or comment

1 on Dave's comment. First, I fully agree that we
2 can say we're in transition. We're not in
3 equilibrium at the moment. We are in the beginning
4 of a process and the market is continuing to
5 evolve.

6 The question that we're all wondering, I
7 think, is what will that equilibrium look like and
8 what can we be doing to make sure that it is as
9 robust a marketplace as possible? But these
10 snapshots are just that, snapshots in a moment as
11 we move towards a more robust market that's
12 evolving.

13 But I would also say that with regard to
14 trying to find comparators, there's, in my mind,
15 two ways to think about that. One, if I understand
16 correctly, Dave's comment is to try to find similar
17 scenarios in the small molecule world and look for
18 differences. I think that there are lessons to be
19 learned from those types of comparisons, but also
20 within the biologic/biosimilar marketplace by payer
21 type.

22 One of the things we know in the small

1 molecule generic space is that we have really high
2 utilization rates of generics pretty much all the
3 time. Shortly thereafter of a launch, we don't see
4 wide disparities by payer type and generics.

5 Another way to look at this in this market is to
6 say are there differences by payer type, or
7 location, or dispensing mechanism. I think it's
8 reasonable to think that there shouldn't be.

9 So not necessarily are we're going to
10 achieve the realization rates that we see in the
11 small molecule space; I think the competition
12 dynamics are different there. But there's no
13 reason in my mind -- and I'd be concerned if we saw
14 very different behaviors in the Medicaid market
15 than we see in the Medicare commercial market.

16 MS. FALB: Following up on that point, are
17 there important differences? It sounds like you
18 don't think that there should be, but perhaps there
19 are between biologics and expensive small molecule
20 drugs that might impact their respective markets.

21 You can take it or someone else can take it.

22 DR. HERNANDEZ: Well, I think -- and I'm

1 going to try to tie it with what I'm going to say
2 in the next few slides -- it comes back to
3 financial incentives. We know that we usually
4 reimburse for generics based on a maximum allowable
5 cost, so then pharmacies can dispense whichever
6 generic they want because everything is going to be
7 at the same level.

8 For that reason also, discounts don't play
9 an important role in the small molecule generics.
10 We have basically brand names with high-list prices
11 and rebates higher or lower, and then we have
12 generics where there's transparency, and the list
13 price is more representative of what we're paying.

14 I'm going to talk a little bit about how
15 that's very different for biosimilars, and I think,
16 especially for the drugs that go through the
17 pharmaceutical benefit, that's an important
18 differentiation with small molecules, how we're
19 paying for them and how we're going to continue to
20 pay for them. If biosimilars are not
21 interchangeable, we cannot pay all of them in a
22 similar way as we're paying for generics, and

1 that's a differentiation that is important to make,
2 I think.

3 MS. FALB: I think we can use that as a
4 segue to your presentation.

5 Presentation - Inma Hernandez

6 DR. HERNANDEZ: I'll get started in the
7 meanwhile and say that I'm going to present a
8 couple of studies that we've done in my research
9 group around biosimilars. The first one of them,
10 we're going to describe what happened to prices of
11 originator biologics when they're faced by similar
12 competition.

13 On the second of them, we're going to talk
14 about financial incentives in Medicaid in the
15 uptake of the biosimilar for Lantus, that I know is
16 not a true biosimilar because it was not approved
17 through a biosimilar pathway, but for financial
18 incentives, works in a similar way.

19 So let's start with the first one. I'm so
20 happy the slides are working. Here we looked at
21 all originator biologics that faced biosimilar
22 competition by December 2018. Again, when I say

1 biosimilar competition, I also include within
2 molecules substitutes that were not approved
3 through the biosimilar pathway. We had the four
4 that are listed on the slides.

5 Here, we wanted to look at what happened to
6 net prices, list prices, and discounts before and
7 after the launch of the biosimilars. I know that
8 Murray already introduced the contents of list
9 price, but I'm just going to go through them again
10 because it's important to know what's in the net
11 price.

12 List prices represent what wholesalers are
13 paying to pharmaceutical manufacturers, but we know
14 this doesn't represent the whole picture. If we
15 have a drug covered through the pharmaceutical
16 benefit, the wholesaler will sell the drug to the
17 pharmacy that will dispense the drug to a patient.
18 We often have patient insurance plans, and the
19 health insurer will reimburse the pharmacy through
20 a pharmaceutical benefits manager.

21 Often pharmaceutical benefits managers and
22 health insurers negotiate formulary placement with

1 the pharmaceutical manufacturers for discounts or
2 rebates. These discounts are proprietary
3 information because they are confidential, so they
4 are not available to us for research or for any
5 other purpose.

6 However, we found out a few months ago that
7 there is an investment firm called SSR Health that
8 tries to calculate discounts using company reported
9 sales to stakeholders. Since these data come from
10 company reported sales, they are only available for
11 drugs manufactured by publicly traded companies, so
12 we will not have BI or Purdue Pharma for instance.

13 The denominator to estimate net comes from
14 Symphony Health, and it tries to estimate all the
15 units sold in the U.S. in a given quarter. Because
16 of this calculation, net represents the average
17 amount that pharma gets per unit of product, and
18 this is net of all discounts, not only rebates to
19 payers but also coupon cards, 340(b), discounts to
20 federal service, anything that you can make. Using
21 this net price, the discount is estimated as the
22 difference, and they are able to separately

1 estimate discounts in Medicaid and in other payers.

2 I'm not going to present another paper where
3 we've validated the data, but we got last week in
4 JAMA a big paper using all of these, and we showed
5 in very comprehensive sensitivity analyses how this
6 data is pretty robust to the research. So if you
7 are wondering about the validity, I'll refer you to
8 that.

9 Now I'll show you the results of this one.
10 This is for filgrastim. You can see that list and
11 net prices increase in parallel until 2013 or so.
12 Net prices for the originator biologic started to
13 decrease in 2015 around the time that Zarxio
14 reached the market, and this was driven by
15 discounts in payers other than Medicaid.

16 Obviously, the Medicaid discount was not
17 going to increase if the list price is not
18 increasing any further. You can also see how the
19 net price continues to decrease over time with the
20 entry of more competition.

21 For pegfilgrastim, we only have one data
22 point after biosimilar entry, so the data is not

1 very robust. But you can see a very similar story
2 where list and net prices increased in parallel,
3 and then once we have competition, list prices
4 stagnate and net prices seem to decrease.

5 This is infliximab, very similar. We see
6 list and net prices increasing in parallel until
7 2013. You can see that net prices have started to
8 decrease around 2013, which is a few years before
9 biosimilar entry. I would like to acknowledge that
10 there are many other factors in the market other
11 than biosimilars.

12 In this case Simponi Aria, which is a direct
13 competitor, was approved in 2013, so it's hard for
14 me also sometimes to say that all of these
15 decreases that we are seeing are just a product of
16 biosimilar competition. Anyway, you can see that a
17 few years later when biosimilars did come to the
18 market, prices continued to decrease.

19 Finally, these are the results for Lantus.
20 You can also see the net prices have started to
21 decrease before Basaglar was approved, but there
22 were other molecules in the long-acting insulin

1 market. I'm not sure of the direct competitors of
2 Lantus, really, but there's also been a lot of
3 social pressure against prices of insulin, so I
4 think there's also a lot of factors that play in
5 account here. All of these results were published
6 last year if someone wants to look at them in more
7 detail.

8 I think this shows, in general, as a
9 summary, the list price of originator biologics is
10 stagnated but did not decrease after biosimilar
11 entry, however, net prices did decrease. This was
12 driven by increasing discounts in payers other than
13 Medicaid.

14 I was asked to talk where the net prices
15 start to decrease before or after biosimilar entry.
16 In the case of infliximab and Lantus, we see that
17 they start to decrease before but, again, there are
18 factors at play in the market, so I don't want to
19 fully attribute these two biosimilars.

20 I was also asked to talk about the more
21 biosimilars that come into the market, the higher
22 the discounts we see. I think we don't have enough

1 data to answer that question yet. For instance,
2 for filgrastim, we see three competitors and net
3 prices have decreased substantially, but the
4 others, I have data to compare only half, one data
5 point after the entry.

6 So I think once we have more data, we'll be
7 able, really, to compare what's the difference in
8 net price between biologics that have seen three
9 biosimilars versus those that have seen one. But
10 again, I don't think this is a fair comparison
11 right now because I don't have enough to say that.

12 With that, we'll change pace to the second
13 paper, which is very similar. It looks at the
14 uptake of Basaglar in Medicaid. Since the passage
15 of the ACA, states collect rebates for drugs that
16 are reimbursed under Medicaid managed-care
17 organizations.

18 What does this mean? We have the same scale
19 that we had before, and this patient is covered
20 under Medicaid. In this case, it's under a
21 Medicaid managed-care organization that has a
22 contract with a state Medicaid agency. Before the

1 ACA, the rebates for the drugs used by this patient
2 could go to the MCO, which are the ones paying for
3 drugs.

4 After the ACA, the rebates for these drugs
5 go directly to the state. So basically the MCO is
6 paying the list price, but the rebates are going to
7 the state. This creates differential incentives in
8 the sense that states are incentivized to use drugs
9 that maybe have higher list price, but after
10 discounts have a lower net. However, MCOs are
11 incentivized to use drugs with a lower list price
12 because they don't see the rebate money, because it
13 comes back to the state.

14 In some cases, to promote the use of branded
15 products among MCOs, Medicaid and state agencies
16 are implementing preferred drug lists, which are a
17 compilation of drugs that they have to favor over
18 others.

19 Here, we look at the utilization of Basaglar
20 in 2018 before four types of states: states that
21 have fee-for-service Medicaid only; states that had
22 managed-care organizations but with carved-out drug

1 benefits, meaning the drug benefits were still paid
2 on a fee-for-service basis; states that had MCOs,
3 and the MCOs did not have to follow preferred drug
4 lists for insulin glargine; and finally, states
5 with MCOs where there were preferred drug lists for
6 insulin.

7 We looked at all the states with preferred
8 drug lists, and we saw that all of them that
9 included insulin glargine in the preferred drug
10 lists, they all preferred Lantus over Basaglar,
11 100 percent. The data to use these comparisons was
12 Medicaid drug list utilization data, which as you
13 may know is publicly available. The outcome was
14 the proportion of insulin units paid for insulin
15 glargine that was accounted by Basaglar.

16 Here you can see the results. You can
17 basically see that the market share of Basaglar is
18 close to zero in all the states, except for the
19 ones that have Medicaid managed-care organizations
20 that are not subject to preferred drug lists. In
21 the paper, we go a little bit further and we show
22 the correlation between the penetration of

1 managed-care organizations and the uptake of
2 Basaglar, and you can see that it's pretty
3 significant.

4 In summary, we only see a substantial uptake
5 of Basaglar in the states that have Medicaid
6 managed-care organizations that are not subject to
7 preferred drug lists. I think this is timely
8 because more states are implementing preferred drug
9 lists these months and these years, and they are
10 also including more drugs in the preferred lists.
11 Originally, many PDLs started just with the drugs
12 for hep C, but increasingly, they are implementing
13 more drugs that are subject to the preferred drug
14 lists.

15 As a summary of my presentation, I don't
16 think the biosimilars are showing they're exerting
17 some competition in the market. It does seem like
18 all the competition happens in the discount space,
19 so it's very important to not only look at what
20 happens in the list price but trying to use these
21 estimates, the same as Murray talked. The best
22 system we have is net prices because it's really

1 where we see the competition. That's all I have.

2 MS. FALB: Thank you.

3 When thinking about the impact of biosimilar
4 entry on the market, what impacts do we see or do
5 we anticipate that are positive, how do we further
6 those, which do we see or anticipate that are
7 negative, and what could be done to either minimize
8 or prevent them?

9 DR. HERNANDEZ: I always make this comment
10 when talking about list and net prices, and I'm
11 also going to make it here. I think it's good that
12 net prices are decreasing. I think that's always a
13 good sign now. It means that premiums are not
14 going to increase at least.

15 I'd still like to point out that there are a
16 lot of patients exposed to list prices. We know
17 that co-payments are usually based on list price,
18 and we know that patients on high-deductible plans
19 or without insurance, they're also exposed to list
20 price.

21 So as much as we like to look at the net
22 price data because it's probably a good sign now of

1 what payers are supposed to, I think we need to
2 remember that the patients that probably have the
3 most access barriers are the ones that are exposed
4 to list. So I think we still need to keep that in
5 mind that there's value in list price.

6 MR. SCHMIDT: I agree with that, but I would
7 also add that I think it would be useful to look
8 directly at what the patients are paying to the
9 extent that we have claims data sets that might
10 identify exactly what the incidence is on patients
11 and not just realize list price as a proxy for
12 that.

13 DR. HERNANDEZ: I forgot to say that. Yes.
14 We haven't looked at out-of-pocket payments yet,
15 but I would like very much to do so. But I'm
16 looking for a grant to do that, so if anybody's
17 interested in funding this type of work,
18 [indiscernible].

19 MR. BRILL: I'll just add that when we think
20 about the winners, we want to think, just as Inma's
21 presentation shows, that the effects across the
22 whole market on all the reference product prices

1 are relevant when we think about the savings. I
2 think this illustrates one of the real differences
3 in the market for biologics and biosimilars
4 relative to the market in the small molecule space
5 for brand and generic products.

6 We're seeing, at least initially, a very
7 different dynamic, where as we know in the small
8 molecule space, the reference products, the brand
9 products, are generally holding their price
10 constant when generics enter and giving up large
11 market shares, and we're seeing a very different
12 behavior among reference products in the biologic
13 space.

14 I think that that's interesting. I think
15 that that was unanticipated by many of the folks
16 who were trying to think about what the cost
17 savings in this market might be. But at the same
18 time, it may present challenges ultimately for the
19 desired maturity of this market because is it the
20 ability of the biosimilars to compete or is their
21 ability relative to the reference product, their
22 pricing relative to the reference product?

1 So there needs to be some opportunity for
2 them to earn back their large fixed-cost
3 investments, so there's a little bit of a tradeoff
4 in that dynamic.

5 MR. SCHMIDT: The thing I was really struck
6 by is it suggests to me that the competition here
7 is more similar to the classic brand-on-brand
8 competition that we see in small molecules, where
9 they don't generally compete on list price and do
10 compete on rebates and other sorts of discounts,
11 co-payment programs and such. I think that's an
12 interesting dynamic in this market.

13 MR. AITKEN: I think what we see is not so
14 much the distinction between the small molecule and
15 the large molecule, but it's more the distinction
16 of the payer type and the channel. This notion
17 that we've had for a while that biologics are
18 different, I think we need to get beyond that and
19 say more different payment types.

20 Fee-for-service Medicaid is different than
21 MCO managed-care Medicaid; that Part B and Part D
22 is different; that commercial is different than

1 Medicare and so on, and to look through that lens
2 at what's going on as opposed to is it a large
3 molecule or a small molecule, now that we have the
4 cohort of large molecules approved and able to
5 access the market that we didn't have three years
6 ago or five years ago.

7 MS. FALB: What impact do you anticipate
8 that the entry of interchangeables will have on the
9 market?

10 DR. HERNANDEZ: I think we discussed it this
11 morning. I think it will be important for the ones
12 covered under mostly the pharmaceutical side
13 because payers will be less concerned about rebate
14 traps. If they are interchangeable, you're going
15 to be able to virtually shift all of the patients.
16 So I think that will be a big improvement in that
17 sense.

18 Still, getting back to the point that we're
19 making, it's very important to think about how we
20 are paying for drugs and how we're going to pay for
21 interchangeable biologics and interchangeable
22 biosimilars.

1 MR. BRILL: I think that's right. I think
2 it's to be determined how the pricing works for an
3 interchangeable obviously because we don't have
4 them. As was discussed in the morning session and
5 as Inma just noted, it's only relevant, I think, in
6 the pharmacy space. But I do think there is the
7 potential for simplicity and reduced friction in
8 the market for an interchangeable biosimilar that
9 could facilitate higher uptake rates.

10 MS. FALB: Thank you. Alex, if you could
11 present?

12 Presentation - Alex Brill

13 MR. BRILL: Thank you very much, and thank
14 you, everyone, for being here this afternoon. I
15 was asked to speak about some of the barriers that
16 we see in the marketplace today for biosimilars,
17 and this is based on some work that I've done in
18 the last few years trying to identify, categorize,
19 and put in buckets these types of barriers. One of
20 the big themes there is there's not one, there's
21 many, and it's the cumulative effect of these
22 barriers that I think may be impeding the market to

1 some extent.

2 I want to talk about this from a broad
3 perspective when we think about barriers. I think
4 the first thought when we say "barriers" is we
5 think barriers are bad; they're things that are
6 blocking.

7 I want to step back a bit and say we need to
8 think about the barriers in the broadest terms
9 possible. There are some good barriers, as I'll
10 get into, and there are certainly many bad
11 barriers. And I think we're here to talk about the
12 bad barriers not the good barriers. But I think
13 it's important to recognize that barriers can be a
14 useful tool, can provide a service, and can provide
15 value, and then I'll talk about some of the
16 consequences and policy implications.

17 As I mentioned, when we say "barriers" I
18 think we think of that as being a negative. I want
19 to speak of two types of barriers. Besides just
20 being good or bad, we can think of barriers as
21 being barriers to entry and we can think of some
22 barriers as barriers to utilization. The

1 utilization barriers I think our uniformly going to
2 be bad. Once we have entry, we shouldn't be trying
3 to inhibit the utilization of a product that is
4 biosimilar and is less costly.

5 When we think about entry, just to be
6 honest, I think it's a little bit more complicated
7 and there are some appropriate barriers to protect
8 both the innovator, to some extent, and to protect
9 the consumer. That's not to say that all barriers
10 to entry are good but it's mixed.

11 So what kind of barriers might be
12 reasonable? Well, it's actually not controversial.
13 I think that patents are barriers and patents are a
14 valid and important part of this ecosystem here.
15 BPCIA created an additional barrier, an exclusivity
16 period.

17 I cut my teeth in this industry arguing over
18 this exclusivity period with a Duke University
19 professor named Henry Grabowski and the economics
20 of exclusivity, and I lost that battle. I would
21 have thought that seven years would have been a
22 sufficient period of time, but I also think that

1 it's true that zero isn't the optimal period and
2 that there's a balance to be struck.

3 I think this is important, in part, in the
4 policy context because oftentimes the disagreement
5 in policy circles between those who are interested
6 in creating barriers and those who are interested
7 in reducing barriers sometimes gets murky and there
8 can be some crosstalk. I think if we split this
9 debate, recognizing that there can be valid types
10 of barriers, we can disarm some of the debate, and
11 we can focus on those barriers that are negative
12 and adverse to competition.

13 Finally, I think there's another set of
14 non-controversial barriers, which is, in essence,
15 the approval process is a barrier. Of course it
16 is. It's costly, it's time-consuming, it's
17 uncertain, and it's for the safety and efficacy of
18 the product. It's in the interest of the patient.
19 We all recognize the importance of having high
20 standards. Even though those standards pose a
21 barrier, they are barriers that are yielding good,
22 good for both the patient of course, but good for

1 the market ultimately.

2 Then of course there are the bad barriers,
3 the barriers that we need to identify and root out.
4 Many of them were discussed this morning.

5 Christine Simmon described them in the first
6 session. They really fall across a whole host of
7 categories. Some of them are policy related and
8 some of them are more market-based. Some of them
9 are things that regulators could do better or
10 differently. They could try to reduce their
11 burdens that they're imposing on the markets.

12 Some may be things that agencies could
13 recognize as bad behavior in the market and they
14 can work to mitigate. A few of them are up here,
15 things like the contracting practices engaged in by
16 the payers that may favor in a near-term
17 arrangement a brand product, and thereby inhibiting
18 or discouraging the development or the maturing of
19 their biosimilar marketplace, and the rebate trap
20 that we've discussed earlier.

21 While I think that patents are an obvious
22 and good barrier in many senses, we should also

1 recognize that that's a tool that can and I think
2 has been abused, whether that's the thicket
3 or other strategies around patenting that are
4 merely about extending monopoly beyond a reasonably
5 fair period.

6 Then there are what I'd call knowledge- or
7 information-related barriers, and this may be
8 getting better. I think we're making progress on
9 this front, but I think we still have a lot of
10 education that needs to be done. I think the FDA
11 is doing a great job of late in trying to fill
12 those gaps, but we should recognize that those gaps
13 still exist and they are not comparable. We
14 haven't closed that gap the way we have I think in
15 the small molecule space with generic drugs.

16 When we think about what the consequences of
17 these barriers might be, the bad barriers, undue
18 barriers to biosimilar entry will have many
19 consequences, and I should say entry and
20 utilization have many consequences. We're
21 extending the monopoly rent period. That's what
22 happens when we don't have competition.

1 As was just discussed a moment ago in the
2 last presentation here, this can have implications
3 for the patient costs. It depends of course on the
4 benefit design, but the limits on competition are
5 going to mean both higher premiums and presumably
6 higher out-of-patient costs as well.

7 Also it's important not to think about this
8 in a binary sense of is there a competitor or not,
9 but the number of competitors is important, and we
10 saw that in Inma's presentation. The more
11 competition we can have for a given reference
12 product, the more discounting, both with respect to
13 the price of the biosimilar we should anticipate,
14 as well as the price of the reference product.
15 Together, those two prices are affecting the
16 average price for a given product and the cost to
17 the healthcare system in total.

18 Finally, there's I think a different type of
19 barrier that's also worth recognizing. What we can
20 do about it I think is tricky, and that's the
21 reality of uncertainty in the marketplace. I think
22 we've faced over the last decade a lot of

1 uncertainty, and we continue to face uncertainty in
2 this biosimilar market. It's getting better. I
3 think the work in the last year or so from the FDA
4 has helped provide more information. I think that
5 the number of products that have successfully gone
6 through the approval process creates some degree of
7 increased certainty and there's learning on both
8 sides in that regard.

9 There are uncertainties that remain, and
10 many of these are natural. They're natural in a
11 free and open market, but it is uncertain to the
12 biosimilar how the reference product is going to
13 behave. As I was mentioning a few minutes ago, I
14 don't think it was well anticipated that the
15 reference product prices were going to evolve in
16 the way that we've seen, and that has implications
17 for pricing strategies for biosimilars. That's an
18 uncertainty that over time will resolve itself as
19 we have more experience.

20 There are a set of uncertainties, again,
21 that can't necessarily be eliminated, but I think
22 we should strive to mitigate, which include the

1 legislative and regulatory uncertainties, the
2 degree to which, on either end, either at the
3 capitol or in the agencies, new policies are being
4 proposed, getting done, and not getting done.

5 These uncertainties impose costs and in fact can
6 encourage biosimilar manufacturers to wait. I
7 think that there's important economic literature
8 around uncertainty and the dynamic by which it
9 causes market participants to wait.

10 So if we ask ourselves why isn't more things
11 happening quicker, it's often because it may often
12 be the case that participants in the market are
13 saying if we wait, we'll know more about this
14 market in the future. So we can combat that by
15 trying to educate participants in the marketplace
16 and have quick and clear and certain regulatory
17 guidance.

18 All of this is to say -- in broad terms
19 again; these aren't action items -- that it's
20 important that we strive for an environment where
21 the biosimilar manufacturers can anticipate the
22 barriers that they're going to face. Barriers can

1 be okay, as I think I made clear, but they should
2 be predictable. So something like an exclusivity
3 period is a very definitive and clear barrier with
4 a specific duration. Things like patent thickets
5 are very unclear. So there's an incredible lack of
6 predictability if there's a sort of self-help
7 strategy that a reference product manufacturer can
8 pursue.

9 To the extent possible, policymakers should
10 try to minimize the costs related to approvals.
11 Again, there's a push and pull here. Of course
12 these barriers can be very valuable because they
13 ensure, I should say, that the products are safe
14 and are in fact similar, but that process we should
15 strive -- and I think we will achieve over time
16 streamlining in that process that will reduce those
17 costs; then finally, the education piece, I think,
18 the information gaps that exist in the marketplace.

19 It's not on this slide, but I think it's
20 also important for policymakers to recognize that
21 in an environment where there are impediments,
22 barriers, that there can be a justified case, at

1 least on a temporary basis, for incentivizing the
2 market to get over a hurdle. Because there are
3 these natural incentives for biosimilars perhaps to
4 wait, and for other market participants to wait,
5 there may be natural logic for prescribers to wait
6 before they start to prescribe biosimilars, to wait
7 for more information.

8 To help resolve some of these frictions in
9 the marketplace, I think it's worth
10 considering -- and this was also discussed this
11 morning -- incentive structures to try to help
12 boost the system to get over an initial hurdle, to
13 help address the information gaps, and to help
14 demonstrate the opportunities and efficiency gains
15 from the utilization of biosimilars.

16 These types of structures, whether it be the
17 Shared Savings Program or the ASP plus 8 program
18 that's been mentioned earlier, can help draw in
19 participants to the market, both on the
20 manufacturer side, as well as the payer and
21 prescriber side.

22 So I'll just wrap up. I'll say that many of

1 these barriers have dissipated over time,
2 particularly in the last couple of years as we've
3 seen more guidance. We're doing better, but I
4 think at the same time, there's still opportunities
5 for policymakers to be engaged. They shouldn't be
6 satisfied with the degree of competition we see in
7 this market place today and should be pursuing
8 policies to help further extend competition in the
9 biosimilar marketplace.

10 Panel Discussion - Alison Falb

11 MS. FALB: Thank you.

12 For the panel, which barriers do you think
13 have the greatest impact on the go or no-go
14 decision for a biosimilar manufacturer?

15 MR. SCHICK: I always think that there are
16 two really important barriers that are particularly
17 problematic in this space. The first one is
18 manufacturing these products consistently with good
19 quality and then to scale up that production. It's
20 just not as trivial in this market as compared to
21 the small molecule market. Of course our small
22 molecules are difficult to manufacture. The

1 biosimilars are just very difficult. It's hard to
2 get the Coca-Cola recipe, as some people refer to
3 it, right each and every time.

4 Another thing I think that is always
5 important to emphasize -- and Murray kind of
6 alluded to this in his talk -- is that this is a
7 very lucrative market. This is the up-and-coming
8 market for getting a high amount of sales.

9 There's a very extensive playbook that's
10 well established for incumbents for how you deal
11 with people not coming into your space and taking
12 away your sales. Unfortunately, the playbook
13 really benefits the incumbents very well. A lot of
14 manufacturers, they're on both sides of this aisle.
15 It's great when they're the incumbent and it's not
16 so great when they're not the incumbent, and how to
17 deal with that is very difficult.

18 One reason -- in addition to everything Alex
19 mentioned -- why we might be seeing so many
20 barriers is that people are fighting very hard to
21 keep their very lucrative cash cows to themselves
22 as long as possible.

1 MR. SCHMIDT: One thing I would add to
2 amplify Alex's point about education is that I
3 think one development that was very important in
4 getting small molecule generics such great
5 acceptance, obviously, was all the state
6 substitution laws. I think FDA can play an
7 important role in educating people and state
8 capitals about what the appropriate role is for
9 interchangeable and biosimilar products.

10 This is complicated stuff. Speaking as an
11 economist, it's very complicated stuff. To the
12 extent that we have scientists here that can help
13 state legislators understand appropriate rules for
14 substitution, I think that could be incredibly
15 helpful.

16 MR. AITKEN: I would add one comment. We
17 haven't really talked about markets outside of the
18 U.S., but as we recognize, we live in a global
19 world, and there is a relevance to the European
20 markets as it relates to decisions made by
21 manufacturers as to whether they will invest in the
22 production capacity and regulatory submissions for

1 additional biosimilars to come to market.

2 I think when we observe what's going on in
3 Europe, there's been a significant decline in the
4 prices there for biosimilars: heated competition,
5 use of winner takes all
6 price-based tenders and so on, all of which reduces
7 the attractiveness of that part of the market; and
8 it's not an insignificant share of the global
9 market for biologics and the potential for
10 biosimilars.

11 So there is an interconnectedness I think as
12 we think about what's it going to take for us to
13 have sustainable levels of competition in this
14 market. We need more than just one or two players
15 in biosimilars. We want to see 3 or 6 or 9
16 different types of competitors to make this market
17 really effective. To that extent, I think just
18 watching what's going on in other parts of the
19 world, in particular Europe, is also very relevant.

20 MR. BRILL: Just to add on to Murray's
21 point, what we've seen so far is competition in the
22 blockbuster market of biologics, and when we think

1 about what other barriers exist, this is a
2 high-fixed cost business. It's hundreds of
3 millions of dollars to get in, not millions of
4 dollars. And over time, I think there's a
5 technology piece that we need to see evolved so
6 that we can see competition in the smaller and the
7 lower size market space as well.

8 MS. FALB: Thank you all very much.

9 (Applause.)

10 MS. IKENBERRY: Hi. My name is Sarah
11 Ikenberry, and I'm the senior communications
12 advisor in CDER's Office of Therapeutic Biologics
13 and Biosimilars. I'm pleased to be able to discuss
14 a very important topic related to biosimilar uptake
15 and acceptance, and unfortunately it's not medical
16 extended reality.

17 (Laughter.)

18 MS. IKENBERRY: It is improving stakeholder
19 engagement, education, and understanding.

20 While we're working on the slides, I'll go
21 ahead and let you know that the objective of the
22 session will be to discuss some real-world

1 considerations surrounding biosimilars and how
2 healthcare providers' and patients' knowledge,
3 awareness, and perceptions regarding biosimilar and
4 interchangeable products can impact uptake and
5 acceptance.

6 I'm co-moderating this panel with Elizabeth
7 Jex, an attorney advisor specializing in
8 biopharmaceutical health policy in the Federal
9 Trade Commission's Office of Policy Planning. Just
10 to kind of give a brief sketch of how we'll work
11 this panel, I'm going to briefly introduce
12 everyone, and then I think give a quick
13 presentation about some of FDA's education and
14 outreach initiatives, and then I'm going to turn it
15 over to the panelists.

16 What's unique about this panel is that we
17 have one of our panelists beamed in from Canada,
18 and she will be presenting remotely, so I believe
19 that she will be on the screen. Her name is Cheryl
20 Koehn. She's from the Arthritis Community Experts
21 in Canada.

22 Do you know if Cheryl can hear us on the

1 line? Is her mic unmuted?

2 MS. KOEHN: I can hear.

3 MS. IKENBERRY: Oh, great. Wonderful.

4 MS. KOEHN: I can see myself. I'm not sure
5 you can see me there in the room, but I don't think
6 that matters, as long as you can hear me.

7 MS. IKENBERRY: Okay. Well, I think we'll
8 work to get your face on the screen as soon as we
9 can.

10 Cheryl is from Arthritis Community Experts
11 in Canada, and she is a patient that lives with
12 rheumatoid arthritis, and in over the last 30 years
13 has become a national patient community leader, a
14 patient research partner, and published author.

15 Let's see here. At the end of the table, we
16 have Michele Andwele. She's the editorial director
17 for health content at the Arthritis Foundation,
18 where she oversees the content strategy and
19 development of patient education materials.

20 We have Sameer Awsare, associate director
21 for the Permanente Medical Group in charge of
22 pharmacy, adult and family medicine, mental health,

1 and many other areas; I did not write them all
2 down; and Hillel Cohen, the executive director of
3 scientific affairs at Sandoz, where he helps
4 explain the principles of biosimilars and related
5 policies to the healthcare community, patient
6 advocacy groups, and other stakeholders. He is
7 also the co-chair of the Education Committee for
8 the Biosimilars Forum.

9 Just briefly, I'm going to give an overview
10 of our education and outreach efforts here at the
11 FDA that we've done. As noted by many on these
12 panels throughout the morning and the day,
13 education has been mentioned quite a lot.

14 Here at the FDA, we take this very
15 seriously, and we've been working for a long time
16 to help improve understanding of biosimilars among
17 patients, healthcare providers, and payers. We've
18 been doing this in a couple different ways, by
19 engaging with various stakeholders and developing
20 materials for the stakeholders to use.

21 The thing is that this requires
22 multistakeholder engagement. What that means is

1 that FDA can't do it alone. We can develop the
2 materials, but what we need is for these healthcare
3 provider organizations and patient stakeholders to
4 take them and disseminate them to the people.

5 People can take our materials and use them, however
6 they would like, to get the information to their
7 constituents.

8 This is just a snapshot of some of our
9 healthcare provider materials. We have an
10 infographic, various fact sheets, some ads, and
11 other web content. I'm not going to go into
12 details.

13 Most recently, we released some educational
14 materials for patients. It's a website and an
15 infographic that uses patient-friendly language, so
16 we really try to boil it down to the most important
17 concepts that are the most important to patients.
18 We tested this, reworked it, and tested it again
19 and reworked it. We're happy with this basic
20 foundational piece, but we are also working on a
21 lot more things.

22 This is just to build a foundation of basic

1 understanding that highlights the similarities of
2 biosimilars and reference biologics, and it
3 highlights the benefits of increased access, so the
4 goodness of biosimilars for patients, and access,
5 and hopefully lowering costs. It demonstrates our
6 efforts to always ensure the safety and efficacy of
7 biosimilars or just patients to talk to their
8 doctor and visit our site for more information.

9 As I alluded to, we are developing
10 additional materials for patients and healthcare
11 providers, and we're going to begin testing for
12 additional patient materials soon. Hopefully,
13 we'll be able to provide some real quality pieces
14 of video and some other information for patients
15 soon, in addition to developing additional
16 materials for healthcare providers.

17 As always, you can go to our website's
18 biosimilars page, our Purple Book, and drugs@FDA
19 for information.

20 I'm going to end that, and turn it over now
21 to Cheryl Koehn, from Arthritis Consumer Experts,
22 to provide her presentation. Thank you very much

1 for joining us, Cheryl.

2 Presentation - Cheryl Koehn

3 MS. KOEHN: Thank you very much, and I
4 apologize I'm not there in person. Given the
5 events of the day, it's probably a good thing that
6 I'm not. But I want to thank the FDA and the FTC
7 for organizing this important meeting, and I look
8 forward to hearing and learning from my fellow
9 panelists.

10 Can you hear me ok, Sarah?

11 MS. IKENBERRY: Yep, we can hear you great.

12 MS. KOEHN: Okay, great.

13 Following on Sarah's comment, I was
14 parachuted in from Canada to give you that
15 perspective. We're this little country just north
16 of your border --

17 (Laughter.)

18 MS. KOEHN: -- and most of our population is
19 sprinkled along the US-Canada border, so we're very
20 aware of the events that have been going on in the
21 United States with respect to biosimilars and have
22 been engaged in the conversation, as have you, for

1 as long.

2 This first slide really speaks to where we
3 come from as a patient organization. I've been a
4 person living with rheumatoid arthritis for the
5 past 31 years and have spent that past 31 years
6 volunteering and working in my community as a
7 health educator and deliverer of evidence-based
8 information.

9 We were the first to be invited into the
10 conversation around biosimilars, or on biosimilars,
11 nine years ago by Health Canada, by BIOTECanada,
12 and then subsequently by our provincial government.
13 The reason being, we are the largest arthritis
14 patient organization in the country with 50,000
15 members coast to coast, and Arthritis Research
16 Canada is our scientific partner. So everything we
17 do is based on the evidence.

18 You've seen my disclosures. I believe
19 they're on the website in my speakers bio. I am
20 employed by ACE full-time, but I'm here today as a
21 volunteer.

22 Truth to power is really an important piece.

1 Really, I think what's most important for this
2 audience to hear from us is, from the beginning, we
3 really clearly articulated what our patient
4 organization rules and responsibilities are. I
5 think that's a really important part of this
6 conversation when we speak about information and
7 education.

8 Knowing the truth and speaking the truth is
9 what we are all about. Operating independently and
10 disclosing all sources of funding in this
11 conversation, and in every conversation, about
12 therapies in particular given the dollars at stake,
13 is an absolute must. To consult incredible
14 independent clinicians and researchers, and most
15 importantly, our membership, is what is the bedrock
16 of the development of our materials.

17 So it doesn't come from the outside. It
18 doesn't come from being bombarded by advertising on
19 television. We feel that to be an honest knowledge
20 broker for your community, policymakers, and
21 payers, you have to actually be so morally solid
22 and have that north star firmly positioned in the

1 sky that you're willing to give up your own
2 financial health, if that's what's at stake, to be
3 credible.

4 To be reasonable and look beyond the needs
5 of your own organization, if it's the right thing
6 to do, is paramount, especially in this
7 conversation that is so shrouded by myth and by
8 many other things like litigation and so on and so
9 forth. I'm sure you've talked about those things
10 already this morning.

11 First, I think the most important thing that
12 we do as an organization is to follow the evidence
13 and then deliver the evidence. Our job as
14 knowledge translators is really to take the
15 evidence in a truthful way and reflect on its
16 impact, and then put that into language that is
17 accessible to our community. ACE does that by
18 developing free research-based information and
19 education programs that are relevant to not just us
20 but the patient at large.

21 Sarah touched on, very briefly, the
22 materials that the FDA-FTC have developed, and

1 they're fabulous. I think for the first time ever,
2 Canada was ahead of the United States. We launched
3 our information hub about biosimilars back in 2016,
4 and it remains one of those beacons for information
5 sources here in Canada and beyond.

6 I think one of the most important things
7 that you may talk about on this panel is the nocebo
8 effect. You have seen in this conversation,
9 patients have seen, and the public has seen on the
10 ground a whole lot of white noise. That white
11 noise is like concerns about safety and efficacy,
12 them not being identical, them not being
13 interchangeable. Those things are actually very
14 strategic when it comes to consumer-level
15 information delivered by, in many instances,
16 originators, originator manufacturers.

17 I think it's really important for everyone
18 to understand that the nocebo effect is real, and
19 the number one way of creating the nocebo effect is
20 actually to speak negatively; to have negative body
21 language in clinic about them; to see ads that use
22 subtle words, or I should say not so subtle words,

1 such as, "I love my product. I love my brand X."
2 I think these are really important and strategic
3 words that are being chosen to create nocebo
4 effect.

5 The way in which you manage a nocebo effect
6 is really important, and it takes this solid
7 information, this evidence-based lay language type
8 information, to manage the nocebo effect as you
9 begin to transition patients from their reference
10 product, or their originator brand, to their
11 biosimilar brand.

12 You heard the previous speaker talk about
13 how this is not an inexpensive proposition making
14 biosimilars or originators. Biosimilars in our
15 view are still brands. They deliver the same
16 thing, but when you use words, like "copy" and
17 "cheaper" and "generic," those things are, in many
18 cases and many instances, intended to create
19 nocebo, and this is just morally wrong when the
20 evidence shows that they're every bit as effective
21 at sustaining efficacy and safety.

22 So it's super important, when it comes

1 downstream from our regulators, for educators,
2 patient organizations, and larger health charities
3 such as the Arthritis Foundation, to use really
4 solid, unbiased, and positive if it applies,
5 information about biosimilars, which mitigates
6 anxiety regarding a switch or a transition from
7 patient to patient or in whole-disease communities.

8 I think lastly, I'll just add this. In
9 Canada, we are, again, finding ourselves in a
10 unique position. We're ahead of the United States
11 in terms of what we call up here transitioning or
12 switching policies.

13 To date, we have three Canadian provinces
14 that have implemented transition policy, the most
15 recent being the province of Alberta. We have 11
16 provinces and territories, and the province of
17 Ontario, which is our largest province here in the
18 country, is now contemplating implementing
19 transition policy. So everyone that is stable and
20 doing well on their originator or their reference
21 product will be moved to the biosimilar that has
22 been authorized for use here in the country.

1 I can say this in closing, that the
2 transition has gone very well. British Columbia's
3 entering almost its first year, and probably 1 to
4 2 percent of all those transitions make special
5 access or exemption requests, and about 1 percent
6 of those were approved. So it's not as though
7 people who have very specific needs are not being
8 considered, they certainly are, and they're being
9 considered by specialists.

10 So all in all, here in the country, we're
11 doing exceedingly well at maintaining gold-standard
12 quality of care, as you see there on my last bullet
13 point. I see my slides were jumping around a bit.
14 I hope that wasn't too confusing for folks.

15 But the bottom line is that we can buy an
16 awful lot of health care for close to \$2 billion
17 Canadian in our publicly-funded healthcare system
18 without compromising quality of care. For me as an
19 individual patient, it's not enough that I can find
20 my way or fight my way, because of my literacy
21 level, to the best treatments available. It's up
22 to me and all of our community to make sure that

1 everyone living with a form of autoimmune arthritis
2 can find their way to effective therapy. So I'll
3 just end there, and thank you for listening.

4 MS. IKENBERRY: Thank you, Cheryl.

5 Now, let's see who slides come up next.

6 (Laughter.)

7 MS. KOEHN: It's like a caffeine finger.

8 I'm sorry. The slides just kept bouncing around.

9 MS. IKENBERRY: No, it was fine. They were
10 stuck on the first one for a little while, but we
11 figured out how to move them. But for everyone
12 watching here in the room and at home, you can
13 access all of the slides on the meeting website, so
14 Cheryl's slides will be there as well.

15 It looks like Sameer is next.

16 Presentation - Sameer Awsare

17 DR. AWSARE: Alright. I'm Sameer Awsare.

18 I'm an internal medicine physician, and I still see
19 patients. For those of you who are not familiar
20 with Kaiser Permanente, a quick slide, that we take
21 care of 12 million patients and spend about
22 \$12 billion dollars on pharmacy expenses. You can

1 see we're in eight states and the District of
2 Columbia with a whole lot of clinicians taking care
3 of these folks.

4 What I wanted to show you is the methodology
5 that we use not only for biologics but also for all
6 of our generics. Unlike the external world, where
7 the health plan actually figures out what the
8 formulary is, and then the physician has to do,
9 "Mother, may I?" we actually do it just the
10 opposite way, where we have the pharmacists and the
11 physicians looking at the research and getting the
12 right specialist involved.

13 So if it's an oncology drug and it's a
14 lymphoma, then the lymphoma specialists all look at
15 it and weigh in on it before it comes to the
16 pharmacy and therapeutics committee, and then we
17 make a decision. And then we go to contracting and
18 say go find a good deal.

19 So rather than doing it the other way as the
20 rest of the competition does, this is what we can
21 do; and when we can do that, we can actually
22 promise to move 90 percent of the market share to

1 whichever product that we're going to then end up
2 choosing. So that really is a big differentiator
3 for us, but it also gets us that engagement.

4 So we don't really have any
5 preauthorization, we don't have step therapy, and
6 our compliance from our physicians is usually in
7 the 99 percent rate without anybody slapping them
8 or telling them to call someone for permission.

9 I'm just using this slide for Inflectra, and
10 as you see, look at the evidence; yes, the European
11 evidence, too. Our doctors are like, "What? Are
12 the studies from Europe?" Do we have studies from
13 America? Okay, we found an American study. "How
14 about some studies from Kaiser Permanente?" I'm
15 like, "Oh well, alright, we can do that, too."

16 So for Inflectra, we initially had to start
17 new patients on the biosimilar. Once we had the
18 experience with about 700 patients, we looked at
19 people who had been on the originator product, and
20 we found no meaningful difference, and people are
21 sold. So it took a little bit of a while.

22 It also helps when we have specialists in

1 that particular area who can then endorse it. We
2 have some world specialists in inflammatory bowel
3 disease who have written articles, et cetera. And
4 if we have other GI doctors who are saying, "Well,
5 I'm not sure about this biosimilar," actually
6 talking to a colleague who has expertise really
7 helps that.

8 We have the right tools in the electronic
9 medical records, and when you're ordering things,
10 the right kind of thing pops up. We actually
11 follow all of these patients to see how they're
12 doing, and we have clinical pharmacists helping our
13 physicians and helping our patients do that, and
14 then we also see what happens post-starting these
15 medications.

16 For this particular one, we actually did do
17 switching, and unlike the provinces in Canada where
18 it was a statewide decision, we actually have
19 conversations with our patients, and we were
20 definitely able to do a lot of switching. The
21 nocebo effect was mentioned, and actually any of
22 these biologics, whether it's the originator

1 product or the reference product, don't always work
2 for this particular disease, so our physicians were
3 a little bit concerned that perhaps even the
4 originator product didn't work and we saw that
5 perhaps the switch rate was about 9 percent. So
6 it's a little higher than Canada, but in line with
7 what you see in Europe.

8 We also found -- and we haven't published
9 this as yet -- when we had clinical pharmacists
10 helping, the switch rate was perhaps 5 percent. So
11 again, patients were quite good at staying on the
12 biosimilar once they had had the right education
13 and the physicians had had the right education.

14 We just published the data. I think we were
15 on a panel two years ago, and you said, "When will
16 Kaiser Permanente actually publish any of this?"
17 So about two weeks ago, we published in BioDrugs,
18 and it's the largest U.S. study on the
19 Inflectra-Remicade switch.

20 We actually found no meaningful difference
21 and no inferiority at all, so patients did just as
22 well on both. It's only available electronically

1 right now. It will be published in the journal
2 very shortly. I think you have to pay \$3,000 or
3 something crazy to get this right now, but
4 electronically you can see it.

5 We have similar experiences with the other
6 two biosimilars that have come out for Avastin and
7 Herceptin. What I would want to point out is when
8 the first biosimilar came, it took a little bit of
9 effort. We had to actually educate our physicians,
10 educate our patients, get the specialists to talk
11 to the right specialists, and it took 3 or 4 months
12 to get that market share.

13 With the last two biosimilars, this uptake
14 to almost 100 percent happened in a 2-week period.
15 So once physicians felt very comfortable with the
16 first one, the next ones have been a lot easier.

17 So I'll stop there and wait until the Q&A to
18 give you other details. Let's see whose name shows
19 up next.

20 MS. IKENBERRY: Thanks, Sameer.

21 (Laughter.)

22 MS. IKENBERRY: I think Michele might be

1 next.

2 Presentation - Michele Andwele

3 MS. ANDWELE: That's why I wore green, but I
4 am next.

5 Hi, everyone. For those who are not
6 familiar with the foundation, we're the largest
7 nonprofit patient advocacy organization for both
8 adults and children with musculoskeletal and
9 rheumatic diseases.

10 We started collecting patient insights
11 around biosimilars when the first biosimilar was
12 approved, the biosimilar for Remicade in 2016. As
13 you can see from the slide, we found naturally a
14 lot of other misleading or confusing information
15 that was available for patients. We did another
16 round when the fifth biosimilar was available, but
17 we recognized that the key concerns remained, and
18 as you can see from this slide, they fall into
19 three categories.

20 Efficacy, obviously, "Will I flare if I
21 switch? Will it work as well for me; because I am
22 stable? Are they safe?" which is a normal

1 medication concern, biosimilar or not. Then the
2 cost coverage matrix gets a little bit more
3 complicated because there are so many variables
4 that determine will I pay less, everything from
5 insurance coverage to are they underinsured, and
6 are they part of a patient assistance program. So
7 navigating that matrix requires a lot more
8 conversation and a lot more variables.

9 We also found what we call a push-pull
10 dynamic for a lot of our patients with regard to
11 healthcare decisions in general, but medication
12 specifically. The push part of that dynamic is the
13 extent to which the patient is kind of personally
14 motivated to make decisions, but the pull dynamic
15 is a lot stronger because they are trusting
16 primarily their ATP to guide them in the right
17 direction. That's the individual they see that has
18 the most information.

19 So to the extent to which their physician is
20 not even bringing it up helps them to determine is
21 it a conversation that they should have, and even
22 if they are personally motivated or interested,

1 that barometer from their physician plays a
2 critical role. To a lesser but also important
3 effect are larger influencers. Are there patient
4 organizations and patient advocates who are looking
5 out for their best interest? That's where
6 foundations like the Arthritis Foundation play an
7 important role.

8 The three key takeaways for what patients
9 are thinking, first, I like to call it interest
10 without urgency. It's kind of floating out there,
11 but they don't really have this tipping point for
12 them to feel that this is something that they need
13 to really focus on; then, as I mentioned before,
14 the provider influence is key.

15 From the HCP patient advocacy perspective,
16 we have been doing -- and I'll mention it in the
17 slide in a minute. As a patient advocate, we have
18 been trying to identify ways to strengthen
19 collaboration with other provider and HCP patient
20 advocate organizations so that we're speaking the
21 same language. What we have identified from some
22 of these earlier conversations is a challenge

1 around language, and that's where education plays a
2 critical role.

3 Within both provider organizations and
4 patient advocates, there is inconsistency with how
5 we're all talking about biologics and biosimilars
6 and the terms that we're using. We recognize the
7 importance of a consensus among all the patient
8 advocates and provider groups of where language
9 should be.

10 Some of the provider concerns are
11 independent of biosimilars. There are time
12 constraints in every conversation. Where does a
13 detailed conversation about biosimilars fit into
14 15 minutes, 20 minutes, 27 minutes, with patients
15 who are dealing with a lot of issues in addition to
16 their medication?

17 I mentioned insurance coverage earlier.
18 Naturally, if it's not going to be covered or there
19 isn't a patient assistance program, why would a
20 provider even bring it up when they understand
21 their patients unique needs? The last is the issue
22 around liability exposure potential with the

1 interchangeability -- I'll try to say that
2 fast -- designation and what that means.

3 There's a shared belief of a promise of
4 biosimilars; we're all clear. We look to the FDA
5 as our continued expert partner, and we recognize
6 their varying levels of knowledge that we really
7 need to address and the role of peer-to-peer
8 information, both from the patient perspective and
9 provider perspective, as Sameer mentioned earlier.

10 We're going to try to learn from our
11 partners in Europe and Canada, from some of their
12 lessons learned. And this is just a takeaway from
13 a physician who transferred all his patients to
14 biosimilars and the extent to which the trust
15 factor played a critical role in him being able to
16 make that move.

17 How are we responding? The foundation,
18 independently we have been focused on a strategy of
19 what we call communicating parity, so we have
20 started to create communication materials to
21 reinforce a singularity in the conversation on
22 biosimilars and biologics. We're going to be doing

1 some additional work with the consortium to see how
2 this needs to evolve and change. We've had
3 discussions about do we keep them separate or do we
4 do them together? We made the decision to test
5 some of our patient education materials around this
6 parity conversation, online and in print, and we
7 also leverage various media as you see here.

8 I mentioned earlier some of the work we're
9 doing around stakeholder and HCP engagement. We
10 have been leading an initiative that we're calling
11 the Biosimilars Consortium. It has currently
12 21 provider and patient organizations that we have
13 put together. We've had a series of meetings, the
14 most recent in October of 2019, I believe, and FDA
15 was there.

16 We are working through our 2020 priorities
17 as a collaborative consortium. Here are the three
18 main areas that we are going to be focused on in
19 2020. Rather than just researching independently,
20 we want to identify ways in which all our
21 organizations can both share data within our own
22 realm and others. We want to really look

1 aggressively at language. We recognize the role
2 that bias plays in the biosimilars conversation, so
3 we want to address that.

4 Once we are able to look at some of those
5 triggers, then we are hoping to collaborate very
6 closely on best practices across all our
7 communication so that we are speaking with one
8 voice, and we think that plays a very important
9 role with regard to consistency in communication
10 and education both for providers and for patients.

11 MS. IKENBERRY: Thank you, Michele.

12 Now, we have Hillel Cohen, who is going to
13 speak a little bit. I believe there's a slide.

14 Presentation - Hillel Cohen

15 DR. COHEN: Hillel Cohen from Sandoz, but
16 I'm speaking today as the co-chair of the Education
17 Committee of the Biosimilars Forum, a trade
18 association group developing and promoting
19 biosimilar use in the U.S. I see my goal here
20 primarily to identify the problems companies have
21 seen over the past several years and to make
22 recommendations to address them.

1 We've seen several different types of
2 disparagement and misinformation over the years,
3 since 2015 when Zarxio was first approved in the
4 U.S. as the first biosimilar. These include -- and
5 people have spoken about them, and my apologies
6 that there will obviously be duplication of what
7 I'm saying with what others have said -- misleading
8 information. We've also seen incomplete
9 information that's factually correct as presented
10 but that omits important facts. FTC has talked
11 about that earlier today.

12 We've also seen negative framing of factual
13 statements to create a negative perception. You
14 can say a patient will have the same clinical
15 outcome, the same safety and effectiveness, or can
16 say there's no clinical meaningful differences.
17 It's the way in which we express it, and I think,
18 Michele, you expressed that a lot just a few
19 moments ago. On occasion, but not often, there
20 actually have been statements that have been
21 factually incorrect.

22 General targets, we've seen. We've seen

1 people talking about efficacy. We've seen some
2 comment and messages on safety, on quality, and on
3 regulatory. We haven't spoken about that yet. Let
4 me give you a couple of specific examples of the
5 messages that we've encountered. This is four
6 member companies, not necessarily one company in
7 particular.

8 On efficacy, we've seen messages that the
9 efficacy of a biosimilar is not yet fully proven.
10 We've talked about the purpose of those trials are
11 not efficacy trials, but still people say it hasn't
12 been proven yet, or we've seen that the efficacy of
13 a biosimilar may not be as good as that of the
14 reference product. We've seen comments about
15 extrapolation. Some type of physicians, or
16 patients, will say extrapolation is not
17 appropriate. It wasn't studied in my indication.

18 Safety. We've seen statements that the
19 safety of a biosimilar's not yet fully proven.
20 Again, it wasn't the purpose of these studies, but
21 those are comments that have been made to us. Some
22 people have said it's a potential that a biosimilar

1 may be more immunogenic than that of the reference
2 product.

3 Switching. We've heard the experience that
4 we talked about in Canada. There still are
5 comments out there that we don't have enough data
6 to let us conclude that switching from a reference
7 product to a biosimilar is safe, the implication
8 being that switching may be unsafe. I realize
9 physicians always have the ability -- we haven't
10 talked about this yet -- to prescribe whatever
11 product they feel is most appropriate. You don't
12 need interchangeability for that.

13 Interchangeability is a pharmacy-level decision.
14 Physicians now have that ability to make the
15 substitution if they make that choice.

16 We've also seen comments about the quality
17 of a biosimilar. Well, the quality of a biosimilar
18 may not be as good as that of the reference
19 product. Probably more often we've seen people say
20 it's only similar or only highly similar, not
21 identical; never mind the fact that its many
22 differences are not clinically relevant. That's a

1 mouthful that's difficult to understand.

2 We've talked about interchangeability.

3 There have been statements out there that
4 interchangeability is a higher standard. Again, I
5 don't want to say everyone is saying that. It's a
6 couple of messages and a couple of statements that
7 have been out there, the implication being that
8 biosimilars are of lower quality than an
9 interchangeable biologic. In fact, it's not the
10 situation. It's just a different standard
11 requiring different additional clinical data. In
12 fact, they're absolutely identical;
13 [indiscernible], so they have to be identical.

14 The regulatory pathway has also created a
15 little bit of a problem in the sense that the BPCIA
16 talks about an abbreviated pathway. The
17 abbreviated pathway talks about the clinical
18 development. Some people would say the regulatory
19 pathway, it's only abbreviated if it's not as
20 rigorous as a pathway for reference products.
21 Actually, it's very rigorous.

22 What recommendations can we make? These are

1 just general messages that we've encountered.
2 Clearly, all parties should be required to share
3 truthful and complete information. There's an
4 information flow that we've talked about, a little
5 more exact: FDA to healthcare professional
6 societies; these societies to their
7 physicians and also to the patient advocacy groups
8 with which they work; and then for the physicians
9 and the patient advocacy groups to patients.

10 The forum believes that patient discussions
11 with the healthcare providers are really extremely
12 important and will go a very long way towards
13 gaining acceptance.

14 Positive framing. Cheryl Koehn talked about
15 that to a degree, and we can talk about it later in
16 detail. You want to highlight the quality and the
17 benefits of a biosimilar, to talk about it in a
18 positive sense.

19 It's also important to have easy to
20 understand messages. The FDA has been developing
21 these messages and making sure that you've been
22 testing them to make sure they're easily

1 understandable by the patients. That's really
2 critical. It's also important to make sure they
3 can be readily accessible. Most patients, and
4 maybe many doctors, go to Dr. Google as an
5 important source of information.

6 (Laughter.)

7 DR. COHEN: Messages should be based on the
8 FDA documents. Not all of the FDA documents are
9 purposely designed to be easy to understand. Some
10 of them are directed to the industry, some to
11 healthcare professionals also, and only some
12 towards patients. But anyway, all the messages
13 designed by the myriad of organizations developing
14 these should be based on the FDA documents and
15 tailored to their audience.

16 It's also important to realize that there
17 actually is a lot of information out there already
18 available in print on the Web, and the material out
19 there, people should review them, those who put
20 them out to review them, and if necessary, revise
21 them. Of course the forum is willing to work with
22 FDA and other stakeholders to create this easily

1 understandable information with biosimilars and
2 interchangeable biologics.

3 Just a few more things. More education is
4 needed for the average patient and the doctor
5 engaged in everyday patient care. I appreciate
6 that for the large purchasing organizations, they
7 may be fully on board with biosimilars. They've
8 read the details, they have now knowledgeable
9 people, and they're on board.

10 Kaiser Permanente, you've done the analysis;
11 you're on board. In fact, the patient advocacy
12 groups, many of them have delved into them in great
13 detail, especially those which have skin in the
14 game. The Arthritis Foundation and the National
15 Psoriasis Foundation have studied these things in
16 detail, but the average patient is not
17 knowledgeable.

18 From bottom up, we need education. Patients
19 need to be educated. The physicians need to be
20 educated. Rheumatologists we found are more
21 knowledgeable; gastroenterologists, maybe less so,
22 so specialties may have to be focused on. Also,

1 obviously, we urge the FDA and the FTC to exercise
2 their authorities when possible and under the
3 jurisdictions to prevent disparagement and
4 misinformation.

5 Now, there's an initiative that I believe is
6 in the early planning stages that the forum
7 strongly endorses, which is incorporating
8 biosimilar education to the curricula of medical
9 schools, nursing schools, and pharmacy schools.
10 There are a small smattering of schools that are
11 already doing that, but it really needs to be
12 incorporated broadly in the U.S.

13 Finally, we would recommend that advocacy
14 groups and lobby organizations -- sometimes they're
15 closely linked -- should disclose their corporate
16 alignments, their funding, and the conflicts of
17 interest. Now, let me be clear. There's nothing
18 wrong with someone speaking their positions.
19 That's absolutely fine. Everyone is entitled to
20 their positions on all sides. It's just that we
21 think it's important to have full disclosure in
22 place. With that, thank you very much for your

1 time.

2 Panel Discussion

3 Sarah Ikenberry and Elizabeth Jex

4 MS. IKENBERRY: Thank you, everyone, for
5 presenting. Now, I'm going to turn it over to Liz,
6 who's going to do some Q&A here with the panelists.

7 MS. JEX: Thank you, again, FDA for hosting
8 this event and for conducting the joint statement
9 with the FTC on this important topic. We've
10 touched on a lot of the questions that I circulated
11 to you all.

12 I think the key question I have is the FDA
13 has recently updated its web pages, for both
14 healthcare providers and patients, to explain that
15 FDA-approved biosimilars are just as safe and
16 effective as the original biologic reference
17 product, and provide the same treatment benefits,
18 and could have the same potential side effects as
19 the reference biologic.

20 How can we best communicate this information
21 to healthcare providers, to the medical
22 professional societies, to patient advocacy groups,

1 and to patients? What recommendations, in addition
2 to those that you've mentioned today, can we make
3 to either the webpage or to future joint efforts,
4 or research as you've discussed today on these
5 topics? So I just lay that out for any and all.

6 MS. KOEHN: It's Cheryl here, Liz. Perhaps
7 what I'll do is just let you know that what we did
8 here in Canada was that it's easy to say everybody
9 needs to be educated, but we live in a time,
10 obviously, when people get education on a
11 catch-if-can basis. So we created a series of
12 videos that live on our website. Our provincial
13 governments are referring people to those. We have
14 online materials that can be printed.

15 I think our little 5-minute video series are
16 super, super helpful, and I would encourage the FTC
17 and the FDA to produce some really bite-size little
18 videos that people can access when it's topical for
19 them. We have to remember, this is not for the
20 general population; this is for the population of
21 people who will be switched or transitioned if in
22 fact that's what happens there. That's what we

1 did, and they have proved to be one of the most
2 accessed areas on our website.

3 I'll just say that even in the course of
4 this panel, if we're all saying language is
5 important, I would really encourage you to change
6 the materials and change our language. I've heard
7 now multiple times, just in the span of 45 minutes,
8 the word "biosimilars" and then "biologic."
9 Biosimilars are biologic. So it's really important
10 to let the public and the patient public understand
11 that we are talking about biosimilar/biologic,
12 otherwise, people think they're two different
13 things, and clearly they're not.

14 MS. ANDWELE: Another thing that I think is
15 important to do is develop an influencer strategy.
16 So much of our decision-making is influenced by
17 peers, whether it is patient peers or provider
18 peers. One of the things at the foundation we have
19 invested a lot of time in is building an online
20 community and establishing a strong support group
21 network across the country because we understand
22 that patients like to see themselves and talk to

1 people who get it and who understand.

2 A lot of people have a positive opportunity
3 to impact and influence other people, so we think
4 that identifying where those influences are and
5 being able to leverage that I think will have a
6 great impact in terms of acceptance.

7 DR. AWSARE: I think the panelists have
8 highlighted the same sort of strategy we used. We
9 also created educational materials for our
10 physicians and for our patients, and then getting
11 the right specialist. But for the FDA, I think
12 working with some of the national societies, the
13 American College of Gastroenterology or
14 Rheumatology, like you are. When Inflectra first
15 came out, some of the GI societies were not in
16 favor of the biosimilar.

17 So having the right education to the right
18 people, people are looking to these folks to give
19 them direction, and if they don't see that coming,
20 they're not interested in switching. I mean, the
21 patient's stable. Why am I going to do that?
22 You're going to call me, you're going to make more

1 visits to my office, and you're doing well on your
2 current biologic. Why am I going to even switch if
3 my professional society is not endorsing that?

4 DR. COHEN: We actually asked that of the
5 four member companies, what key messages we would
6 wish the FDA to have. Obviously, it's different
7 than disparagement, so I'm talking in the positive
8 sense.

9 The positive messages we want, same safety
10 profile and effectiveness if possible. I think
11 that would go a very long way. That's probably
12 number one. Evidence requirements of biosimilars
13 are very high. We would like people to be aware
14 that there's lots of experience with biosimilars.
15 It's at least 700 million patient-days, and I think
16 it's actually quite a bit more right now.

17 There's a lot of experience. The EMA is on
18 the record with their document that came out in
19 November of 2019, saying they don't see any
20 difference in safety with the originators. Another
21 key message is that the scientific methods used to
22 characterize the manufacturer and evaluate them are

1 rigorous, and they show that the biosimilars work
2 just as well as the reference products. So to get
3 back to will it work for me, the answer would be
4 yes.

5 Finally, the fifth point that we had as a
6 group is that the regulatory pathway is based on
7 sound scientific policy. Doctors and patients are
8 used to looking at clinical trials. You don't have
9 it with biosimilars. It's a different paradigm.
10 But these methods are very sound, and they use
11 methods that really ensure the safety, efficacy,
12 and the quality of a biosimilar.

13 I think a coordinated effort from the FDA to
14 the professional societies, working with the
15 patient groups -- and I know that this is an effort
16 that you've been initiating; the forum has been
17 part of that as well. As I said before, it's a
18 cascade that has to come down.

19 MS. ANDWELE: One thing I'd like to add is
20 some work around message segmentation because
21 you're going to have patients who are treatment-
22 naive, who a biosimilar may be their first

1 medication versus someone who is stable on a
2 biologic. To the same extent, you'll have
3 physicians who have been working with biologics for
4 a very long time and those who are newer with
5 biologics. I think looking at segmentation, both
6 on the patient and provider perspective, may have
7 an impact on the communication strategy.

8 MS. JEX: I see we're out of time. I want
9 to thank my panelists for your excellent insights
10 into the patient and doctor experience with
11 biosimilars and ask everyone to give them a hand.
12 Thank you very much.

13 (Applause.)

14 MS. IKENBERRY: Thank you, all. I think we
15 could have sat up here for at least another half an
16 hour and discuss this. But as always, we're
17 interested in everything and what everyone has to
18 say about this, and take that into consideration as
19 we develop additional materials and information.

20 MS. TEMKIN: We're going to have a break
21 now, and we'll be back at 2:15.

22 (Whereupon, at 2:04 p.m., a recess was

1 taken.)

2 MR. WEINSTEIN: Everyone, welcome back. My
3 name is Randy Weinstein. I'm an attorney at the
4 Federal Trade Commission. Earlier today, we've
5 talked about disparagement in the context of FDA
6 and FTC enforcement, but what about private rights
7 of action? Does disparagement resonate in the
8 context of antitrust enforcement, either by the
9 government or private litigants? These are the
10 questions we're going to talk about right now.

11 Joining me today are Michael Carrier.
12 Michael carrier is a distinguished professor at
13 Rutgers Law School. He is an expert in
14 intellectual property and antitrust law. Rebecca
15 Tushnet is the inaugural Frank Stanton professor of
16 First Amendment law at Harvard Law School. Her
17 work focuses on copyright, trademark, and
18 advertising law. I also learned, in fact, that
19 she's an expert on the law of engagement rings.

20 Professor Carrier, by chance, are you an
21 expert in any matrimonial hardware?

22 (Laughter.)

1 DR. CARRIER: No, I'm not.

2 MR. WEINSTEIN: Okay.

3 Of course you all know Rich Cleland, my
4 colleague, from the Federal Trade Commission who
5 spoke earlier today.

6 Both Professors Carrier and Tushnet are
7 experts in their respective fields, which happened
8 to be the topics of this panel. More information
9 about their prestigious backgrounds can be found on
10 our web page.

11 Let's begin. We talked a little bit earlier
12 today with some examples of disparagement that
13 we're seeing in this industry, but is there a way
14 to kind of organize these thoughts into some
15 buckets, for example, or a way to kind of think
16 more broadly about them?

17 Presentation - Michael Carrier

18 DR. CARRIER: Yes. We certainly have heard
19 a whole bunch of examples. Let me categorize them
20 into four categories. The first category is the
21 most extreme. We haven't heard it, but it was
22 explained in a Washington Post article in January

1 2019. It will be discussed by a couple people who
2 will show up in the public comment period, things
3 like -- and this is from the Alliance for Safe
4 Biologic Medicines -- "We need to proceed
5 cautiously with moving to biosimilars," quote, "'so
6 we don't end up with another thalidomide.' That's
7 when we had children with birth defects," or,
8 quote, "'all the other things that happen when
9 safety is not considered.'"

10 Then we had another quote from someone
11 affiliated with the organization who said that,
12 "Switching," quote, 'disrupts the continuity of
13 care. You could end up in an emergency room or
14 being hospitalized. You can exacerbate or flare
15 your disease or even bring it out of remission.'"

16 So this is not appropriate given that, by
17 definition, biosimilars are highly similar to and
18 have no clinically meaningful differences from.
19 That's the first category that really makes a joke
20 of what the standard is, and then we get a little
21 more subtle.

22 The second category is where we hear that

1 the biosimilar is not identical to or acts
2 differently from the original reference product. A
3 lot of this stuff shows up in the Pfizer citizen
4 petition, so if you look at that filed with the
5 FDA, we see that Amgen says that no two biologic
6 medicines are identical; they behave differently in
7 the body. You look at an Amgen tweet, "Biologics
8 or biosimilars. It's not just apples to apples.
9 It may be highly similar, but the patient may react
10 differently." The Genentech website says that the
11 FDA requires highly similar but not identical.

12 So the benefit to the FDA's proposed
13 guidance is that it takes on these
14 misrepresentations precisely. If you look at
15 question 6, the biosimilar is not required to be
16 identical, that's really important, and I'm glad to
17 see that.

18 The third category deals with
19 interchangeability, and as we've heard this
20 morning, there are some intimations that just
21 because a biosimilar's not interchangeable, maybe
22 it doesn't meet that highest standard of safety and

1 efficacy. For example, Janssen said, "Even though
2 the biosimilar is very similar to Remicade, it
3 doesn't mean it's interchangeable," and really
4 emphasized that throughout its materials. And
5 there in question 6 in the FDA's guidance, we see
6 that just because it's not interchangeable doesn't
7 mean it's not safe and effective.

8 Then finally, and perhaps most subtly, is
9 where the company says that the drug acts
10 similarly. Janssen for example says you may be
11 asked to switch to a biosimilar that works in a
12 similar way to Remicade. This is a little more
13 subtle than the others, but still the assumption is
14 that it doesn't act the same way. And we see the
15 FDA in question 5 on its guidance, the FDA also
16 saying you don't look at the number of indications
17 for which the product is licensed; that doesn't
18 tell you how safe it is.

19 So with all of this, we see different levels
20 of categorization, but in all of them there is some
21 sense in which there is not equivalency with the
22 biosimilar and that it presents real issues. As we

1 go through this panel, it's worth thinking about
2 what the net impression is. If there is one
3 interpretation that really shows that it's not as
4 safe or effective, what can we do with it? So that
5 would be how I would categorize these statements.

6 MR. WEINSTEIN: Thank you, Professor
7 Carrier.

8 Professor Tushnet, we talked in an earlier
9 panel today about the FDA and FTC enforcement
10 paradigm. What about private rights of action in
11 the context of disparagement?

12 Presentation - Rebecca Tushnet

13 DR. TUSHNET: Great. I'm just going to give
14 a quick overview of the Lanham Act false
15 advertising cause of action. Private competitor
16 plaintiffs can often also bring state law claims,
17 but they probably shouldn't detain us for very
18 long.

19 The key element of the Lanham Act claim are
20 the falsity or misleadingness of a statement, the
21 materiality of the statement to a reasonable
22 consumer's purchase decision, and the likelihood of

1 harm to the plaintiff. In the kind of case that
2 we're talking about here, the likelihood of harm to
3 the plaintiff is probably fairly clear.

4 A couple things that are mostly unique to
5 the Lanham Act cause of action compared to an FTC
6 or state consumer protection claim, the key thing
7 is the sharp doctrinal difference between false and
8 misleading claims. False and misleading claims are
9 actionable, but in a Lanham Act case, the burden on
10 the challenger is much greater if a claim is
11 misleading than if it is literally false.

12 That puts a premium on distinguishing
13 falsity from misleadingness. How does a plaintiff
14 establish that a claim is false? Courts ask what
15 is the explicit meaning of the claim? Once you
16 know the explicit meaning, you can then determine
17 whether that factual claim is false. However, of
18 relevance here is that courts are sometimes willing
19 to make general inferences from disparagement about
20 what the claim is. It is also important to
21 distinguish lay audiences and expert audiences.
22 Different people may differ or different groups may

1 differ in their understanding of the term.

2 My favorite example of this is a case where
3 the defendant said that the competitor's product
4 was subject to catastrophic failure. It was a
5 medical device, and the engineering dictionary says
6 catastrophic failure is failure that happens
7 without any warning; the device is performing,
8 performing, performing, and then it stops. But the
9 plaintiff established that, to doctors,
10 catastrophic failure meant a failure that harms a
11 patient, which is a very different thing, and the
12 court found literal falsity because of the meaning
13 of the term to doctors. So dictionary meanings may
14 not be as important as what people are likely to
15 understand.

16 Suppose a claim is not false? How do you
17 establish whether it's misleading? This is
18 relevant if a claim is ambiguous and it has
19 potentially true and potentially false meanings,
20 much of the stuff that we've been talking about
21 here.

22 The question is what message does a

1 reasonable consumer receive? This is usually done
2 through surveys of the relevant consumers, and the
3 rule of thumb is that if 15 percent or more of
4 consumers, the net of some control, receive a
5 message, then the plaintiff is relatively likely to
6 prevail.

7 When is this empirical evidence of consumer
8 reaction necessary? It's not in literal falsity
9 cases. Literal falsity is presumed to reach a
10 substantial number of reasonable consumers, but
11 surveys are basically always required in
12 misleadingness cases.

13 There are a couple of exceptions. If
14 there's an intent to deceive consumers, then that
15 can substitute for evidence of consumer reaction.
16 Sometimes direct testimony from deceived consumers
17 can substitute but probably this is not a great
18 scenario for that just because you can always find
19 someone who's confused about something. So if you
20 have a really broad range of consumers, the survey
21 is going to give you a better idea of what's going
22 on.

1 I did want to mention, and I do have a slide
2 from this because I think it's hilarious, there's a
3 Seventh Circuit case, Eli Lilly versus Arla Foods.
4 If we could get the image up. Eli Lilly sued over
5 images from an organic producer portraying RBST,
6 which is a hormone given to cows to increase milk
7 production. So it's being portrayed as a
8 scary-toothed monster with electric fur that will
9 shock you if you touch it.

10 The Seventh Circuit finds that there's
11 nothing in this ad that is literally false, but
12 that it is still misleading and enjoins it without
13 any evidence of consumer perception, basically
14 because of the disparagement. When you look at
15 this, it is obvious that they are telling you,
16 well, it's complicated but RBST is scary, which is
17 a very relevant case for this scenario that we find
18 ourselves here.

19 The court says the use of monster imagery,
20 weird stuff language, and child actors combined to
21 colorfully communicate the message that responsible
22 consumers should be concerned about RBST-derived

1 dairy products, so I think this case is quite on
2 point to some of the claims that we've seen.

3 The other thing that is clearly of relevance
4 that we haven't really talked about is the
5 relevance of the First Amendment for the regulation
6 of these claims. In Lanham Act cases, courts
7 generally say that the Lanham Act false advertising
8 cause of action raises no constitutional issues at
9 all. By definition, it targets only false or
10 misleading commercial speech that can
11 constitutionally be banned.

12 According to Supreme Court doctrine, when it
13 comes to direct government regulation of speech,
14 there is a distinction between inherently or
15 actually misleading versus potentially misleading.
16 So whether the speech can just be banned or whether
17 instead a disclosure must be added to try and draw
18 the sting of the misleadingness, this distinction
19 is not well worked out. Maybe we can address it in
20 the questions.

21 It's largely been done by courts guessing,
22 or worse, about what's inherently or actually

1 misleading versus what is only potentially
2 misleading. There's a lot of room here for
3 presenting courts with facts about misleadingness.
4 It is not the same distinction that's made in
5 Lanham Act cases, where misleadingness is actually
6 just one category distinct from falsity.

7 This leads to a related issue, which I hope
8 we'll discuss, which is the relationship between
9 private and public enforcement. Courts in private
10 litigation regularly do defer to the FDA's factual
11 findings about what is true, but without a lot of
12 explanation about why they're deferring or with
13 general references to the FDA's expertise.

14 The First Amendment may start to bear on the
15 question of the review of these agency
16 determinations, so what are the medical facts and
17 what our consumers' perceptions of the messages
18 that they receive?

19 Those are both actually facts about the
20 world, but the level of deference that they receive
21 may differ because courts may have their own sense
22 of how good they are at figuring out whether

1 deception is going on. So as a practical matter, I
2 would expect more deference to agency findings
3 about safety and efficacy itself versus findings
4 about deceptiveness, even though both really are
5 subject to the ordinary mechanisms of proof.

6 So that is my lightning tour of the relevant
7 concepts from my perspective, and hopefully we can
8 now add some richness to that.

9 Panel Discussion

10 Randall Weinstein and Richard Cleland

11 MR. WEINSTEIN: Professor Tushnet, in the
12 Lanham Act, those are actions brought by
13 competitors; is that right?

14 DR. TUSHNET: Yes.

15 MR. WEINSTEIN: What about like a consumer?
16 Where's the ability of the consumer to bring an
17 action for disparagement?

18 DR. TUSHNET: Really, it would be relatively
19 difficult, although one can imagine a consumer
20 class action saying that the disparagement deterred
21 a whole bunch of people from trying this drug. It
22 could be done. I think as Professor Carrier will

1 talk about, the real possibilities for consumers
2 here probably do lie in the realm of antitrust.

3 MR. WEINSTEIN: And is that because there's
4 just no good law under which consumers have
5 standing to bring a claim?

6 DR. TUSHNET: Consumers have standing under
7 their state consumer protection acts, but there are
8 just a lot of barriers to a successful class action
9 at this point, not the least of which are the
10 contracts that you might likely sign when you buy
11 something. So depending on how the medication is
12 transmitted to the consumer, they might actually
13 have waived their rights.

14 Courts are also very tough on claims that
15 not all consumers may have seen. So if the
16 advertising is not actually on the package, then
17 it's going to be hard to sustain a class action.
18 So in this space, I think the false advertising
19 issues are really Lanham Act issues.

20 MR. WEINSTEIN: Thank you.

21 MR. CLELAND: Let me follow up on the First
22 Amendment issue with just one question here. You

1 mentioned the difference between inherently
2 deceptive and potentially deceptive. One of the
3 things is, for example, in the Palm case, where the
4 D.C. Circuit said we've now determined that these
5 claims are deceptive; there go [ph], no First
6 Amendment issue.

7 If the fact-finder first finds deception or
8 a misleading, the potentially deceptive part of
9 that equation should go into what kind of relief is
10 ordered, not whether the court can ban the claim
11 that is found deceptive; right?

12 DR. TUSHNET: I think that's a completely
13 logical way of looking at it. My only caution is
14 that courts have been very far from logical in the
15 order in which they approach these issues.
16 I think that's completely right, but sometimes
17 courts get a bee in their bonnet about the order of
18 operations here.

19 MR. CLELAND: And in terms of the
20 materiality prong on the Lanham Act cases, that's
21 materiality for the competitor.

22 DR. TUSHNET: It's actually materiality for

1 the consumer; that is it has to be likely to affect
2 a reasonable consumer's decision, and then the
3 materiality to the consumer then produces the
4 negative effect on the competitor. And again,
5 you're not looking for it to affect everybody's
6 decision. As long as a substantial number of
7 reasonable consumers are likely to be affected,
8 then we can see an effect on the market.

9 MR. CLELAND: But given, in this particular
10 market, usually it's the physicians that are making
11 or at least having a great impact on the decision,
12 how does that affect materiality?

13 DR. TUSHNET: I think the best answer is
14 that it's actually open to the plaintiff to show
15 either the patient or the doctor. As I'm sure
16 you're all aware, there's plenty of evidence about
17 the impact that patients have on doctors when
18 they're asking for a specific medicine. I think
19 you could readily show actually either group being
20 a relevant market actor, especially given that the
21 standard is substantial number rather than uniform
22 effect.

1 MR. WEINSTEIN: Turning then to the
2 antitrust framework, Professor Carrier, can you
3 walk us through the current framework for
4 evaluating disparagement as an antitrust violation?

5 DR. CARRIER: Sure. So the big picture here
6 is we're talking about monopolization, which is
7 Section 2 of the Sherman Act. We're not talking
8 about mergers. We're not talking about agreements
9 among rivals. For monopolization, you have to show
10 monopoly power and exclusionary conduct.

11 The first piece is monopoly power. You can
12 either show it indirectly or directly. Indirectly
13 tends to be through a share of the market. We
14 usually see at least 90 percent of the market,
15 although you could see perhaps lower, maybe
16 70 percent, together with barriers to entry. For
17 direct monopoly power, we tend to see price
18 increases or the price maintained at a high level
19 or output reductions.

20 Do we have that sort of power here? I think
21 that we do. It's clear that biologic products are
22 a generally very expensive product. So even if the

1 biologics are not as much in terms of the
2 biosimilars, in terms of the number we see, the
3 amount of money is a ton.

4 You look, for example, at one case, Pfizer
5 sued J&J, Pfizer claimed J&J increased the price
6 10 percent and still has 96 percent market share
7 and 90 percent of producers refused to stock their
8 product at all. In these cases, there tends to be
9 such power, there are very few substitutes. So I'd
10 say monopoly power is not something that we spend a
11 lot of time on.

12 Then the question is what about exclusionary
13 conduct, and courts here have fallen into one of
14 three buckets. The first bucket is that there is
15 no liability at all for something like
16 disparagement; the second bucket is assuming that
17 the harm is de minimis; and the third bucket is a
18 case-by-case approach.

19 So the first bucket as shown by the Fifth
20 and Seventh Circuits is that there's no liability
21 at all. These courts say that false statements
22 enhance competition in advertising markets; that

1 business torts are different than anticompetitive
2 conduct; and that false statements set the stage
3 for competition in the advertising market.

4 In short, they basically say there is
5 nothing to do about false statements. I think that
6 that is wrong. I have an article forthcoming.
7 Professor Tushnet and I also have an article
8 forthcoming in which we both think it's wrong. You
9 can't say that there's no liability at all when you
10 engage in this conduct. It's certainly possible to
11 get or maintain monopoly power by engaging in this
12 behavior of disparaging your rivals. It's
13 certainly not something that the rival can fix. It
14 certainly can have a significant effect on the
15 overall market.

16 So we would say that this approach is wrong.
17 Nonetheless, if a court were to adopt it, then
18 there's no liability because that's just what
19 courts say following this approach.

20 The second approach is a de minimis
21 approach. It's followed in the Second, Sixth,
22 Ninth, Tenth and Eleventh circuits. Basically,

1 it's presumption that the exclusionary effects of
2 disparagement are de minimis. That presumption can
3 be rebutted if the plaintiff could show six things.
4 The case law is not clear as to whether or not you
5 have to show all six, but those six are that it is
6 a clearly false statement; it is clearly material;
7 clearly likely to induce reasonable reliance; made
8 to buyers without knowledge of the subject matter;
9 continued for prolonged periods; and not
10 susceptible of neutralization.

11 So again here, the bar is too high. This
12 case arose in the leading treatise, or the
13 framework is taken from the leading treatise, the
14 Hovenkamp treatise in antitrust law. It was
15 adopted at a time that the standards of false
16 advertising really aren't clear, and there is
17 something to say; that not every instance of false
18 advertising is monopolization. Certainly, there
19 are lots of instances that are not monopolization,
20 but the cases that we're worried about, the cases
21 in which biologics are disparaging biosimilars, are
22 ones where there is monopoly power.

1 How would this test be applied? Well, we
2 start off saying that it is de minimis, then you
3 look at the factors. So the first is clearly
4 false. And if we've learned anything from the day
5 so far, it's that you can have deceptive and
6 misleading statements even if they're not clearly
7 false. So I would take issue with this factor.
8 And if we expand it a little bit to what's
9 deceptive and misleading, then, again, that is what
10 we've talked about for hours, saying, oh, they're
11 not identical; they're not interchangeable; they
12 don't work the same way, these are deceptive and
13 misleading.

14 The second factor, is it clearly material?
15 Of course it is. This deals with safety and
16 health. What's more material than that?

17 Third. Does it induce reasonable reliance?
18 Yes, relatedly. Doctors and patients and payers
19 are going to care a lot about the assertions that
20 are made.

21 Fourth, buyers without knowledge of subject
22 matter. Here, there's a lot of emphasis on the

1 drug companies and what the drug companies are
2 saying, so this factor shouldn't apply as much.

3 Fifth, lasting for prolonged periods. Yes,
4 these are monopolies. The monopolies, as we saw in
5 one slide, go on for years, so certainly that is
6 satisfied.

7 Finally, the plaintiff can't neutralize it.
8 It's hard to neutralize. Once the biologic company
9 says we have some real safety problems here or
10 maybe you'll go to the ER, it's tough for you to
11 say, "Well, we're not going to go to the ER." It's
12 really tough to rebut.

13 So applying the test, the first factor of
14 clear falsity I'd say is too high a standard, but
15 that one you could argue if you were to have
16 deception or misleading, and I'd say all the other
17 factors are satisfied. So even if it starts off
18 with a presumption that it's de minimis, I'd say
19 that the factors can be rebutted.

20 Then finally, the third bucket is the
21 case-by-case approach. This is followed in the
22 Third, the Eighth, and the D.C. circuits. Here,

1 for example, in D.C., the court said there are too
2 many forums. It's too dependent on context to
3 enumerate all of the varieties. The multiple
4 courts say the false statements could be so unfair
5 that they constitute an unreasonable restraint.
6 Courts have looked at things like whether false
7 statements lead to inflated financing costs and
8 whether they lock in decision-making.

9 So how would all of that apply here?
10 Because it's case by case, we have a lot more
11 flexibility. Just on those two last factors that I
12 mentioned, the first is financing high expenses.
13 It's really hard for a biosimilar to get the
14 financing it needs if it's subject to all of these
15 inappropriate claims. In terms of decision-making,
16 that's locked in as well.

17 Then we step back and see the regulatory
18 situation. It was so rewarding to hear FDA
19 Commissioner Hahn, just like FDA Commissioner
20 Gottlieb before, talk about things like
21 shenanigans. These are not appropriate types of
22 behavior.

1 It certainly is wonderful to see the FDA and
2 the FTC working together and this is incredibly
3 important, but it's possible that the agencies
4 might not be able to solve this problem completely
5 on their own. As we've seen for the past several
6 decades, drug companies think it's in their
7 bottom-line interest to play these games, to get
8 away with a slap on the wrist, and to keep their
9 monopoly power for years.

10 So there could be a role for courts to play
11 a role here in terms of the different barriers to
12 entry. I'll just mention, as we saw before, the
13 cost of development is extremely high. We haven't
14 talked about trade secrecy and the manufacturing
15 processes that the biologic companies do not want
16 to share with their rivals. We've seen that there
17 are patent thickets that make it extremely
18 difficult.

19 Settlements could be a good thing, but
20 pay-for-delay is not. The Supreme Court and
21 activists said you cannot pay your rival to stay
22 off the market. So while we want settlements in

1 this case, we don't want one company paying another
2 to stay off; that's not right.

3 Third, the bundling, exclusive dealing, and
4 rebates we've heard about, and finally established
5 patients are unlikely to switch. So in some of
6 these cases there's bundling with the established
7 patients and the new patients, which makes it even
8 harder for the new patients to consider the
9 biosimilars.

10 So you put all of these barriers to entry
11 together, and you see it's really hard for the
12 biosimilar to enter the marketplace. There are so
13 many barriers already there. Then on top of that,
14 for the few new patients who could consider a
15 biosimilar, you threaten all of these safety
16 concerns, it's going to be extremely hard.

17 So I'd say following the case-by-case
18 approach, which I think is the most justifiable of
19 the three approaches, I think there's a strong
20 antitrust case that could be made.

21 MR. WEINSTEIN: Thank you, Professor
22 Carrier.

1 Let's back up and maybe just ask at a high
2 level, do we need a disparagement cause of action
3 arising in antitrust? I guess on the one hand, is
4 there a regulatory or a policy fix available that
5 might accomplish the same thing or is the
6 enforcement of private or public framework we have
7 in the consumer protection context sufficient
8 standing alone?

9 DR. CARRIER: I'd say yes to all three; yes
10 to antitrust; yes to consumer protection; and yes
11 to regulatory things that we're talking about
12 today. It certainly is wonderful to see the FDA
13 and FTC getting together using their complementary
14 expertise to go after this conduct, which is subtle
15 in nature.

16 Is there a role for antitrust? There is a
17 role for antitrust because no matter what the
18 agencies can do, there's always the possibility
19 that some bad actors will cross the line and commit
20 an antitrust violation.

21 The benefit of antitrust law is that it
22 focuses on market-wide effects. There could be

1 increased price and reduced output that antitrust
2 is uniquely able to deal with. Antitrust offers
3 treble damages; it offers attorneys fees; it offers
4 injunctions; and it offers the chance to consider
5 all of this conduct in combination.

6 For example, you have a case involving
7 Suboxone where you have a grab bag of
8 anticompetitive conduct. You have citizen
9 petitions, product hopping, and sample denials.
10 The court on the sample denial piece said, "Well,
11 this is pretty nuance stuff."

12 So standing by itself, it's not a violation,
13 but as part of the overall course of conduct, it
14 could be, and that should be on the table here.
15 These biologic companies are not just doing one
16 thing; they're doing a whole a bunch of things. So
17 putting antitrust on the table is one way of
18 dealing with all of that together.

19 MR. WEINSTEIN: Now, earlier, Professor
20 Tushnet mentioned that perhaps a private class
21 action claim in the consumer protection context
22 would be hard. What about in the antitrust

1 context? How would you characterize the
2 distinction between
3 public and private enforcement from a normative
4 perspective?

5 DR. CARRIER: Well, I think it also would be
6 hard here as well. Courts are not always receptive
7 to class actions, and then the question is who's
8 going to organize a class when the conduct is
9 really nuanced? Saying, well, it's not identical,
10 that's a bit nuanced.

11 So I think there's always a role for the
12 government to play. The FTC uniquely has power
13 under Section 5 to go after unfair methods of
14 competition and unfair deceptive acts or practices.
15 That gives us a little more leeway than antitrust
16 law. So I think there's a crucial role for the FTC
17 to play.

18 MR. WEINSTEIN: With the disclosure that I
19 may have had some insight into your forthcoming
20 article, have courts correctly evaluated
21 disparagement in either of these three
22 circuit-split options? If not, is there a better

1 approach?

2 DR. TUSHNET: The fundamental problem with
3 the majority approach is we have one branch of
4 competition law that presumes correctly that false
5 advertising harms competition; it poisons the
6 communicative environment; it makes it harder to
7 understand and compare products and services; and
8 it is anticompetitive in the most basic way.

9 In the majority approach, we have
10 competition law that presumes that false
11 advertising is fine and maybe even good. Those
12 things both can't be true, and false advertising
13 law is right about the harms of false advertising
14 to competition.

15 We think that false advertising law has had
16 the chance to develop a lot of thinking about how
17 you prove falsity and how you prove that it affects
18 consumers. These are tools that are available and
19 should be used both in Lanham Act cases and where
20 relevant in antitrust cases to show that, in fact,
21 the market did move.

22 Right now, there's a situation where you can

1 be put into a heads-I-win/tails-you-lose position.
2 There's a case in the Fifth Circuit that is really
3 reflective of what happens, involving Becton
4 Dickinson. Basically, there was a bunch of false
5 advertising, but it seems to have harmed all the
6 competitors in the market.

7 The Court of Appeals first said, "Well, you
8 can't win a false advertising claim because you
9 can't show which of the sales were lost to you
10 because it harmed everybody else in the market,"
11 and then the court says, "And there's no antitrust
12 claim because it's false advertising, which can't
13 harm the market," and does not seem to appreciate
14 the -- that just can't be right.

15 So I think we do need a rethinking, and
16 hopefully at least the circuits that do a balancing
17 or a case-by-case approach at least have the better
18 idea of it.

19 MR. WEINSTEIN: So if you were the king of
20 the world, if you were, or perhaps just the one
21 crafting all of the laws of the United States, what
22 would be the cause of action?

1 DR. CARRIER: Again, Professor Tushnet and I
2 have an article where we lay out what
3 monopolization should look like. So we presume
4 that there is an anticompetitive effect if you have
5 a monopolist engaging in false advertising. The
6 presumption is appropriate because we're only
7 talking about monopolists.

8 If you go back and look at the treatise,
9 it's worried and it doesn't want to have every
10 instance of false advertising become a case of
11 monopolization. And that's fair, but that is
12 implicit in what we're doing because our test only
13 applies to monopolists. So if you have 1 percent
14 of the market, go do whatever you want. If you
15 have a monopoly, however, there are certain things
16 that you can't do.

17 What we do, as Professor Tushnet pointed
18 out, is we take the learning from false advertising
19 law. We don't think it's appropriate for antitrust
20 courts to say there's no role at all for antitrust.
21 We don't think it's appropriate to say let's just
22 assume the harm is de minimis.

1 False advertising has built up a
2 well-developed body of law. So if we can show, or
3 if the plaintiff can show, that the conduct is
4 literally false or misleading; if it is material;
5 if it deceives or is likely to deceive consumers;
6 and if it causes or is likely to cause harm, then
7 the elements of false advertising are met and the
8 presumption is that there is monopolization. And
9 the defendant could always come back and show that
10 the false or deceptive conduct is ineffective; that
11 somehow it lost market share or wasn't able to put
12 away its rivals.

13 So we think that is appropriate with
14 thinking about false advertising. It ensures that
15 false advertising is limited to the place where it
16 can do the most damage, and we think it makes a lot
17 more sense than what some of the courts are doing
18 today.

19 MR. CLELAND: Can I follow up with one
20 question? If I'm understanding this correctly, the
21 more penetration that the biosimilar makes in the
22 market, the less compelling the antitrust argument

1 becomes.

2 DR. CARRIER: Certainly. If the biosimilar
3 is able to enter the market to the extent that a
4 generic has entered the market, where you see the
5 price fall dramatically and the penetration
6 increased significantly, then that would be a less
7 strong case; correct.

8 MR. CLELAND: So it's 20 percent or
9 25 percent?

10 DR. CARRIER: Well, in generic space, you
11 see the generic taking 90 percent of the market and
12 having the price fall dramatically. I'm not sure
13 if we'll ever get that sort of penetration and
14 discounting given how expensive biosimilar
15 development is. So we'd have to think of something
16 in between, to have more competition than we've had
17 now, but maybe a little bit less might be okay as
18 compared to generics.

19 MR. WEINSTEIN: How do we establish
20 competitive harm here, harm to competition? Is it
21 enough to show that we can prove deception? Is
22 that sufficient, or that folks were misled?

1 DR. CARRIER: Yes. For a biologic company
2 that has monopoly power, I think that's the case.
3 You see this sort of behavior. You see that
4 biosimilars are injured. You also see the
5 regulatory scheme in which this is not like any
6 other industry. We have biosimilars that are
7 supposed to play a crucial role in lowering price.
8 They haven't done it like they should. So the fact
9 that competitors are harmed means that consumers
10 are harmed, and then you supplement that with high
11 price and lack of market share, and I think that
12 you still have an antitrust case.

13 MR. WEINSTEIN: An earlier panelist today
14 mentioned his belief that it would be hard going
15 forward to deceive at least the prescribing
16 physicians or the folks working in hospitals that
17 biosimilars were not as safe or effective as the
18 reference product. If that's true, is there still
19 a role here for harm to competition, at least for
20 the patient and the consumer?

21 DR. CARRIER: Absolutely. The markets that
22 we're talking about here are unique because we have

1 what's been famously called by the Federal Trade
2 Commission, decades ago, the price disconnect
3 because it's not like any other market where the
4 price quality determination is made by one party.

5 So you have the doctors that are making the
6 decision as to what to prescribe. You have the
7 payors or the insurance companies that pay for it.
8 So there is a lot of room for anticompetitive
9 conduct going here, not just the doctors -- and I'm
10 not sure that that problem has been completely
11 solved -- but the patients as well, and the
12 insurance companies, and the PBMs with the big
13 rebates. I think there's a lot of room for
14 anticompetitive conduct here, so that's why I
15 wouldn't rest on our laurels yet.

16 MR. WEINSTEIN: Professor Tushnet, you
17 mentioned that there was a body of research -- I
18 don't want to mischaracterize you -- describing the
19 role that patients have in their own prescribing
20 decisions. I'm curious what your thoughts are in
21 this context, where perhaps the physician is not
22 persuaded by some disparaging comment but the

1 patient is.

2 DR. TUSHNET: From my perspective, as
3 somebody who mostly thinks of this from the Lanham
4 Act perspective, I think it's just a matter for
5 proof what is actually going on in the market, and
6 when we figure that out, we will know. I do think
7 that you can infer something from the fact that
8 companies are trying to reach patients directly.
9 They wouldn't be trying to reach patients directly
10 if they didn't think that it had some chance of
11 moving the market or keeping the market where it is
12 in this case.

13 MR. WEINSTEIN: Thank you.

14 Is there any case law currently that exists
15 that supports this -- I don't want to
16 mischaracterize it -- what I'll call a
17 reinterpretation of how we should think about these
18 kinds of cases?

19 DR. TUSHNET: Certainly from the Lanham Act
20 perspective, this is actually a pretty
21 straightforward Lanham Act cause of action. It's
22 just a question of what are the elements and can

1 you prove them. Certainly, I wouldn't expect the
2 originators to roll over and agree that all the
3 elements have been met, of course not, but at least
4 it's straightforward about what needs to be done to
5 prove the case.

6 Then from the antitrust side, there is this
7 case-by-case approach, which at least is open to
8 hearing about the anticompetitive effects, the harm
9 to the market. Especially in a very small market,
10 by the way, of course harm to one entrant may well
11 be harm to the market if that's all you have, which
12 in some of these cases is what you have.

13 MR. CLELAND: Are you aware of any pending
14 cases raising the antitrust for disparagement of
15 biosimilars, other than I think Johnson &
16 Johnson-Pfizer?

17 DR. CARRIER: I'm not aware. But I would
18 say, going back to the last question, that
19 antitrust, as Professor Tushnet points out,
20 certainly does take the common-law approach. The
21 big picture here is we're talking about the
22 pharmaceutical industry. Pharma is basically

1 giving us whack-a-mole all the time. Every time
2 you think you've figured out what's going on,
3 there's another mole to whack.

4 Just a couple days ago, we saw the judge
5 denied most of the motion to dismiss in the Gilead
6 case, in which there's a new combination of
7 settlements and product hopping that we haven't
8 seen before. Go back a little while, once you
9 thought you figured out everything that pharma was
10 doing, they transferred patents to a Native
11 American tribe to avoid review at the patent
12 office. We couldn't see that coming, but again --

13 (Laughter.)

14 DR. CARRIER: -- it comes with the
15 territory.

16 So this is just the next stage, and there
17 are so many different hurdles here, that it's
18 really clear that this is part of the game, and
19 antitrust is certainly well equipped to deal with
20 these, as we've heard about, shenanigans.

21 MR. WEINSTEIN: One of the other possible
22 options would be some sort of a rulemaking.

1 Commissioner Chopra, FTC Commissioner Chopra, has
2 stated that he wants to see the FTC make broader
3 use of its rulemaking authority. Is this an area
4 where FTC rulemaking might be useful?

5 DR. CARRIER: Sure. As I said to a previous
6 question, yes and yes; yes for rulemaking and yes
7 for enforcement in the courts. Rulemaking could
8 shed light on the problem here, and I think the
9 guidance that FDA has offered is really helpful.
10 Why not have the FTC offer similar guidance; just
11 to make clear that you can't hide behind this fig
12 leaf of clear falsity and that there's a lot of
13 deception and misleading conduct that is going on?

14 So I'd say sure. Rules could make a lot of
15 sense, but certainly not at the effect of enforcing
16 the antitrust laws because we need to do that, too.

17 MR. WEINSTEIN: What about the distinction
18 between this claim as a private versus a public
19 cause of action? What are some of the incentives
20 that should motivate the government versus the
21 private sector, either the consumers or
22 competitors?

1 DR. CARRIER: I think an argument for the
2 government to act is that sometimes this conduct is
3 pretty nuanced. And again, imagine that it's not
4 clearly false but we're raising some sort of safety
5 intimations that maybe it's only similar to.
6 That's pretty nuanced and, to me, that sounds like
7 an ideal recipe for effective FTC enforcement.

8 DR. TUSHNET: The other thing that I would
9 say, too, is it's always an enforcement decision.
10 Government agencies have limited resources. There
11 is definitely a role for private companies. If
12 they think that they're losing millions of dollars,
13 they really at some point should put their money
14 where their mouth is and go to court and fight
15 about the money that they are losing.

16 So there's a reason that the FTC's
17 discretion is often limited, where markets are
18 deconcentrated and where we don't think that
19 there's some private interest that will actually
20 fulfill consumer interest by going after its own
21 interests. But at a certain point, when the
22 consumer harm is great enough, if for various

1 reasons private companies aren't acting, then, yes,
2 there's definitely a role for the government, too.

3 MR. CLELAND: Forgive me. I'm not as
4 familiar with all of the players in this area as
5 others. Obviously, the cost is a big barrier for
6 private rights of action. Are the companies that
7 are suffering the most really in a position to
8 litigate those rights and assume those costs?

9 DR. CARRIER: It certainly is possible.
10 We've seen with biosimilars these are really big
11 companies. Pfizer suing J&J, we don't usually
12 think of Pfizer as the little guy plaintiff. To
13 just enter the market, or try to enter the market,
14 as a biosimilar, you need to have a lot of
15 resources. So, yes, I think they could litigate.

16 MR. WEINSTEIN: So if there are no other
17 questions, let me just offer Professors Tushnet and
18 Carrier an opportunity to make any final remarks.

19 DR. TUSHNET: I just think it's great that
20 we're having this conversation. The law of false
21 advertising is actually pretty good at grasping the
22 realities of the market. I hope that also when we

1 think about antitrust, we can think about being
2 better at empirics, which antitrust prides itself
3 on in many other categories, and then for false
4 advertising has just decided to pretend that there
5 are no empirical effects of false advertising.
6 That's weird. Hopefully, we can create some change
7 on that, and then be realistic about market harms.

8 DR. CARRIER: I just want to say how
9 promising it is that the FDA and FTC are working
10 together on these issues. This is such important
11 stuff. It's so nuanced, and the FDA and FTC have
12 such unique skills and experiences that they can
13 bring to bear, that I really think it's helpful
14 because the pharmaceutical industry knows how to
15 play these games, and sometimes we need the
16 government agencies working together to counteract
17 these games.

18 So I think it's a wonderful development to
19 see the agencies working together on such important
20 issues.

21 MR. WEINSTEIN: Thank you. I hope you all
22 will join me in thanking our panel.

1 (Applause.)

2 Open Public Comment

3 MS. IKENBERRY: We have some folks eager to
4 get started on the public comment portion of this
5 workshop. Again, my name is Sarah Ikenberry. I'm
6 a senior communications advisor in the Office of
7 Therapeutic Biologics and Biosimilars.

8 For the open public comment session, we have
9 I think 17 speakers registered. I'm not sure if
10 they're all here. But each of them will have
11 4 minutes to present. If a speaker finishes early,
12 I will ask if the members of the panel have any
13 questions for the speaker. If the speaker and/or
14 if the questions from the panel do not take the
15 full allotted period, we intend to move on to the
16 next speaker.

17 For the speakers. You can see where she is
18 putting up the microphone, so that is your place.
19 We have timer lights to guide you. You can see
20 them right here on the top of the podium. The
21 timer will give you a 2-minute warning before the
22 red light goes on. If you have not concluded your

1 remarks by the end of your allotted time, I will
2 ask you to do. Please don't make me do that.

3 (Laughter.)

4 MS. IKENBERRY: We have a lot of people
5 registered to speak, so please be mindful of your
6 time and courteous to your fellow speakers. Also,
7 please remember that the hearing is being
8 transcribed, so please be sure to use the
9 microphone with speaking and introduce yourself so
10 that your name will be included in the transcribed
11 remarks.

12 I will now ask the panelists to introduce
13 themselves, starting with Eva.

14 MS. TEMKIN: Hi. I'm Eva Temkin. I am the
15 acting director for policy in CDER's Office of
16 Therapeutic Biologics and Biosimilars.

17 MS. GRAY: I'm Caty Gray. I'm the
18 supervisor for the advertising and promotion policy
19 staff in OPDP.

20 MS. DUTTA: I'm Antara Dutta. I'm an
21 economist at the Bureau of Economics at the FTC.

22 MS. BLACK: Hi, everyone. I'm Armine Black.

1 I'M an attorney in the healthcare division of the
2 Federal Trade Commission.

3 MS. IKENBERRY: Alright. Thank you,
4 everyone.

5 With that, our first speaker is Juliana Reed
6 from the Biosimilars Forum?

7 MS. REED: Good afternoon. I'm Julie Reed,
8 the vice president of global corporate affairs at
9 Pfizer, but also the president of the Biosimilars
10 Forum. The Forum really appreciates the
11 opportunity to provide our perspective on the need
12 to discourage false and misleading communications
13 about biosimilars and to deter anticompetitive
14 behaviors that interfere with efforts to establish
15 a competitive marketplace for all biologic drugs.

16 The members of the Forum represent the
17 majority of the biosimilars approved and marketed
18 in the U.S. to date as well as those under
19 development. The Forum is committed to ensuring
20 that patients and prescribers have complete
21 truthful and non-misleading information about
22 biosimilars.

1 As my colleague, Hillel Cohen, mentioned in
2 his remarks, we are very concerned that there has
3 been and continues to be a pattern of negative
4 information about biosimilars to patients,
5 healthcare professionals, and others who have a
6 role in adoption of biosimilars in the U.S.
7 Continued misleading information about biosimilars
8 will have a negative impact on the U.S. healthcare
9 system, physicians, and patients, ultimately
10 leading to ongoing lost of cost savings and uptake
11 of biosimilars in the U.S.

12 But we know misleading information is not
13 the only barrier. As all of the speakers have said
14 today, there are multiple barriers that are
15 preventing the success of this marketplace. The
16 members of the Forum have spent hundreds of
17 millions of dollars to bring each biosimilar to the
18 market. Pfizer alone has 8 approved biosimilars in
19 the U.S., but we all know the market is not
20 working, and it is not working for the patients we
21 are here to serve.

22 We are grateful to the FDA for your

1 incredible work to date over the years. We're also
2 grateful for the FTC and your incredible work over
3 the years to help support biosimilars. What we
4 need now, though, is every other stakeholder to
5 join us in this fight and to get engaged to
6 proactively support policies that will remove these
7 barriers.

8 We need not only the FDA and the FTC to be
9 engaged and be proactive when you walk out of the
10 door here today to get this done, but we also need
11 Congress, CMS, payers, patients, and others to
12 start to proactively support the uptake of
13 biosimilars in this country.

14 This is about cost savings and it's about
15 cost savings to patients and the healthcare system.
16 This is about innovation in the future so that we
17 can all afford the innovation that is coming, but
18 ultimately this is about the patients we're here to
19 serve and that the members of the Biosimilars Forum
20 are here to serve. Thank you.

21 MS. IKENBERRY: Thank you.

22 Our next speaker is Philip Schneider from

1 the Ohio State University College of Pharmacy.

2 DR. SCHNEIDER: Thank you, and thank you for
3 the opportunity. My name is Philip Schneider. I
4 am a professor of pharmacy at the Ohio State
5 University where I've been on faculty for almost 40
6 years, as well as the chair of the Advisory
7 Committee for the Alliance for Safe Biologic
8 Medicines, which I've done for 11 years.

9 I'd like to make a statement, first of all,
10 correcting misperception, a true and misleading
11 communication related to my quote in the Washington
12 Post. That relates to a quote I made about
13 supporting the FDA's role in assuring the safety of
14 the medication supply in our country.

15 ASBM has been involved in working with
16 regulators around the world, including FDA, on
17 policies that focus on safety, including
18 distinguishable non-proprietary names and an
19 interchangeability classification for biosimilars.
20 In no way do we feel that is anticompetitive, and I
21 want to correct the perception that ASBM is
22 spreading misperceptions and that I did that

1 personally myself.

2 Today I'd like to address my comments on
3 what we think to be an incorrect assumption
4 underlying the proceedings today, namely that
5 biosimilar uptake in the U.S. is strongly linked to
6 low physician confidence levels in biosimilars and
7 physician confidence has been depressed because of
8 anticompetitive practices.

9 Last year, ASBM conducted a survey of 579
10 physicians in six Western European countries:
11 France, Germany, Italy, Spain, Switzerland, and the
12 UK. We surveyed physicians in 10 different areas
13 of practice, including rheumatology,
14 gastroenterology, oncology, dermatology, and
15 neurology. All of these physicians prescribe
16 biologic in their practice.

17 What we found is these physicians were very
18 familiar with and confident in biosimilars. This
19 is not perhaps surprising because European
20 physicians have had 13 years of experience with
21 biosimilars.

22 Depending on the country, between 82 and

1 93 percent of prescribers consider themselves
2 familiar or very familiar with biosimilars.
3 Between 80 and 99 percent would feel comfortable
4 prescribing a biosimilar to a new treatment-naive
5 patient. Between 46 and 76 would be comfortable
6 switching a patient from a reference product to a
7 biosimilar even if they were stable on the current
8 medicine.

9 In spite of that, if we look at the
10 biosimilar market share in the six countries that
11 we surveyed, there's very wide variation among
12 biosimilar adoption in each of these countries.
13 For example, market share for the epoetin
14 biosimilar ranges from 6 to 84 percent. There are
15 similar ranges for other biosimilars.

16 Clearly, there are other factors besides
17 physician confidence, which is uniformly high
18 across the countries. These factors are likely to
19 include differences between each country's payer
20 policies; differences in the length of time a
21 biosimilar has been on the market; the number of
22 biosimilars in a given product class; the discount

1 each product receives relative to the originator
2 product; and other factors.

3 Healthcare professionals here in the U.S.,
4 as in Europe, are not antisimilar. It is
5 inaccurate to suggest that negative perceptions are
6 holding up biosimilar development and
7 commercialization. We are enthusiastic about
8 biosimilars and want to see them as much as anyone
9 else, and we are pleased to see how far the U.S.
10 has come in a few short years. We urge the FDA and
11 FTC to continue their work to build a strong and
12 sustainable biosimilars market. Thank you for the
13 opportunity to comment.

14 MS. IKENBERRY: Thank you very much.

15 Madelaine Feldman, Alliance for Safe
16 Biologic Medicines.

17 DR. FELDMAN: Thank you. As you said, my
18 name is Madelaine Feldman. I'm a rheumatologist in
19 private practice in New Orleans. I'm also
20 president of the Coalition of State Rheumatology
21 Organizations and the founder of the Rheumatology
22 Alliance of Louisiana.

1 ASBM is an organization of more than 140
2 patient advocacy groups and physician societies.
3 The work includes sharing the perspectives of
4 pharmacists, patients, and physicians with
5 regulators and other policymakers at the state,
6 national, and international level. I'd like to
7 speak on a couple of issues regarding biosimilars.

8 The first is that misinformation continues
9 to affect the objectivity of physicians and make us
10 essentially antibiosimilar. Perhaps
11 rheumatologists are a different lot. I just
12 presided over a national rheumatology meeting this
13 past weekend and polled the entire group coming
14 from around the country if anyone felt that
15 biosimilars were inferior to originators. No one
16 said yes; everyone said no and that they all
17 thought they were not inferior; and then would
18 anyone have any hesitancy in prescribing a
19 biosimilar, and no one had any hesitancy.

20 So at least for that group of
21 rheumatologists, which was quite representative,
22 there appeared to be at least no negative feelings

1 in that regard. But I have to admit, clinicians
2 are generally more cautious and conservative
3 regarding new treatments and are hesitant to
4 change, particularly when it comes to changing a
5 stable patient.

6 Because it can take years to months and
7 months to years to stabilize the rheumatoid
8 arthritis patient, rheumatologists have been
9 sensitized to non-medical switching by payers,
10 wherein that they are told the medicine that
11 finally stabilized our patient will no longer be
12 paid for.

13 By changing formularies often to a higher
14 priced drug that cost the patients more to solidify
15 the formulary profit margin, middlemen can legally
16 switch patients in the United States and switch
17 their medicines every six months. This could
18 involve switching back and forth between
19 originators and biosimilars, which wouldn't be
20 horrible, but they even switch patients, and this
21 has happened, to completely different biologics.
22 So yes, physicians are leery of a great American

1 switching experiment.

2 Speaking of incentives in our supply chain
3 on the pharmacy side, formulary placement, hire
4 list prices, and higher market share are the ones
5 that are preferred. That puts biosimilars behind
6 the eight ball from the get-go once they've been
7 launched. If incentives are implemented for
8 biosimilars, any cost consideration should be
9 directed to the patient because
10 incentives that monetarily benefit the physician
11 could actually undermine the patient's trust in
12 their doctors.

13 Finally, repeating what everyone has said,
14 considering the perception that U.S. lags behind
15 Europe, thinking that at 5 years out from
16 biosimilar approval in Europe, there were
17 11 products approved, in the United States we have
18 26. The FDA deserves credit for their support in
19 building a biosimilar market so quickly without
20 compromising on safety or efficacy standards.

21 Physicians are enthusiastic about
22 biosimilars and the benefits they can bring in

1 terms of therapeutic offerings and true cost
2 savings, and through price reduction to our
3 patients in the larger health system and not merely
4 increasing middlemen-pocketed-fees and price
5 concessions.

6 The most important strategies to continue
7 the process in the U.S. are strong FDA educational
8 programs for healthcare professionals and patients,
9 along with pharmacovigilant programs, particularly
10 in light of the payer's ability to frequently
11 switch patients every 6 months. This will allow
12 clinicians the opportunity to learn from real-world
13 experience with biosimilars and to gain confidence
14 in using them. Thank you for allowing me to -- and
15 I have no time for questions.

16 MS. IKENBERRY: Thank you.

17 Our next speaker is Sundar Ramanan, Biocon.

18 DR. RAMANAN: Hi. My name is Sundar
19 Ramanan, vice president and head of global
20 regulatory affairs for Biocon Biologics, a fully
21 integrated biosimilars company. Our goal is to
22 transform health care and transform lives by

1 bringing affordable high-quality biosimilars to the
2 U.S. patients. We're also an innovative company,
3 and we intend to transfer the value of innovation
4 to the health systems and patients. We thank the
5 agencies for setting up this public workshop and
6 working towards a fair and balanced marketplace for
7 biosimilars.

8 The things that I'm going to cover fall
9 under five buckets. Number one, insulin guidance.
10 We applaud the agency for issuing a draft guidance
11 for insulin. The draft guidance is science-based
12 and patient-focused. Despite the expected
13 opposition that has come from few companies, we
14 urge the agency to finalize the guidance.

15 In addition, for molecules like insulin with
16 high financial unmet need, we request the agency to
17 consider a shorter time frame for the review
18 process once the filing is made. The agency
19 already has precedence in the generic space. This
20 is another critical component to bringing these
21 much needed products to insulin patients faster and
22 fostering competition.

1 Number two, interchangeability. With the
2 abundance of real-world evidence and frequent
3 marketplace driven switching demonstrating the
4 safety of biosimilars globally, we request the
5 agency to reconsider ON/R [indiscernible], and
6 evaluate the need for multiple switch studies for
7 interchangeability.

8 Furthermore, we ask the agency to reconsider
9 the need for any distinction between the evidence
10 requirements for biosimilarity and interchangeable
11 biologics. Any regulatory requirement must be
12 based on science and evidence and not based on
13 fear. Needless to say, we collectively must put
14 the patient's safety first.

15 The immunogenicity data requirement for
16 biosimilarity already satisfies the data
17 requirement for interchangeability. No new or
18 additional information will be gained from multiple
19 switch studies, however, it only results in time
20 delay and wasted resources in bringing
21 interchangeable products to patients.

22 From a practical point of view, either due

1 to the use of exclusive formulary replacement in
2 retail pharmacy or through institutional buying
3 practices, interchangeability is the de facto
4 practice in a large number of cases. Practically
5 speaking, though, the regulatory distinction ends
6 up giving an opportunity for originators to create
7 an incorrect perception that biosimilarity standard
8 is not necessarily adequate for safe and effective
9 use while not having a meaningful impact on actual
10 usage.

11 Number three. Disincentivize
12 anticompetitive behavior on the part of reference
13 product manufacturers and provide positive
14 incentive for biosimilars. The biosimilar market
15 is at the critical juncture, and the steps taken to
16 encourage it now will be critical to ensure its
17 viability.

18 There have been multiple instances where
19 biosimilar products have not been encouraged, but
20 have been actively excluded from insurance
21 coverage. It is critical that positive incentives
22 such as ASP plus 8 percent reimbursement and steps

1 like additional biosimilar or specialty tiers in
2 Medicare Part D be provided in order to avoid
3 originator behavior intended to discourage entry of
4 biosimilars and reduce long-term competition.

5 Delays and cost to frivolous patent
6 litigation and patent thickets should also be
7 disincentivized. We also request the agency to
8 take strong action against misinformation
9 campaigned by the reference product manufacturers.
10 Allowing innovation in the biosimilar development
11 with regards to evidence required, related to
12 immunogenicity, there is little clinical relevance
13 of immunogenicity in oncology settings and general
14 immunosuppressant status.

15 For drugs with less frequent dosing, say,
16 for example, every 6 months, the need for switch
17 studies is not value-added. Scientific rationale
18 should be encouraged based on the risk of
19 immunogenicity.

20 With regard to sample size determination,
21 the methodologies need to evolve further to keep in
22 time with the times. Specifically, we request the

1 agency to utilize Bayesian statistics for residual
2 uncertainty. We also request the agency to allow
3 for mathematical models in PK/PD for extrapolation
4 of indications.

5 Lastly on naming, we request the agency to
6 consider, with significant experience in the
7 marketplace, the need for suffix for biosimilars.
8 We have additional comments, and we'll be
9 submitting to the docket. We thank you for the
10 opportunity to present.

11 MS. IKENBERRY: Thank you.

12 Next, Andrew Spiegel, Global Colon Cancer
13 Association.

14 MR. SPIEGEL: Good afternoon. My name is
15 Andrew Spiegel, the executive director of the GCCA,
16 and today I am proud to not only represent that
17 organization but also the Alliance for Safe
18 Biologic Medicines, an organization which I am a
19 founding member for more than 10 years ago. We
20 have advocated for patient-centered policies
21 regarding biosimilars since then.

22 To that end, I have testified numerous times

1 before the FDA in support of approving biosimilars
2 and before state legislatures all across the nation
3 in support for updating pharmacy practices to
4 facilitate biosimilar substitution. We have also
5 worked and held three joint meetings with the FDA,
6 Health Canada, and the World Health Organization,
7 all with the goal of advancing a harmonized
8 international standard for biologic naming to
9 improve global pharmacovigilance for all biologics
10 and biosimilars.

11 I can assure you as a founding member of
12 ASBM that no ASBM member has ever suggested that a
13 patient went to the emergency room as a result of
14 switching to a biosimilar. Those patients are here
15 and can tell you their own story later, but I can
16 assure you that not only did that not happen, but
17 ASBM has never advocated or suggested that a
18 biosimilar is inferior to a biologic originator
19 product, and to the contrary, we've been fierce
20 advocates for biosimilar uptake all around the
21 world.

22 It's also been my privilege to serve in a

1 number of leadership roles in the international
2 patient community such as the International
3 Alliance of Patient Organizations and now chairing
4 the World Patients Alliance. We know that biologic
5 medicines have helped more than 800 million people
6 worldwide, and in the case of colorectal cancer, in
7 my organization, which has 49 members around the
8 world, we've seen these medicines help triple the
9 life expectancy of the most advanced colorectal
10 cancer patient. We're talking about a life
11 expectancy from 10 months to now 3 years thanks to
12 not only these new treatment options but also
13 getting these treatment options at a reduced cost,
14 and we're hoping that biosimilars will help expand
15 access to these therapies.

16 With respect to the U.S. marketplace, first
17 and foremost, speaking as the head of an
18 international patient organization, let me be clear
19 that I'm unaware of any attempt to undermine
20 confidence in biosimilars, either in the minds of
21 the public, or in the patient community, or among
22 physicians.

1 To the contrary, I am encouraged by the
2 extremely positive reaction biosimilars have had in
3 the United States thus far, and patients,
4 physicians, and healthcare providers have all
5 seemed to accept biosimilars as a part of standard
6 medical care, and they recognize what an important
7 tool it can be in containing healthcare costs.

8 Just as a few days ago, I chaired a panel at
9 a biologics conference in San Diego, where a number
10 of people who are here today were at, and that
11 included chairing a panel where we had one of the
12 largest reference companies, as well as a
13 representative of one of the largest biosimilar
14 companies on that panel. I was very encouraged
15 that both agreed that the U.S. biosimilar market
16 thus far is very much a success story, and both
17 agreed that the future looks very positive.

18 This great enthusiasm and confidence
19 surrounding biosimilars is in no small part due to
20 the phenomenal work that the FDA has done in
21 approving so many biosimilars in a relatively short
22 period of time, almost half of those approvals

1 happening within the last year, and the FDA doing
2 so without compromising on its standards for safety
3 and efficacy.

4 The heart of the U.S. health system, like
5 any other country, has its own unique challenges
6 different from those in the EU, Canada, Australia,
7 or places where we work, but nevertheless, there
8 are things that we can learn from other countries'
9 successes, particularly those of the EU countries
10 who enjoy a robust biosimilars market.

11 The one thing that we've seen across Europe
12 is that more and more biosimilars are launched in a
13 given product, that more competition drives prices
14 down where discounts increase substantially and
15 biosimilar market share goes up, and we know what
16 to expect and what things to look for, and
17 thankfully we're seeing that happen here in the
18 United States.

19 Here, we had a biosimilar that launched with
20 a relatively low 15 percent discount over its
21 reference product, and today with increased
22 competition, that product has gained a majority

1 share in the U.S. market with 55 percent. We have
2 every reason to believe this pattern will continue
3 as we see it becoming routine for 3, 4,
4 5 biosimilar approvals for a reference product.
5 And as these come to market, manufacturers will
6 continue to compete on price, going from relatively
7 low discounts to higher discounts.

8 Speaking as a representative of the broader
9 patient community, we of course want more
10 biosimilars approved and available, but our
11 enthusiasm is tempered by the understanding that
12 with anything of this scale and where people's
13 lives and health are at stake, it's not an
14 instantaneous process.

15 Simply put, the system is working, a little
16 slower than some would have hoped. But just as we
17 don't want biosimilars or any other medicines rust
18 through the approval process, we urge our
19 regulators to be mindful not to unnecessarily and
20 possibly counterproductively interfere with a young
21 but steadily growing biosimilars market.

22 MS. IKENBERRY: Thank you.

1 MR. SPIEGEL: Thank you very much.

2 MS. IKENBERRY: Thank you.

3 Our next speaker is Kim Caldwell,
4 Pharmaceutical Care Management Association.

5 MS. CALDWELL: Good afternoon. I am Kim
6 Caldwell, a registered pharmacist with more than
7 four decades of experience throughout the practice
8 of pharmacy. Included in this time is more than 12
9 years as a member of the Texas State Board of
10 Pharmacy and a year with CMS as a leader engaged in
11 the creation of the program rules for Medicare Part
12 D. I appreciate the opportunity to be here today
13 on behalf of Pharmaceutical Care Management
14 Association, PCMA.

15 PCMA is a national association representing
16 America's pharmacy benefit managers, which
17 administer prescription drug plans and operate
18 specialty pharmacies for more than 270 million
19 Americans with health coverage through Fortune 500
20 companies, health insurers, labor unions, the
21 Medicare and Medicaid programs, the Federal
22 Employees Health Benefits Program, and health

1 insurance marketplaces.

2 PCMA commends the FDA and the FTC for their
3 collaboration to enhance competition in the
4 biologic products marketplace. We also commend and
5 strongly support the many important steps the FDA
6 has taken to facilitate greater availability of
7 biosimilar and interchangeable products, including
8 its final guidance on interchangeable biosimilars,
9 the 2018 Biosimilars Action Plan, in its
10 comprehensive campaign to educate clinicians about
11 the benefits and savings possible through these
12 innovative therapies.

13 We are encouraged by the FDA's more recent
14 efforts to reduce barriers to achieving
15 interchangeability, including final guidance
16 limiting the cases in which switching studies were
17 required. The agency also has designed an approval
18 pathway allowing manufacturers to use comparative
19 products not approved in the U.S. for biosimilar
20 development.

21 These are encouraging steps. Now, we urge
22 the agency to sustain this forward progress by not

1 adopting unnecessary barriers as it finalizes
2 industry guidance relating to licensure and
3 labeling

4 Another encouraging development is FTC's
5 commitment to address manufacturer tactics used to
6 block biosimilar entry with anticompetitive patent
7 settlement agreements. Increasing competition
8 through the approval of biosimilar and
9 interchangeable products is key to lowering the
10 prescription drug costs for consumers, employers,
11 and public programs.

12 We appreciate the collaboration between the
13 FDA and the FTC, which has argued that tactics
14 aimed at gaming FDA rules may be anticompetitive
15 and unlawful, and we urge consideration for further
16 action when manufacturers employ tactics using
17 anticompetitive patent settlements and patent
18 thickets to delay widespread use of lower costs and
19 biosimilars.

20 An important and necessary next step to
21 further facilitate a competitive biosimilar
22 marketplace is for FDA to promote the therapeutic

1 substitution of lower cost, interchangeable
2 biosimilars for the reference products.
3 Additionally, we recommend the FDA provide clear
4 direction to states in favor of product
5 substitution without burdening barriers such as
6 notification provisions.

7 Patients and clinicians need expressed
8 clarity that these therapeutic substitutions are
9 really and truly interchangeable. For many
10 patients and clinicians alike, these therapies are
11 new, and there may be a degree of uncertainty
12 around switching and substitution.

13 As the FDA's voice is the gold standard for
14 safety and efficacy, when the FDA has approved a
15 product for interchangeability, it should be
16 labeled and marketed as such without conflict or
17 confusion. Anything short of that clarity would
18 reinforce caution with patients and clinicians, and
19 thus impede the ability to achieve a truly
20 competitive biosimilar market. Thank you for the
21 opportunity to provide input. I'll welcome your
22 questions. We have 25 seconds.

1 (Laughter.)

2 MS. IKENBERRY: I'm not sure I could get a
3 whole question in 25 seconds.

4 MR. SPIEGEL: Oh, go ahead. We have time.

5 MS. IKENBERRY: But you mentioned in your
6 statement some guidance considerations around
7 licensure and labeling, and I would encourage you,
8 to the extent that you intend to submit written
9 comments to the docket, to spell those out a little
10 bit because I didn't quite follow what you were
11 saying.

12 MR. SPIEGEL: We do and we will. Thank you
13 very much.

14 MS. IKENBERRY: Thank you

15 MR. SPIEGEL: And just so you know, that was
16 a lot of words for a guy from Texas to say in that
17 time period --

18 (Laughter.)

19 MR. SPIEGEL: -- and I really wanted to say
20 whack-a-mole, but I didn't know if I could get that
21 in. Thank you.

22 (Laughter.)

1 MS. IKENBERRY: Yeah, shenanigans and
2 whack-a-mole are two of the nice words of the day.

3 Next is Andrew Greenspan, Janssen
4 Immunology, vice president of medical affairs.

5 DR. GREENSPAN: Good afternoon. My name is
6 Dr. Andrew Greenspan, and I'm the vice president of
7 medical affairs for immunology at Janssen, the
8 pharmaceutical company of Johnson & Johnson. At
9 Janssen, we have more than three decades of
10 experience with biologic development,
11 manufacturing, postmarketing safety, and promotion.
12 We pioneered biologic therapy with the first ever
13 approved monoclonal antibody, Remicade, or
14 infliximab, a TNF blocker for which there are
15 currently four approved biosimilars.

16 From the beginning, we have led in
17 advocating for a biosimilar pathway. We have seen
18 patients struggle for years with chronic
19 progressive disease before getting diagnosed and
20 finding a biologic therapy that finally brings them
21 relief.

22 We are deeply committed to helping patients

1 remain healthy and safe throughout their treatment
2 journey and have affordable access to the therapies
3 that they and their doctors decide on. We are also
4 committed to reducing overall healthcare costs and
5 believe that these goals can and must be
6 accomplished together.

7 With this perspective in mind, we'd like to
8 ask FDA and FTC to consider four points. First, as
9 you collaborate to spur biosimilar adoption,
10 continue to uphold the critical role of the
11 patient-doctor relationship and individual
12 treatment decisions. Many patients endure long and
13 painful journeys before achieving clinical control
14 of their disease. They need valuable information
15 about their options to make informed treatment
16 decisions with their doctor.

17 Second, we heard many perspectives today on
18 interchangeability. We believe patients and their
19 doctors deserve clear and complete communication on
20 the interchangeability status of a biosimilar. For
21 treatments that require multiple administrations,
22 such as infliximab, patients and doctors should

1 have relevant data on alternating back and forth
2 between products before deciding to do so.

3 Implying that a biosimilar is
4 interchangeable when it has not been approved as
5 such is misleading. To ensure that patients and
6 their doctors have clear and complete information
7 on the interchangeability status of a biosimilar,
8 communications on a biosimilar should disclose its
9 interchangeability status.

10 Third, we urge the FDA to clarify that
11 communications on biosimilars to payers and
12 formulary committees continue to be governed by the
13 FDA guidance on manufacturer communications with
14 payers, formulary committees, and similar entities.

15 Fourth, we would like to underscore that
16 biosimilar policies are delivering on the promise
17 of the BPCIA with lowered costs for the system and
18 will continue to as long as there is a level
19 playing field for biosimilar and reference
20 products.

21 The Remicade and infliximab biosimilars
22 experience shows that competition is bringing down

1 prices for the reference biologic and its
2 biosimilars alike. Since the introduction of
3 infliximab biosimilars, Remicade's average sales
4 price, or ASP, has fallen by 31 percent. Remicade
5 is now the market's lowest priced innovator
6 anti-TNF therapy with annual costs less than half
7 of other innovator TNFs.

8 Because of Remicade's price competitiveness
9 and uptake of biosimilars, the system has seen over
10 \$4.8 billion in savings in the past three years.

11 Additionally, it is important to note that
12 biosimilar development continues to expand with 19
13 biosimilars in FDA's biosimilar product development
14 program in January 2013 to 63 as of last year.

15 In closing, as the FDA and FTC look to spur
16 biosimilar adoption, we call on you in parallel to
17 1) take a patient-centric approach in your policy
18 decisions; 2) ensure interchangeability status is
19 disclosed to patients and providers; and
20 3) safeguard the competitive market dynamics that
21 are dramatically bringing costs down. Thank you
22 for the opportunity to speak.

1 MS. TEMKIN: Can I squeeze in one question?
2 The red light just went on.

3 You said that communications on a biosimilar
4 should disclose interchangeability status. Do you
5 have something specific in mind or can you expand
6 on that a little bit?

7 DR. GREENSPAN: Sure. As explained earlier,
8 as the market dynamics may lead to switching as
9 frequently as every 6 months with a chronic therapy
10 like infliximab, we think the patients and
11 providers will have questions about the possibility
12 that they may be switched as frequently as twice a
13 year from the products.

14 My area is immunology where we market
15 infliximab, which is a highly immunogenic molecule,
16 and we think the interchangeability standard was
17 created by the FDA for a very valid reason. I
18 think the point made by a speaker this morning is
19 very valid, that the interchangeability standard
20 should consider specific characteristics of
21 molecules. Some are more immunogenic than others,
22 and that's why it's more important for particular

1 molecules like Remicade, for example.

2 MS. TEMKIN: Thank you.

3 MS. IKENBERRY: Our next speaker is Kathleen
4 Arntsen, president and CEO of Lupus and Allied
5 Diseases Association.

6 MR. GREENBLATT: Hi. I am not Kathleen
7 Arntsen. My name is Corey Greenblatt.

8 FEMALE VOICE: I think Steve Lucio is next
9 on the --

10 MS. IKENBERRY: Oh, I'm sorry.

11 MR. GREENBLATT: Okay, back up.

12 MS. IKENBERRY: Steven Lucio, Vizient.

13 DR. LUCIO: Thank you. To the members of
14 the workshop and to all esteemed employees of the
15 FDA and FTC, my name is Steven Lucio, vice
16 president of the Center for Pharmacy Practice
17 Excellence at Vizient, the largest member-driven
18 healthcare performance improvement company in the
19 U.S., on behalf of Vizient, I'd like to express our
20 deepest appreciation not only for this forum, but
21 also for all the enduring efforts that have been
22 made to enhance competition, thereby improving

1 patient access to safe and effective biologic
2 molecules.

3 Vizient provides solutions for more than
4 50 percent of the nation's acute care providers,
5 including 95 percent of the nation's academic
6 medical centers, a wide array of leading integrated
7 health systems and pediatric hospitals, and more
8 than 20 percent of ambulatory providers in the U.S.

9 Vizient has focused its array of expertise
10 of supporting health systems evaluation and
11 adoption of biosimilars to lower pharmaceutical
12 expenditures and to maintain or improve patient
13 care. Still more work is required to alter the
14 trajectory of pricing growth for many biologic
15 drugs. Therefore, Vizient would like to offer
16 three key insights and recommendations to advance
17 the desired competitive landscape related to the
18 approval process, education, and payer decisions.

19 First, Vizient would like to thank the FDA
20 for its efforts at improving the understanding of
21 the approval process through the publication of
22 regulations and guidance documents. The additional

1 clarity is essential for perspective manufacturers,
2 as well as the population of providers that will
3 ultimately be prescribing these medications.

4 Vizient would like to note the FDA's
5 decision regarding the clinical immunogenicity
6 considerations for biosimilar and interchangeable
7 insulin products, specifically the decision not to
8 require comparative clinical immunogenicity studies
9 in the approval of these agents, and scientifically
10 substantiated efficiencies and approval will
11 decrease the investment expense required to develop
12 competing molecules.

13 We encourage FDA to continue evaluating the
14 opportunity for similar decisions to be applied to
15 other biologics. For example, the European
16 community has identified certain molecules and/or
17 product classes where comparative effective studies
18 have been or could be waived, and we would ask that
19 FDA continue to evaluate additional opportunities
20 to streamline approval requirements up to, and
21 including, and eliminating the need for comparative
22 effectiveness studies where scientifically

1 justified.

2 We would also like to commend the FDA for
3 increasing the level of education provided to
4 improve the understanding of foundational concepts
5 of biosimilar licensing. We especially thank FDA
6 for increasing the timeliness of access to approval
7 documents for approved biosimilars, even those not
8 subject to an advisory committee hearing.

9 This information, even the more detailed
10 aspects of analytical characterization, has been
11 invaluable as we have worked to educate pharmacists
12 and physicians on the fundamental differences
13 between the approval methodology of biosimilars as
14 compared to new molecular entities.

15 Vizient would ask FDA for additional
16 information concerning biologic production. Right
17 now, given the tremendous desire for increased
18 transparency in pharmaceutical manufacturing,
19 including the origination source of API due to our
20 lingering history of drug shortages, as well as the
21 concerns about coronavirus outbreak, while these
22 issues are not primarily impacting biologics, there

1 is additional transparency that would be helpful
2 addressing any lingering concerns about biosimilar
3 quality and safety.

4 One of the biggest gaps we found regarding
5 biologic manufacturing understanding is the fact
6 that all biologics, originator or biosimilar,
7 demonstrate variability. In Europe, where this
8 information is disclosed, the content referring to
9 the clinical literature has been very informative
10 in educating pharmacists and physicians.
11 Therefore, we would ask if the FDA could provide
12 information on manufacturing changes related to
13 U.S. biologics. It would further the understanding
14 that the monitoring of biologic variation through
15 analytical means is not novel to the biosimilar
16 experience.

17 As has been discussed today, there are
18 challenges associated with payer reimbursement
19 decisions, which impact providers and most
20 importantly patients. Beyond educational issues
21 and messages questioning the validity of the
22 approval mechanism, biosimilar adoption continues

1 to be delayed due to variable coverage and payment
2 policies. It is one of the most substantial
3 hurdles facing the market and will continue to
4 require appropriate attention and focus, and we
5 would appreciate any guidance from either agency on
6 ways to further conversation regarding this hurdle
7 with the appropriate audiences.

8 We appreciate FDA's and FTC's leadership and
9 working collaboratively to support a more
10 competitive approval landscape for biosimilars.

11 Thank you.

12 MS. IKENBERRY: Thanks, and sorry for the
13 mix-up.

14 Next is Kathleen Arntsen.

15 MR. GREENBLATT: Hello. My name is Corey
16 Greenblatt, and I'm representing Kathleen Arntsen
17 from LADA and ASBM. Before I begin, I just want to
18 say I have no disclosures to make today regarding
19 my comments on behalf of Lupus and Allied Diseases
20 Association.

21 Good afternoon and thank you for the
22 opportunity to provide our unique patient

1 viewpoint. Biosimilars hold tremendous promise and
2 therapeutic advantages for people like us, just as
3 biologics have revolutionized treatment for
4 millions of individuals living with life-altering
5 diseases.

6 Lupus is an extremely complex, chronic
7 inflammatory autoimmune disease affecting virtually
8 any organ system of the body with few approved
9 drugs, no known cause or cure, and a challenge to
10 live with and treat. There is no cookie-cutter
11 approach to treat intricate patients like us, and
12 it requires access to the entire arsenal of
13 treatments and open and transparent communication
14 between us and our providers.

15 In order for biosimilars to reach their
16 potential and improve stakeholder engagement,
17 education, and access, we need to ensure confidence
18 that biosimilars are as safe and as effective as
19 the reference biologic products among patients,
20 healthcare providers, pharmacists, payers, and
21 other stakeholders while prioritizing patient
22 safety and affordability.

1 We are pleased that the agency has finalized
2 guidance for interchangeable biologics by
3 clarifying safety, efficacy, and immunogenicity
4 methodologies by requiring manufacturers to conduct
5 vigorous multiple switching studies that alternate
6 between a biosimilar and its reference product. We
7 are also thrilled that the FDA supports robust
8 pharmacovigilant mechanisms for postmarketing
9 safety monitoring of an interchangeable in order to
10 not diminish efficacy and patient safety.

11 Developing an aggressive postmarketing tracking
12 system will also help to guarantee stakeholder
13 confidence and facilitate market uptake while
14 establishing a longitudinal electronic medical
15 record.

16 We suggest that you consider adopting
17 methods such as apps on electronic devices and
18 patient-reported outcomes to monitor real-world
19 events. Engaging patients and teaching them to be
20 more proactive in their care will be empowering and
21 can help diminish any lack of trust.

22 Biosimilars have the potential to promote

1 greater price competition among biologics, and we
2 hope that they are more affordable, but the
3 variance in terminology when referring to
4 biosimilars is both confusing and a hindrance.
5 Stakeholder adoption of more uniform language such
6 as the FDA's would foster more confidence.

7 One of the biggest impediments to the
8 advancement of innovative therapies is the
9 overabundance of egregious payer utilization
10 management policies such as step therapy and
11 non-medical switching protocols. These
12 cost-containment measures impact provider ethical
13 obligations by requiring them to follow a set
14 course of care regardless of their best personal
15 judgment.

16 As an individual who is harmed by step
17 therapy, I am concerned that patients who are
18 stable on any drug will be switched for non-medical
19 reasons, and in particular those doing well in a
20 biologic will be switched to a biosimilar that has
21 not been determined to be interchangeable.

22 We urge you to establish robust patient

1 safeguards by applying strong scientific safety
2 standards, stating that switching of stable
3 patients should only be determined by the treating
4 provider and the patient, and facilitating dialogue
5 among multistakeholders, including payers. We ask
6 you to reach out to other federal agencies and work
7 with them to develop sound policies that address
8 such issues.

9 In closing, I want to reiterate that we are
10 unwavering in our belief in the sanctity of the
11 doctor-patient relationship and that only providers
12 who are familiar with an individual's personal
13 medical history should be making treatment
14 decisions. Patient safety must be first and
15 foremost in choosing the most appropriate therapies
16 for any person with complex medical conditions.

17 We have faith that we can advance
18 biosimilars while still allowing physicians to make
19 decisions in the best interest of their patients.
20 Sometimes that decision is to keep a patient on a
21 successful biologic throughout their therapy;
22 sometimes it is switching to a biosimilar or

1 starting a naive patient on a biosimilar.

2 There are millions of people who could
3 benefit from access to innovative therapies now and
4 many more in the future who are yet to be
5 diagnosed. We need to work together to make that
6 happen. We thank you for the opportunity to share
7 our perspective and applaud the FDA for continually
8 recognizing the importance of the patient voice
9 during the regulatory process. Thank you.

10 MS. IKENBERRY: Thank you.

11 Our next speaker is Ian Orekondy,
12 AdComplyRx.

13 MR. OREKONDY: Hello. Thank you for the
14 opportunity to comment today. My name is Ian
15 Orekondy. I'm the founder of AdComplyRx. We work
16 with industry to monitor prescription drug
17 advertising and identify ads that appear to
18 inadvertently infringe on FDA guidance so that
19 firms can fix them. Currently, we have a focus on
20 digital ads and search engine marketing.

21 My input is specific to the draft guidance
22 for promotional labeling and advertising

1 considerations for prescription biological
2 reference products and biosimilar products.
3 Earlier we heard about Dr. Google and the
4 importance of patient education and healthcare
5 professional education around biosimilars.
6 Dr. Google is often the number one driver of
7 traffic to a prescription medication's website
8 where patients can learn about a specific
9 biosimilar or biosimilars in general.

10 We also note that there was an FDA warning
11 letter issued last month that was specific to
12 search ads on Google, so our request is that the
13 final guidance documents specifically get into how
14 this biosimilar guidance would apply to internet
15 marketing platforms with character space
16 limitations; for example, Google and Twitter.
17 Additionally, how would this guidance apply to,
18 quote/unquote, "brand-connected ads," that is ads
19 that do not mention any brand within the ad itself
20 but then link directly to a brand.com website.

21 These are important questions that impact
22 virtually all prescription biologic and biosimilar

1 brands. We can elaborate on the specific scenarios
2 where we believe more specific guidance would be
3 useful when we submit our comments via the public
4 docket, and we thank you again for the opportunity
5 to comment in person today. Thank you.

6 MS. IKENBERRY: Thank you.

7 Our next speaker is Gregory Schimizzi,
8 Coalition of State Rheumatology Organizations.

9 DR. SCHIMIZZI: Yes, hello. My name is
10 Gregory Schimizzi, and I'm a board-certified
11 rheumatologist with 39 years of experience in
12 private practice. I'm speaking on behalf of the
13 CSRO, which is a national organization composed of
14 state and regional rheumatology societies in the
15 U.S. and Puerto Rico.

16 To date, some rheumatologists have
17 experienced occurrences of adverse effects or
18 decreased efficacy of biosimilars, but the vast
19 majority of rheumatologists do not believe that
20 biosimilars are inferior. We also have not
21 observed noticeable deceptive marketing practices
22 or received disparaging information on biosimilars

1 in our offices, at educational meetings, or seen
2 them in journal advertisements. Therefore, we do
3 not believe that these are responsible, to a
4 meaningful degree, for the impaired patient access
5 to these products. We do see significant access
6 issues developing as a result of other marketplace
7 player activities.

8 Increasing patient access to these
9 medications can only be achieved if cognitive
10 distortions in the marketplace are addressed.
11 Developing remedies that disregard and ignore
12 manipulations designed to maximize profits from
13 fees, rebates, and other schemes that greatly
14 impede access may not be successful. We believe
15 these activities, which are at the core cause of
16 formulary design, far outweigh the impact of
17 deceptive marketing on patient access.

18 Formulary changes are rarely, if ever, based
19 on comparative clinical outcomes, or studies, or
20 safety, or tolerability, or even wholesale
21 acquisition costs, but rather on profitability to
22 the insurer, the large pharmacy, and PBM entities.

1 The preeminent access barrier to address is the
2 control of an overly consolidated industry of
3 unregulated middlemen with unfettered power,
4 demanding ever-increasing tolls from patients,
5 community pharmacists, and manufacturers, almost
6 always to the detriment of patients' and
7 physicians' therapeutic options and the quality of
8 health care. Described earlier as one of the bad
9 barriers, these are also a major driver of rising
10 medication costs.

11 This should not be allowed to continue. It
12 is gratifying to hear that the FDA and FTC are
13 aligned with our own goal here. We urge addressing
14 these reprehensible and egregious insurance and PBM
15 behaviors, much of which exists due to
16 overconsolidation. These abuses need to be
17 addressed either through existing authority or by
18 requesting additional authority where needed and/or
19 petitioning statutory solutions.

20 We must end the profiteering inherent in the
21 current formulary design process by insurers, large
22 pharmacy, and PBM conglomerates. These are the

1 main barriers to a fair, robust market of biologic
2 medication access and indeed to all medications.

3 Thank you very much.

4 MS. IKENBERRY: Thank you.

5 Next, Laura Brand, Biosimilars Global
6 Commercial Lead, Amgen.

7 MS. BRAND: Good afternoon. My name is
8 Laura Brand, and I'm the biosimilars global
9 commercial lead at Amgen. Thank you for allowing
10 me to share Amgen's perspective on a topic of
11 critical importance to the future of our nation's
12 healthcare system.

13 As a manufacturer of both innovator and
14 biosimilar products, Amgen shares a deep commitment
15 to the FDA's and FTC's goal of promoting a
16 robust-to-competitive marketplace for biological
17 products, including the adoption of biosimilars.
18 Although the U.S. market for biosimilars is still
19 maturing, it is competitive.

20 The FDA has approved significantly more
21 biosimilar products in the first nine years since
22 the U.S. pathway was established compared to other

1 regions such as Europe, and there are currently
2 over 80 biosimilar programs enrolled in the FDA's
3 biosimilar product development program. Amgen
4 believes this reflects robust manufacturer interest
5 in the current market opportunity under current
6 payment and coverage systems.

7 Patients in the U.S. healthcare system have
8 benefited from considerable cost savings as a
9 result of biosimilar products already in the
10 market. Competition in the marketplace is likely
11 to yield additional savings as more biosimilars are
12 launched throughout 2020 and the coming years.

13 Cost savings are just one benefit of
14 biosimilars. Biosimilar manufacturers can also
15 benefit the market by offering improved patient
16 choice by competing on delivery devices and improve
17 reliability of supply. With this portfolio of
18 10 biosimilar products and development, including
19 four approved by the FDA, Amgen is committed to
20 delivering potential savings and expanded treatment
21 options to patients.

22 In Amgen's experience, a level playing field

1 that encourages competition, not only with
2 innovator products but also among biosimilars,
3 creates a robust and sustainable marketplace. This
4 head-to-head competition drives meaningful cost
5 savings and also supports continued innovation to
6 expand biologic treatment options for providers and
7 patients. Our experience demonstrates that the
8 current regulatory and reimbursement policies for
9 biosimilars are working to promote competition.

10 Amgen has faced competition from biosimilars
11 for innovator products since 2015. Currently,
12 three of our innovator products, Neupogen,
13 Neulasta, and Epogen, compete against multiple
14 biosimilars. Biosimilars of Amgen's Neupogen
15 product together sell more units than Amgen, and a
16 Neupogen biosimilar competitor has obtained
17 preferred status over Neupogen with several
18 formularies, even though this competing biosimilar
19 does not have an interchangeability designation.

20 In 2019, Amgen launched the first
21 therapeutic oncology biosimilars in the U.S. The
22 list prices for both products are markedly lower

1 than the average sales price of the respective
2 reference products, generating significant cost
3 savings for patients and payers. Amgen's two
4 biosimilars are gaining adoption quickly, having
5 each secured approximately 20 percent share of the
6 market in just over six months as recently reported
7 by the Bernstein report.

8 These examples demonstrate the current
9 policies, for example separate coding, are
10 supporting biosimilar uptake and encouraging price
11 competition. At Amgen, we believe the long-term
12 viability of industry depends on a competitive
13 marketplace in which patients, providers, and
14 payers have a real understanding of and confidence
15 in biological products, including biosimilars.

16 We share the FDA's and the FTC's goal of
17 promoting stakeholder confidence in biosimilars
18 through scientifically accurate educational
19 outreach. Such educational initiatives are crucial
20 to preserving patient choice, driving uptake of
21 biosimilars, and supporting a sustainable
22 marketplace.

1 In summary, competition is robust,
2 biosimilar market share is increasing, and prices
3 are coming down. Amgen remains fully committed to
4 the success of biosimilars within the U.S.
5 healthcare marketplace. Thank you.

6 MS. IKENBERRY: Thank you.

7 Our next speaker is David Balto, Coalition
8 to Protect Patient Choice.

9 MR. BARLOW: Hi. Good afternoon. This is
10 Andre Barlow on behalf of David Balto, a public
11 interest attorney and the founder of the Coalition
12 to Protect Patient Choice, an entity that
13 advocates on behalf of consumer and patient
14 advocacy groups. We're also speaking on behalf of
15 consumer action.

16 We are appreciative of the opportunity to
17 provide comments today and we commend the FTC and
18 FDA's efforts to work together to promote
19 biosimilar competition, which will hopefully result
20 in patients having increased access to more
21 affordable drugs. Biologics are essential for the
22 treatment of serious debilitating and

1 life-threatening diseases.

2 While fewer than 2 percent of all
3 prescriptions are for biologic drugs, they account
4 for almost 40 percent of all drug spending. In
5 other words, biologics are extremely expensive, and
6 they are the fastest growing segment of drug
7 spending in the United States. The expectation 10
8 years ago was that a robust biosimilar market would
9 substantially lower the price of biologic drugs.
10 It has been estimated that biosimilars can save
11 U.S. consumers \$54 billion by 2026.

12 In Europe, where biosimilars have entered
13 the market, biologics such as AbbVie's branded
14 blockbuster Humira has been discounted by
15 80 percent. Unfortunately, biosimilars have faced
16 numerous obstacles in obtaining commercial success
17 in the United States. There are a number of
18 anticompetitive behaviors, or shenanigans,
19 including sample blockage, patent thickets,
20 pay-for-delay agreements, and rebate walls. We
21 would like to highlight rebate walls because we do
22 not believe that they're getting enough attention.

1 We believe the agencies need to use their
2 enforcement muscle to prohibit rebate contracting
3 practices that block biosimilars from competing on
4 drug formularies. There is increasing evidence
5 that rebates actually raise the cost of
6 prescription drugs.

7 What is important to understand about these
8 rebates is that they are not discounts for
9 patients. Because the rebates go to PBMs and plans
10 rather than to consumers, payers have perverse
11 incentives to negotiate higher list prices so they
12 can secure higher rebates without regard to patient
13 well-being or patient cost. These rebates actually
14 increase patients' cost because the patient's
15 coinsurance is based on the inflated list price of
16 the branded drug. If the patients had access to
17 lower cost biosimilars, their co-insurance costs
18 would go down.

19 How does a rebate wall work? A rebate wall
20 or trap is erected when an incumbent manufacturer
21 uses existing market power to secure preferred
22 formulary access for its drug by offering

1 volume-based rebates to PBMs and plans on the
2 condition that they deny or limit the formulary
3 access of rival drugs.

4 The rebate is bundled across multiple
5 products, indications, and/or therapeutic
6 specialties, the breadth of which cannot be matched
7 by a new rival. The rebate wall, a manufacturer
8 with a dominant incumbent drug, can prevent entry
9 of a newly approved biosimilar even if the
10 biosimilar is offered at a greater rebate or for
11 free. That's because the new biosimilar has few
12 prescriptions, if any, so even a larger rebate will
13 not overcome the potential loss of the rebate
14 dollars from the market-leading product.
15 Biosimilars lose because they can't get on a
16 formulary. Patients lose because they do not have
17 access to lower cost drugs.

18 A related practice that keeps patients from
19 detaining access to biosimilars is step therapy,
20 also known as fail-first policies, whereby patients
21 are forced to try a drug preferred by the payer
22 before being approved to use a drug originally

1 prescribed by their doctors.

2 Remarkably, most health plans have
3 instituted fail-first policies for new biosimilars,
4 meaning that a patient must fail on a more
5 expensive branded product before the plan will
6 cover a biosimilar of that same branded product.
7 This is noteworthy because, historically, generics
8 which are less expensive than branded drugs have
9 been the first option on the fail-first policy.

10 One explanation for discrimination against
11 biosimilars is that PBMs and health plans secure
12 significant rebates from branded drugs.

13 In short, the FTC needs to prioritize
14 investigations of rebate walls and step therapy
15 rules, which can be used to foreclose biosimilar
16 competition, which limits patients choices and
17 raises patients costs. Thank you.

18 MS. IKENBERRY: Thank you.

19 Our next speaker is Jocelyn Ulrich, deputy
20 vice president at PhRMA.

21 MS. ULRICH: Hello. Thank you. My name is
22 Jocelyn Ulrich, deputy vice president of medical

1 innovation policy at PhRMA. I appreciate the
2 opportunity to represent PhRMA and our member
3 companies at today's Workshop on a Competitive
4 Marketplace for Biosimilars.

5 PhRMA represents the country's leading
6 innovative biopharmaceutical research companies,
7 which are devoted to discovering and developing
8 medicines that enable patients to live longer,
9 healthier, and more productive lives. Consistent
10 with that mission, PhRMA is dedicated to advancing
11 policies that promote innovation and competition in
12 the biologics and biosimilars marketplace.

13 While the BPCIA is less than a decade old
14 and biosimilar development is significantly more
15 complex and expensive than generic drug
16 development, the benefits of the BPCIA on
17 innovation and competition are already being seen.
18 As of today, there are 15 biosimilars on the market
19 competing against 7 innovator biologics, with an
20 additional 10 approved by the FDA coming to the
21 market over the next several years.

22 In addition, the upcoming transition of some

1 products to licensure as biologics and the recently
2 enacted change to the definition of biologic will
3 provide additional opportunities for more
4 biosimilar applications and patient choice.

5 Publicly available data on the current U.S.
6 market has shown that in every case where a
7 biosimilar has entered the marketplace, both the
8 average sales price of the biosimilar and the
9 innovator biologic have decreased, and as noted by
10 the FTC, basic economic principles support that
11 this indicates the competition is indeed leading to
12 lower prices, increased consumer access and choice,
13 and innovation.

14 PhRMA supports FDA's efforts to implement a
15 science-based approach to regulating biosimilars
16 that both ensures patient safety and facilitates a
17 robust biosimilars market, and we believe it is
18 critically important to ensure the long-term
19 stability of the BsUFA through financial
20 transparency, efficiency, and accountability.

21 We also support many aspects of the FDA's
22 biosimilars action plan. In particular, we concur

1 with FDA that physician education and experience
2 with biosimilars will be critical for fostering
3 biosimilar uptake, and we applaud continued efforts
4 to develop effective communications to improve
5 understanding of biosimilars among patients,
6 clinicians, and payers.

7 PhRMA believes that FDA and FTC have a
8 robust set of authorities available to them to
9 continue to foster competition and encourage the
10 maturing biosimilars market. To further support
11 the market, we believe policymakers and
12 stakeholders should take the following additional
13 steps. First, we should increase transparency for
14 certain patents on biologic products consistent
15 with what is currently available in the FDA Orange
16 Book for drug products.

17 Second, to the extent there were issues with
18 access to samples, the recent enactment of what had
19 been previously referred to as the CREATES Act may
20 facilitate access to samples, which in turn will
21 facilitate biosimilars entering the market.

22 Third, we believe that policymakers should

1 address barriers to appropriately structured
2 alternative payment models, particularly in
3 Medicare, that have the ability to increase
4 competition among innovator and biosimilar
5 products. And finally, policymakers must advance
6 meaningful rebate reform that would remove barriers
7 to biosimilar uptake and promote access and
8 competition.

9 In enacting the BPCIA a decade ago, U.S.
10 policymakers rightly sought to balance increased
11 competition with policies that support the United
12 States' leading role in finding new treatments for
13 patients. By allowing the market to continue to
14 evolve and enacting policies that support this
15 evolution, we'll continue to see biosimilars'
16 benefits for patients and society. Thank you.

17 MS. IKENBERRY: Thank you.

18 Next we have Corey Greenblatt, manager of
19 policy and advocacy, Global Healthy Living
20 Foundation. Hi, again.

21 MR. GREENBLATT: Hello, again. Before I
22 begin, I just want to disclose I have no

1 disclosures to make regarding my travel here today.
2 The Global Healthy Living Foundation accepts grants
3 and charitable contributions from pharmaceutical
4 companies, the federal government, private
5 foundations, and individuals. The organization has
6 received scientific briefings from pharmaceutical
7 companies as well as our independent medical
8 advisory board.

9 Good afternoon. My name is Corey
10 Greenblatt, and I'm the manager of policy and
11 advocacy for the Global Healthy Living Foundation.
12 On behalf of GHLF, I want to thank this committee
13 for allowing me to speak. GHLF is a 20-year-old
14 501(c)(3) organization representing chronically ill
15 patients and their caregivers across the country.
16 GHLF works to improve the quality of life for
17 patients living with chronic disease by ensuring
18 their voices are heard and advocating for improved
19 access to care.

20 The barrier for entry in the U.S. biosimilar
21 market has been too high for too long. Despite the
22 Biologics Price Competition and Innovation Act, the

1 U.S. is about seven years behind Europe. Not
2 having a robust biosimilar market is a failure in
3 U.S. health care. Patient and provider education
4 is one reason for this failure; economics is
5 another.

6 Patients understand generic versus branded
7 drugs, but they do not understand biosimilars,
8 especially in the aggressive context in which they
9 are presented by insurers. Even many healthcare
10 professionals don't understand when to use
11 biosimilars and what the positives and negatives of
12 biosimilar use are. They are instead instructed
13 when to use them by insurers.

14 Switch biosimilar patients are required to
15 abandon a medication that works with little or no
16 explanation, education, or counseling. The
17 healthcare provider gets a letter in the mail
18 telling them to switch the patient or the patient
19 will pay the full retail price of their current
20 drug. This is obviously not the way to sell the
21 benefits of biosimilars to patients or physicians.

22 Government is being asked to favor one group

1 of manufacturers making biosimilars over another
2 which doesn't, with complete opacity to the
3 patient. Our hope is that the agencies will work
4 to create a transparent environment for the
5 patient, one that does not show a bias for
6 biosimilars or biologics, allows the patient to
7 directly benefit from generic-like lower price, and
8 feel positive about switching to or starting on a
9 biosimilar. We believe that only then will a
10 robust biosimilar market emerge for chronically ill
11 patients.

12 GHLF, the FDA, and other patient groups can
13 handle the education issues around biosimilars if
14 you can clear up the economic inequalities. To the
15 patient, biosimilars are generic biologics. Your
16 job is to create the market that allows them to be
17 priced this way. We need a system that allows
18 therapies to compete based on clinical outcomes and
19 costs to the patient, not a system that allows
20 anticompetitive practices such as rebates, rebate
21 walls, favorable pricing to physicians,
22 access-restricting formularies, co-pay accumulator

1 adjusters, and step therapy.

2 Non-medical switching needs to be defined.

3 Patients and physicians should be able to
4 voluntarily non-medically switch drugs when it
5 benefits the patient, not only the insurer and the
6 PBM. If a patient can save money and their
7 healthcare professional does not object, they
8 should be allowed to switch brands, whether it's a
9 biologic or a biosimilar.

10 Forced non-medical switching, which occurs
11 now, offers no quantifiable financial benefit to
12 patients, only profits to insurers. The patient is
13 the only one who shows up to the table with a
14 checkbook but no power. Everyone else shows up
15 with varying degrees of power that are used to
16 protect profits. It is nearly impossible to
17 identify any other market where the person paying
18 the bills has so little influence on the price of
19 the product or the product itself.

20 You can change this by recognizing the need
21 for strict regulation of insurance practices and
22 market-based price lowering incentives to

1 biopharmaceutical companies. If there's no
2 financial relief for patients from what to them is
3 a generic drug, then biosimilar growth will
4 continue at its slow pace compared to other
5 generics and biosimilars in other countries.

6 We thank the FDA and the FTC for emphasizing
7 the value of the patient perspective through public
8 meetings, and we will continue to mobilize our
9 patient communities and create a better life for
10 those who will benefit from biosimilar therapies.
11 Thank you for your time and attention. It is
12 greatly appreciated.

13 MS. IKENBERRY: Next is Fouad Atouf.

14 DR. ATOUF: Good afternoon. My name is
15 Fouad Atouf. I'm vice president of global
16 biologics at the United States Pharmacopeia, USP.
17 I appreciate the opportunity to present on behalf
18 of USP our comment on the competitive marketplace
19 for biosimilars. USP is an independent scientific
20 non-profit organization dedicated to improving
21 health through the development and dissemination of
22 public standards for medicines, foods, and dietary

1 supplement.

2 Through a long-standing collaboration with
3 the FDA, we have worked continuously to benefit
4 public health by facilitating broader access to
5 quality medicines. USP supports FDA's and FTC's
6 effort to foster access to biosimilars and to
7 pursue initiatives that facilitate increased
8 competition to biological products. Furthermore,
9 we believe that our public standards serve an
10 important role in fostering a competitive
11 marketplace.

12 First and foremost, USP public standards
13 help ensure quality medicines. For example, USP's
14 quality standards for insulins have been used by
15 manufacturers for a decade to meet quality
16 expectations. Additionally, USP standards provide
17 valuable information to biological manufacturers to
18 support early development of new or biosimilar
19 products and address common quality issues. These
20 standards can add flexibility by offering choices
21 of analytical approaches.

22 Furthermore, studies indicate that public

1 standards help foster a more competitive
2 marketplace for medicines because the standards
3 provide transparency on the quality expectation for
4 medicine, which helps new manufacturers bring new
5 products to the marketplace.

6 USP standards are developed in an open
7 transparent process. They're established by
8 independent experts and scientific experts, and
9 development of the standards takes into account
10 public input. The expert who works with USP will
11 collaborate closely with stakeholders and
12 government agencies such as the FDA.

13 USP is committed to ensuring that our
14 approach evolves with the science of biologics and
15 the needs of stakeholders by developing solutions
16 that support the adoption of emerging analytical
17 tools for biological product innovation and
18 competition. We are currently developing standards
19 that are broadly applicable to classes and families
20 of biological products and also working on tools to
21 address quality of raw materials with an overall
22 goal to support analytical testing throughout the

1 product life cycle.

2 USP is a convener and will continue to
3 convene stakeholders to identify areas of needs and
4 improvement for development of biological products.
5 In recent years, we hosted a series of roundtables
6 to address and discuss with the stakeholders the
7 common quality challenges and to develop together a
8 set of solutions that address biological products
9 throughout the product life cycle.

10 We will continue that convening role and we
11 plan to hold in the next coming month a series of
12 roundtables to address topics like ensuring quality
13 of biologics globally, but also ensuring quality of
14 insulins and other topics such as the role of
15 genomics analysis and personalized medicines.

16 We are very much interested in hearing from
17 the FDA and FTC any additional topics you would
18 like to discuss with stakeholders and would be
19 happy to facilitate those discussions. Thank you
20 again for the opportunity to present, on behalf of
21 USP, our perspective. Thank you.

22 MS. IKENBERRY: Thank you.

1 Laura McKinley, director of regulatory
2 policy, Pfizer.

3 DR. MCKINLEY: Hello. Thank you. I am
4 Laura McKinley as she said, director of regulatory
5 policy at Pfizer, and we appreciate the opportunity
6 to present here today and applaud the FDA-FTC
7 collaboration to support appropriate adoption of
8 biosimilars.

9 The introduction of biosimilars in the U.S.
10 was intended to increase competition by providing
11 additional safe and effective biologic treatment
12 options, thereby reducing healthcare costs. This
13 goal will not be realized if patients and
14 healthcare professionals receive incomplete or
15 misleading information.

16 In August 2018, Pfizer filed a citizen
17 petition requesting that FDA issue guidance to help
18 ensure communications by sponsors concerning the
19 safety and effectiveness of biosimilars are
20 truthful and non-misleading.

21 In this regard, Pfizer appreciates the
22 important steps FDA has taken to address

1 misinformation, including the publication of draft
2 guidance that specifically notes that reference
3 product promotional materials should avoid
4 representing or suggesting that a biosimilar
5 product is less safe or effective than its
6 reference product because it has not been studied
7 in all clinical indications and/or is not licensed
8 as interchangeable.

9 The Federal Register notice seeks input on
10 promotional materials for interchangeables. Pfizer
11 believes it is essential to avoid inaccurate
12 perceptions of the safety and effectiveness of
13 biological products based on their licensure
14 pathway. Therefore, we encourage FDA to also
15 address interchangeable biosimilar labeling and
16 promotional materials to help ensure these to avoid
17 representing or suggesting that a biosimilar
18 product is less safe or effective because it has
19 not been licensed as interchangeable.

20 Pfizer fully supports the rigorous
21 evaluation standards that FDA applies to all
22 products, including biosimilars, but believes

1 further opportunities exist to optimize the
2 approval process for biosimilars without
3 compromising scientific standards.

4 For example, FDA has indicated they intend
5 to review and act upon supplement-seeking licensure
6 for an additional condition of use in a 6-month
7 review time as opposed to the 10-month review time
8 frame outlined in the BsUFA II goals letter.
9 However, the BsUFA II goals letter is limited to
10 supplements with clinical data.

11 We think consideration should be given to
12 reduce even further the review time for supplements
13 seeking licensure for additional indications
14 supported by scientific justification of
15 extrapolation in the absence of additional clinical
16 data. This would avoid unnecessary delays in
17 patient access to biosimilars.

18 It would also be beneficial to have further
19 guidance regarding the post-approval process for
20 adding safety information to biosimilar labels. In
21 particular, Pfizer urges the agency to consider
22 biosimilar safety labeling updates that are

1 consistent with the risk information in the
2 reference product labeling as a CBE-0 submission.
3 Treating such updates as CBE-0's will help ensure
4 important risk information is being disseminated to
5 healthcare providers and patients in a timely
6 manner.

7 Finally, Pfizer is concerned about
8 anticompetitive contracting practices by which a
9 biologic manufacturer undertakes systemic efforts
10 to maintain unlawfully a monopoly in connection
11 with its reference products. The practice of
12 withholding significant rebates for both current
13 and future patients, unless insurers agree to
14 biosimilar exclusion contracts, effectively block
15 coverage of biosimilars. Without such coverage,
16 providers are reluctant to stock biosimilars.

17 Further, anticompetitive contracts
18 effectively conditioned on the providers not
19 purchasing biosimilars in exchange for discounts on
20 the reference or other products prevent physicians
21 from trying and patients from accessing
22 biosimilars. Pfizer again thanks FDA and FTC for

1 convening this workshop and for the opportunity to
2 speak.

3 MS. IKENBERRY: Thank you. That was our
4 last registered commenter. So with that, I will
5 turn it over to Caty for final remarks.

6 Closing Remarks - Catherine Gray

7 MS. GRAY: I have the best job of the day.

8 On behalf of FDA and FTC, I'd like to thank
9 all the speakers and panelists and everyone in the
10 audience for participating in today's workshop.

11 Whether you attended in person or via webcast, we
12 greatly appreciate your attention and your interest
13 in today's sessions and presentations. I'd like to
14 also send out one last acknowledgment to the many
15 folks at FTC and FDA who worked tirelessly in
16 preparing for this meeting. Thank you for your
17 persistence.

18 As a reminder, we strongly encourage you to
19 submit your comments to the docket, which will be
20 open until April 9th. If you would like any
21 details on how to submit your comments to the
22 docket, we have placed copies of the Federal

1 Register notice announcing this meeting at the
2 registration table just outside the meeting room.

3 A transcript from the workshop should be
4 posted to the workshop website within 30 days. We
5 will provide copies of today's presentations upon
6 request and contact information about getting those
7 copies is also available at the registration table.

8 On that note, I'm closing the workshop.
9 Thank you again for participating and have a safe
10 trip home.

11 (Applause.)

12 (Whereupon, at 4:18 p.m., the workshop was
13 concluded.)

14

15

16

17

18

19

20

21

22

	195:15;197:4;209:5;236:4;239:2;244:11;245:3;319:3	136:17;284:6	acting (4) 6:9;23:5;253:1; 256:15	Adalimumab (2) 50:9;135:17
\$		accomplishes (1) 81:3		ADCOM (1) 39:12
\$1044 (1) 130:1	absence (1) 326:15	accordance (1) 84:9	action (26) 27:18;30:8;45:1,6; 62:10;164:19;213:7; 218:10,15;219:5; 223:8;225:17,20; 226:8,17;238:2; 239:21;242:22; 248:21;251:19; 253:6;271:8;279:9; 280:16;307:15; 313:22	AdComplyRx (2) 298:12,15
\$12 (1) 185:22	absolute (1) 179:13	according (2) 89:7;223:12		add (14) 47:20;53:7;69:19; 73:8;94:20;152:7,19; 169:1,16;170:20; 183:8;211:19;225:8; 321:20
\$125.5 (1) 25:3	absolutely (4) 20:13;201:12; 205:19;246:21	account (8) 18:13,16;48:19; 56:4;104:19;146:5; 308:3;322:9		added (1) 223:17
\$144 (1) 129:12	abundance (1) 269:2	accountability (1) 313:20		adding (1) 326:20
\$2 (1) 184:16	abused (1) 161:2	accounted (1) 149:15	actionable (1) 219:9	addition (10) 55:19;119:8;120:4; 137:22;168:18; 176:15;194:15; 207:1;268:15;312:22
\$291 (1) 130:4	abuses (2) 42:13;302:16	accumulator (1) 318:22	actions (6) 21:11;26:22;85:17; 98:4;225:12;240:7	additional (33) 10:12;37:15;44:13; 45:4,9,17;131:16; 134:16;158:15; 170:1;176:10,12,15; 196:1;201:11; 212:19;269:18; 271:1;272:8;289:22; 290:19;291:15; 292:1;302:18; 304:11;312:20; 313:3;314:12; 323:17;324:11; 326:6,13,15
\$3 (1) 54:6	ACA (3) 147:15;148:1,4	accurate (8) 10:2;15:17;75:11; 110:7;112:1;113:4; 114:1;306:18	active (4) 54:20;72:16; 110:19;113:15	
\$3,000 (1) 190:2	academic (2) 58:4;289:5	accurately (4) 106:17;112:20; 117:6,21	actively (3) 49:18,19;270:20	
\$344 (1) 129:4	acceleration (1) 16:16	ACE (2) 178:20;180:17	activists (2) 27:9;236:21	
\$4.8 (1) 286:10	accept (3) 63:4;77:10;275:5	achieve (5) 42:2;74:13;139:10; 165:15;281:19	activities (7) 15:8,20;21:10,16; 85:5;301:7,15	
\$40 (1) 133:3	acceptance (5) 169:5;171:15; 172:5;202:13;209:6	achieved (1) 301:9	activity (1) 22:7	
\$435 (1) 130:3	accepted (1) 95:19	achieving (2) 279:14;284:13	actor (1) 228:20	
\$54 (1) 308:11	accepts (1) 316:2	acknowledge (4) 12:10,14,16;145:9	actors (2) 222:20;238:19	
\$85 (1) 129:11	access (46) 6:21;7:13;15:21; 28:21;30:13;38:16; 18;40:2;73:7;75:8; 126:9;152:3;155:5; 176:3,4;184:5; 185:13;207:18; 274:15;284:2;289:1; 291:6;294:12,17; 298:3;301:4,5,8,14, 17;302:1;303:2; 307:20;309:16,22; 310:3,17,19;313:12; 314:18,20;315:7; 316:19;321:4,6; 326:17	acknowledgment (1) 328:14	acts (5) 94:3;216:1;217:9; 226:7;240:14	Additionally (4) 281:3;286:11; 299:17;321:16
[acquisition (1) 301:21	actual (1) 270:9	address (28) 11:14;12:19,20; 13:8,22;43:19;55:13; 85:17;102:1;106:21; 120:20;166:13; 195:7;197:3,22; 223:19;261:2;280:5; 297:7;302:1;315:1; 321:19;322:21; 323:6,8,12;324:22; 325:15
[indiscernible] (3) 152:18;201:13; 269:5		across (19) 12:20;16:5;19:13; 34:11;52:3;60:15; 72:13,15,22;86:4; 152:21;160:6;197:6; 208:21;262:18; 273:2;276:11;310:4; 316:15	actually (42) 28:11;34:17;37:6; 39:4;49:3;135:21; 158:12;179:21; 181:13,20;186:7,9, 21;188:5,10,16,18, 21;189:16,20;190:9; 198:20;201:21; 203:17;210:4,16; 223:15,22;224:5,19; 226:12,16;227:22; 228:14,19;248:5,20; 252:19;253:21; 266:11;309:5,13	
[ph] (2) 100:10;227:5		Act (39) 17:9;26:8,11,16; 34:2;37:7;53:20; 79:6;81:10,18,21; 85:6,18,22;93:22; 97:3;104:5,13; 119:13;217:14; 218:14,19;219:5,9; 223:6,7;224:5; 225:12;226:19; 227:20;229:7; 241:19;248:4,19,21; 252:2;314:19; 316:22;326:5	ad (7) 88:6;95:20,21; 96:1,4;222:11; 299:19	
A		act (39) 17:9;26:8,11,16; 34:2;37:7;53:20; 79:6;81:10,18,21; 85:6,18,22;93:22; 97:3;104:5,13; 119:13;217:14; 218:14,19;219:5,9; 223:6,7;224:5; 225:12;226:19; 227:20;229:7; 241:19;248:4,19,21; 252:2;314:19; 316:22;326:5		
abandon (1) 317:15	accessed (2) 9:19;208:2	actavis (1) 27:6		addressed (5) 48:21;85:14; 105:16;301:10; 302:17
abbreviated (7) 27:21;28:2,8;34:7; 201:16,17,19	accessibility (1) 19:4			addressing (4) 43:6;78:4;292:2; 302:13
AbbVie (1) 54:14	Accessible (4) 32:20;134:1; 180:17;203:3			adequate (2) 91:6;270:8
AbbVie's (1) 308:13	accessing (1) 327:21			adjudicated (4) 49:4;56:10;61:11, 22
ability (15) 42:19;54:13;55:7, 12;69:1;72:1;74:10; 153:20,21;200:9,14; 225:16;267:10; 281:19;315:3	access-restricting (1) 318:22			adjudication (1) 62:15
able (22) 23:15;56:18,20; 62:14;64:4;74:1; 137:3;143:22;147:7; 155:4,15;171:13; 176:13;188:20;	accompanied (1) 86:16			

<p>adjusters (1) 319:1</p> <p>adjusting (2) 129:20,21</p> <p>adjustments (1) 129:19</p> <p>administer (2) 63:5;278:17</p> <p>administered (4) 46:15;52:17;57:13;66:7</p> <p>administering (1) 62:7</p> <p>administration (4) 68:17;114:22;115:4,10</p> <p>administrations (1) 284:21</p> <p>administrative (2) 7:16;55:9</p> <p>administratively (3) 55:14;68:17;98:5</p> <p>admit (1) 265:1</p> <p>ado (2) 32:6;80:4</p> <p>adopt (2) 136:10;231:17</p> <p>adopted (1) 232:15</p> <p>adopting (2) 280:1;295:16</p> <p>adoption (21) 6:16;7:7;15:1;56:12,19;57:1;59:5;67:8;75:22;77:22;258:6;262:12;284:9;286:16;289:11;292:22;296:5;303:17;306:4;322:16;324:7</p> <p>ads (7) 175:10;181:21;298:17,20;299:12,18,18</p> <p>adult (1) 173:22</p> <p>adults (1) 191:8</p> <p>advance (4) 15:5;289:16;297:17;315:5</p> <p>advanced (1) 274:9</p> <p>advancement (1) 296:8</p> <p>advances (2) 16:4;21:5</p> <p>advancing (2) 273:7;312:10</p> <p>Advantage (2) 131:17;132:5</p> <p>advantages (1)</p>	<p>294:2</p> <p>adverse (3) 111:19;159:12;300:17</p> <p>advertisement (11) 94:4,6,7;95:3,5,8,9,13,16,17;96:8</p> <p>Advertisements (3) 95:4;103:22;301:2</p> <p>advertiser (2) 95:22;96:5</p> <p>Advertising (57) 14:9;29:14,15,16;75:2;79:19,21;80:1,13,22;82:3,6;85:8;86:5,22;91:9,16;93:11,12,20;100:11,20;101:14;103:10;110:2;119:7;179:18;213:18;218:15;223:7;226:16,18;230:22;231:3;232:16,18;241:5,11,12,13,15;242:5,8,12;243:5,10,18;244:1,7,14,15;253:21;254:4,5;256:18;298:17,22</p> <p>advice (2) 79:15;121:16</p> <p>advisor (4) 28:13;171:12;172:7;255:6</p> <p>Advisory (3) 260:6;291:8;316:8</p> <p>advocacy (12) 174:6;191:7;193:15;202:7,9;204:11;205:13;206:22;264:2;307:14;315:19;316:11</p> <p>advocate (2) 193:17,20</p> <p>advocated (2) 272:20;273:17</p> <p>advocates (5) 193:4;194:4,8;273:20;307:13</p> <p>advocating (2) 283:17;316:18</p> <p>affairs (5) 174:3;257:8;267:20;283:4,7</p> <p>affect (5) 110:12;228:1,5,12;264:9</p> <p>affected (1) 228:7</p> <p>affecting (2) 162:15;294:7</p> <p>affects (1) 241:17</p> <p>affiliated (2)</p>	<p>62:17;215:11</p> <p>afford (1) 259:17</p> <p>affordability (1) 294:22</p> <p>affordable (4) 268:1;284:2;296:2;307:21</p> <p>afoul (1) 97:2</p> <p>afternoon (12) 125:2,8;156:14;257:7;272:14;278:5;283:5;293:21;303:7;307:9;316:9;320:14</p> <p>again (53) 18:21;19:1;22:14;32:14,22;34:9;42:18;43:16;44:1;47:20;49:6;51:17;57:14;61:9;63:20;65:12;68:22;73:1;102:11;116:5;117:8;128:2;129:13;130:19;133:19;134:13,21;141:22;142:9;146:17;147:10;163:20;164:19;165:11;175:18;183:9;189:11;199:20;201:4;206:7;228:4;232:11;233:9;243:1;250:12;252:3;255:5;300:4;315:20,21;323:20;327:22;329:9</p> <p>against (8) 27:1;30:8;136:11;146:3;271:8;305:13;311:10;312:19</p> <p>agencies (15) 13:18;14:17;148:15;160:12;164:3;236:3;238:18;252:10;254:16,19;268:5;297:6;309:1;318:3;322:12</p> <p>agency (29) 12:6;19:13;23:20;24:8;25:6;43:6;45:1,16;69:12;73:13;110:16;147:22;224:15;225:2;268:10,14,16,18;269:5,8;271:7;272:1,2,5;279:17,22;293:5;295:1;326:21</p> <p>agency's (4) 11:11;27:5;53:15;86:13</p> <p>agent (3) 62:7,8;66:8</p> <p>agents (2)</p>	<p>61:6;290:9</p> <p>aggressive (2) 295:11;317:8</p> <p>aggressively (1) 197:1</p> <p>ago (21) 17:8;25:16;27:19;39:20;63:22;64:10;143:6;155:6,6;162:1;163:13;178:11;189:15,17;198:19;247:2;250:4;272:19;275:8;308:8;315:9</p> <p>agree (5) 51:18;138:1;152:6;249:2;327:13</p> <p>agreed (2) 275:15,17</p> <p>agreements (14) 26:17;27:4,7,12,15;30:20,22;54:14,15,21;55:5;229:8;280:7;308:20</p> <p>ahead (4) 171:21;181:2;183:10;282:4</p> <p>aid (4) 87:6,7,10,12</p> <p>aimed (1) 280:14</p> <p>aisle (1) 168:14</p> <p>AITKEN (7) 125:8,9,12,15,16;154:13;169:16</p> <p>Alberta (1) 183:15</p> <p>alert (1) 88:11</p> <p>Alex (4) 124:21;156:10,12;168:18</p> <p>Alex's (1) 169:2</p> <p>aligned (1) 302:13</p> <p>alignments (1) 205:16</p> <p>alike (3) 16:9;281:10;286:2</p> <p>Alison (2) 124:16;167:10</p>	<p>30:16</p> <p>Alliance (7) 215:3;260:7;263:15,22;272:17;274:3,4</p> <p>Allied (2) 288:4;293:19</p> <p>allotted (4) 10:6,8;255:15;256:1</p> <p>allow (6) 26:2;62:14;63:15;68:8;267:11;272:2</p> <p>allowable (1) 140:4</p> <p>allowed (2) 302:11;319:8</p> <p>allowing (7) 267:14;271:10;279:18;297:18;303:9;315:13;316:13</p> <p>allows (6) 82:19,22;318:6,16,17,19</p> <p>alluded (3) 54:18;168:6;176:9</p> <p>almost (7) 27:19;184:3;190:14;260:5;275:22;302:5;308:4</p> <p>alone (3) 175:1;238:8;258:18</p> <p>along (3) 9:5;177:19;267:9</p> <p>Alright (3) 185:17;187:15;257:3</p> <p>alter (2) 95:16;289:13</p> <p>alternate (1) 295:5</p> <p>alternating (1) 285:1</p> <p>alternative (1) 315:2</p> <p>although (8) 35:7;46:13;90:21;111:7;117:21;225:19;229:15;303:18</p> <p>always (22) 10:20;19:9;64:10;72:8;83:20;151:9,12;167:15;168:4;176:6,17;189:1;200:9;212:16;221:11,18;238:18;240:6,11;244:9;252:9;302:6</p> <p>amazing (1) 16:15</p> <p>ambiguous (1) 220:18</p>
---	--	---	--	--

ambulatory (1) 289:8	Andre (1) 307:10	229:2,4;232:14; 237:20;238:3,10,16, 17,20,21;239:1,2,17, 22;240:15;241:20; 242:11;243:19,20; 244:22;246:12; 249:6,14,19;250:19; 251:16;254:1,2	12:4;22:14;45:18; 71:21;204:5;242:13; 278:12;280:12; 293:5,8;312:1; 320:17;324:5;328:12	279:19;281:14; 283:13,15;285:4; 291:7;294:8;303:20; 304:19;310:9,22; 312:20
amending (1) 48:18	Andreas (1) 125:5		appreciated (1) 320:12	approving (2) 273:1;275:21
amendment (6) 68:19;213:16; 223:5;224:14; 226:22;227:6	Andrew (4) 272:12,15;283:3,6		appreciates (3) 121:20;257:10; 324:21	approximately (3) 9:19;10:4;306:5
amendments (2) 26:15;77:9	ANDRUS (13) 31:16,17;33:3; 44:5,6;45:21;49:16; 55:21;59:7;60:16; 69:3;70:19;74:16	anxiety (1) 183:6	appreciation (1) 288:20	apps (1) 295:17
America (1) 187:13	Andwele (5) 173:16;191:2,3; 208:14;211:19	anymore (1) 59:2	appreciative (1) 307:16	April (2) 10:22;328:20
American (17) 12:19;13:13;14:6; 15:19;18:6;19:1; 20:3;21:8,8;23:1; 31:4;77:9;124:22; 187:13;209:13; 250:11;265:22	anecdotaly (1) 58:21	API (1) 291:19	approach (26) 18:3;36:6;37:2,22; 52:14;57:4,12; 121:17;227:15; 230:18;231:16,19,20, 21;234:21;237:18; 241:1,3,9;242:17; 249:7,20;286:17; 294:11;313:15; 322:14	apropos (1) 65:5
Americans (3) 18:9;19:5;278:19	animal (1) 36:20	apologies (1) 198:5	Approaches (3) 75:1;237:19; 321:21	area (12) 8:14;14:19;18:5; 21:9;49:6;72:3; 79:22;96:3;188:1; 251:3;253:4;287:14
America's (1) 278:16	anniversary (1) 39:17	apologize (1) 177:4	appropriate (23) 6:16;30:7;79:2,5; 97:22;106:9;116:22; 118:5;158:7;169:8, 13;199:17;200:11; 215:16;235:21; 243:6,19,21;244:13; 293:4,7;297:15; 324:7	areas (14) 44:12;45:8;60:2; 70:16;83:4;127:20, 21;130:19;131:1; 174:1;196:18;208:2; 261:12;323:3
Amgen (12) 216:5,7;303:6,9, 14;304:3,19;305:10, 15,20;306:11;307:3	announced (2) 98:16;120:3	apparent (4) 85:5,12;86:11;95:2	argue (2) 43:9;234:15	argued (1) 280:13
Amgen's (4) 303:10;304:22; 305:14;306:3	announcements (1) 7:16	Appeals (1) 242:7	arguing (1) 158:17	argument (2) 244:22;252:1
among (15) 30:21;122:4; 148:15;153:12; 174:16;194:7;229:9; 262:11;274:21; 294:19;296:1;297:5; 305:2;314:5;315:4	announcing (1) 329:1	appear (1) 298:17	Aria (1) 145:12	arising (1) 238:3
amount (7) 18:14;24:12;70:13; 127:4;143:17;168:8; 230:3	annual (1) 286:6	appeared (1) 264:22	arls (1) 222:3	armamentarium (1) 75:13
amounts (1) 92:16	anonymous (1) 84:22	applaud (5) 71:20;268:10; 298:7;314:3;324:6	Armine (1) 256:22	Arntsen (4) 288:4,7;293:14,16
amplify (1) 169:2	Antara (1) 256:20	Applause (10) 11:18;23:10;31:15; 74:18;100:8;123:2; 171:9;212:13;255:1; 329:11	armed (1) 145:12	arose (1) 232:12
analyses (1) 144:5	antibiosimilar (1) 264:10	apples (2) 216:8,8	around (41) 12:12,17;14:14; 39:13;41:8,12,19,21; 43:2,7,10;47:6;48:3; 53:5,19;67:14;70:4; 73:4;121:21;141:9; 144:13;145:8;161:3; 164:8;178:10; 184:13;185:8; 191:11;194:1,22; 196:5,9;211:20; 260:16;264:14; 273:20;274:7; 281:12;282:6;299:5; 318:13	
analysis (4) 36:12;125:7; 204:10;323:15	antibody (1) 283:13	applicable (3) 84:5;119:12; 322:19		
analyst (1) 101:3	anticipate (5) 151:5,6;155:7; 162:13;164:21	applicant (1) 35:12		
analytical (8) 36:9,10,19;291:10; 292:15;321:21; 322:16,22	anticipated (1) 163:14	applicants (1) 26:6		
analyzing (1) 136:20	anticompetitive (29) 6:18;11:14;15:12; 25:9;26:13,21;27:3, 11,14;30:21;33:16; 231:1;239:8;241:8; 243:4;247:8,14; 249:8;257:13; 260:20;261:8; 270:12;280:6,14,17; 308:18;318:20; 327:8,17	application (6) 36:11;49:9;86:17; 115:19;116:10; 126:18		
and/or (5) 255:13;290:16; 302:18;310:5;325:7	anti-kickback (1) 52:20	applications (1) 313:4		
Anderson (1) 11:8	antisimilar (1) 263:4	applied (3) 83:13;233:1; 290:14		
	anti-TNF (1) 286:6	applies (6) 87:16;105:18; 106:8;183:4;243:13; 325:21		
	antitrust (34) 27:7;29:12,21; 213:8,14;226:2;	apply (8) 104:10,13;109:19; 120:17;234:2;235:9; 299:14,17		
		applying (2) 234:13;297:1		
		appreciate (14)		

arranged (1) 49:7	93:21;230:16	64:5	244:9;249:18;250:8; 265:18;285:1;288:11	315:1,6
arrangement (1) 160:17	assumption (2) 217:13;261:3	authorized (1) 183:22	background (2) 45:13;102:19	bars (2) 133:22;134:13
arrangements (1) 50:22	assure (3) 12:18;273:11,16	autoimmune (2) 185:1;294:7	backgrounds (1) 214:9	Basaglar (8) 145:21;147:14; 148:19;149:10,15,17; 150:2,5
array (2) 289:6,9	assuring (1) 260:13	automatic (2) 26:3;46:19	backwards (1) 40:20	based (22) 22:4;34:3;95:4; 110:7;111:17; 112:16;115:9; 125:21;140:4; 151:17;156:17; 178:17;203:7,14; 211:6;269:12,12; 271:18;301:18; 309:15;318:18; 325:13
arsenal (1) 294:12	Atouf (3) 320:13,14,15	availability (4) 7:2;13:13;120:3; 279:6	bad (10) 157:5,10,12,20; 158:2;160:2,13; 161:17;238:19;302:8	badad@fdagov (1) 84:17
Arthritis (13) 172:20;173:10,12, 17;176:21;178:4,13, 15;183:3;185:1; 193:6;204:14;265:8	ATP (1) 192:16	available (31) 8:16,17;15:19; 16:20;17:13;31:7; 50:7;57:19;61:18; 86:14;89:11;97:20; 133:9;134:9;135:1,6; 143:4,10;149:13; 184:21;189:22; 191:15,16;203:18; 238:4;241:18; 277:10;313:5;314:8, 15;329:7	BadAd (1) 84:17	basic (4) 175:19,22;241:8; 313:10
article (6) 93:16;214:22; 231:6,7;240:20; 243:2	attempt (2) 36:8;274:19	Avastin (1) 190:6	badad@fdagov (1) 84:20	basically (14) 62:13;63:10;66:9; 74:2;134:6;140:10; 148:5;149:17; 221:11;222:13; 231:4,22;242:4; 249:22
articles (1) 188:3	attend (2) 8:1;10:10	avenue (1) 64:22	bag (3) 62:16;63:20;239:7	basis (10) 61:17;66:6;117:16; 125:22;129:3,19; 131:8;149:2;166:1; 207:11
articulated (2) 50:2;179:3	attended (1) 328:11	average (9) 17:20;67:17; 143:16;162:16; 204:4,16;286:3; 306:1;313:8	bagging (1) 66:5	bask (1) 39:10
artificial (1) 30:3	attendees (2) 7:20;9:5	avoid (13) 40:22;76:21;100:2; 111:2;113:1,5;114:2; 250:11;271:2;325:3, 11,16;326:16	balance (4) 80:19;102:14; 159:2;315:10	battle (1) 158:20
ASBM (8) 260:15,21;261:9; 264:1;273:12,12,17; 293:17	attends (1) 84:6	aware (7) 64:12;119:22; 177:20;210:13; 228:16;249:13,17	balancing (3) 78:9,20;242:16	Bayesian (1) 272:1
aside (1) 28:10	attorney (7) 28:13;31:17;101:2; 172:7;213:3;257:1; 307:11	awful (1) 184:16	ball (1) 266:6	beacons (1) 181:4
asleep (1) 92:1	attorneys (1) 239:3	away (6) 12:3;76:9;95:21; 168:12;236:8;244:12	Balto (2) 307:7,10	beamed (1) 172:17
ASP (7) 67:16,18,19,19; 166:17;270:22;286:4	attractiveness (1) 170:7	awful (1) 184:16	ban (1) 227:10	bear (2) 224:14;254:13
aspect (1) 63:14	attributable (1) 8:10	Awsare (5) 173:20;185:16,17, 17;209:7	banned (2) 223:11,16	became (1) 28:8
aspects (3) 136:6;291:10; 313:21	attribute (2) 106:1;146:19	back (32) 28:13;38:8,12; 50:1;52:9;56:8; 57:14;61:5;64:20; 67:3;71:9;73:21; 120:8;122:21;140:2; 148:13;154:2; 155:18;157:7;181:3; 211:3;212:21;213:2; 235:17;238:1;243:8;	bar (4) 90:3;134:8;135:11; 232:11	become (2) 173:13;243:10
assertions (1) 233:19	attributes (1) 93:6		barometer (1) 193:1	becomes (2) 48:11;245:1
assess (1) 129:1	audience (10) 9:8;67:20;84:16; 86:13;92:4;95:7; 106:2;179:2;203:15; 328:10		barrier (12) 50:13;93:21; 158:15;159:15,21; 160:22;162:19; 165:3;253:5;258:13; 302:1;316:20	becoming (1) 277:3
assessment (2) 36:20;111:7	audiences (4) 121:8;219:21,21; 293:7		barriers (61) 30:3;124:12;152:3; 156:15,19,22;157:3, 4,5,8,9,11,12,12,13, 17,19,20,21,22,22; 158:1,7,9,11,13; 159:6,7,10,11,14,21; 160:2,3;161:7,17,17, 18;164:22,22;165:12, 22;167:1,12,16; 168:20;171:1;226:8; 229:16;236:11; 237:10,13;258:14; 259:7;279:14;280:1; 281:5;302:9;303:1;	Becton (1) 242:3
assistance (3) 27:20;192:6; 194:19	audio (2) 7:18;8:4		barro (1) 193:1	bedrock (1) 179:15
assistant (3) 79:19;91:16;125:3	August (1) 324:16		barro (1) 193:1	bedside (1) 16:8
associate (2) 75:4;173:20	Australia (1) 276:6		barro (1) 193:1	bee (1) 227:17
associated (3) 87:4;93:9;292:18	author (1) 173:14		barro (1) 193:1	begin (9) 7:15;23:21;74:17,
Association (8) 32:19;197:18; 272:13;278:4,14,15; 288:5;293:20	authorities (5) 79:7;86:17;99:10; 205:2;314:8		barro (1) 193:1	
assume (2) 243:22;253:8	authority (7) 46:5;81:14;98:6; 100:3;251:3;302:17, 18		barro (1) 193:1	
assuming (2)	authorization (1)		barro (1) 193:1	

<p>22;176:11;182:9; 214:11;293:17; 315:22 beginning (4) 124:8;138:3;179:2; 283:16 behalf (17) 23:14;31:8;52:1; 81:1,16;104:1; 278:13;288:19; 293:19;300:12; 307:10,13,14;316:12; 320:17;323:20;328:8 behave (2) 163:13;216:6 behavior (10) 11:15;30:12;33:16; 153:12;160:13; 231:12;235:22; 246:3;270:12;271:3 behaviors (7) 6:19;15:12;21:1; 139:14;257:14; 302:15;308:18 behind (6) 6:5;136:16;251:11; 266:5,14;317:1 belief (3) 195:3;246:14; 297:10 believes (5) 202:10;304:4; 314:7;325:11,22 believing (1) 29:9 beneficial (1) 326:18 benefit (47) 46:15,16;48:12; 49:13;51:16,17,20; 52:2,7;53:12;56:9; 57:3,12;61:1,13,21; 64:8,9,13,14;65:6,6, 12;66:11,18;67:6,9, 11;68:5,12;80:20; 91:4;102:15;140:17; 142:16;162:4; 216:12;238:21; 266:10;278:16; 298:3;304:13,15; 318:7;319:11; 320:10;321:3 benefited (2) 31:4;304:8 benefits (23) 49:5;59:18;61:11; 74:7;75:7,9;93:8; 124:4;142:20,21; 149:1,1;168:13; 176:3;202:17; 206:17;266:22; 278:22;279:11; 312:16;315:16;</p>	<p>317:21;319:5 Bernstein (1) 306:7 Besides (2) 157:19;262:16 best (15) 16:3;20:2;63:1; 66:3;73:17;125:13; 150:21;184:21; 193:5;197:6;206:20; 228:13;296:14; 297:19;328:7 Betsy (7) 100:17;101:2,8; 114:10;116:20; 120:11;121:12 better (15) 18:5,22;57:16; 74:8,10;85:20;160:9; 161:8;163:2;167:3; 221:21;240:22; 242:17;254:2;320:9 bevacizumab (2) 56:16;57:18 beyond (6) 30:11;154:18; 161:4;180:4;181:5; 292:20 BI (1) 143:12 bias (2) 197:2;318:5 big (13) 45:11;51:3;66:13; 129:2;144:4;155:16; 156:20;187:2;229:5; 247:12;249:21; 253:5,10 biggest (2) 292:4;296:7 bill (5) 53:18;63:5,16; 67:15;68:21 billing (1) 63:6 billion (9) 25:3;129:4,11,12; 133:3;184:16; 185:22;286:10; 308:11 bills (1) 319:18 binary (1) 162:8 bio (1) 178:19 Biocon (2) 267:17,20 BioDrugs (1) 189:17 biologic (70) 6:19;7:14;27:19; 28:7;29:7,11,18,51:2,</p>	<p>8;53:20;63:18;67:18; 99:3,6;100:21; 106:15;127:20; 130:12,17,21;133:12; 135:14;144:12; 153:12;201:9; 206:16,19;208:8,9; 210:2;212:2;215:4; 216:5;229:21;234:8; 236:15;239:15; 246:1;257:15;260:7; 261:16;263:16; 272:18;273:8,18; 274:4;279:4;283:10, 12,20;286:1;289:1, 14;291:16;292:5,14; 294:19;296:20; 297:21;299:22; 303:1;305:6;308:3,9; 313:2,9;314:14; 319:9;324:11;327:9 biologic/biosimilar (1) 138:20 biological (25) 13:19;14:1,10,22; 15:11;33:22;34:12; 76:7;79:9;101:15; 102:2;104:3;105:9, 20;119:6;299:1; 303:16;306:15; 321:8,17;322:17,20; 323:4,8;325:13 Biologics (94) 6:10;13:2;16:2; 17:9;18:13;20:16; 23:2;24:3,17,20,21; 25:2;26:18;27:17; 28:16,20;30:9,20; 31:21;33:2;34:3; 53:16;60:21;69:13; 102:9,10;122:17; 124:17;125:17; 127:8,19,22;128:9, 13;129:10,15;130:3, 10,14;131:2,3; 132:17;134:12,19; 135:5,20;139:19; 141:11,21;146:9; 147:8;153:3;154:17; 155:21;170:9,22; 171:12;176:2;186:5; 188:22;194:5; 195:22;204:2;212:3, 5;216:7;230:1; 232:21;255:7; 256:16;265:21; 267:20;269:11; 273:9;275:9;290:15; 291:22;292:6,13; 294:3;295:2;296:1; 307:21;308:5,13; 312:12,19;313:1; 316:22;318:6,15;</p>	<p>320:16;322:14; 323:13 biopharmaceutical (3) 172:8;312:6;320:1 biosimilar (278) 7:5;14:10;15:1; 18:3,11,21;19:11; 20:19;21:12;29:10, 18;30:4;32:21;34:8; 35:4,7,12,16;36:11; 39:19;41:20;42:20; 45:5,6,6;50:13;51:2; 53:13;54:1,7;55:7; 58:10;60:4,19;63:17, 18;66:15;68:11; 72:18;73:22;76:2,16, 17;79:3,10;83:6; 96:10,13,16,21; 97:10,14,16;98:20; 99:13,14;100:21; 101:15,20;102:3; 103:6,15,21;104:3, 11;105:8;106:8,11; 107:3,13,15,17; 108:1,6,10,17,21; 110:14,16,17;111:3, 11,12,16;112:4,7,9, 13,19,20,22;113:2,6, 8,10,12,13,17,22; 114:3,18;115:1,8,20; 116:11;118:17; 121:19;124:10,11,12; 128:18,21;133:1; 134:15,22;135:1,5,6, 14;141:15,16,17,21; 142:1,3;144:22; 145:9,16;146:10,15; 151:3;156:8;158:4; 160:19;161:18; 162:13;163:2,12; 164:6,21;167:9,14; 169:9;171:14;172:3; 182:11;183:21; 187:17;188:5; 189:12;190:8; 191:11,12,16;192:1; 197:19;198:4;199:9, 13,22;200:7,17,17; 202:17;205:8; 209:16;211:12,22; 216:1,15;217:2,11, 22;235:13;237:12, 15;244:21;245:2,14; 253:14;258:17; 261:5;262:4,7,10,12, 14,21;263:6;264:19; 266:16,19;270:14,19; 271:1,10;273:4,14, 18,20;275:13,15; 276:15,19;277:4; 279:7,19;280:6,8,21; 281:20;283:17; 284:9,20;285:3,7,8,</p>	<p>16,19;286:12,13,16; 287:3;290:6;291:5; 292:2,6,15,22;295:6; 296:20;297:22; 298:1;299:2,9,14,22; 303:14,21;304:2,3,9, 14,18;305:16,18; 306:10;307:2,19; 308:8;310:9,10,11; 311:6,15;312:14; 313:4,7,8;314:3; 315:4,7;316:20; 317:2,12,14;318:9, 10;319:9;320:3,10; 321:18;325:4,15,17; 326:20,22;327:14 biosimilar/biologic (1) 208:11 biosimilarity (15) 34:13;36:2,13; 37:2,5;65:1;108:9, 20;109:17;111:20; 113:20;117:4; 269:10,16;270:7 Biosimilars (320) 6:8,11,16,18;7:3,4, 8;13:3,10;17:4,14; 19:6;20:21;21:20; 23:2;26:18;27:22; 28:17,19;30:9,14,20; 31:22;32:18;33:2,13; 34:18;38:13,18;39:1, 8,13;40:11;41:1,9,14; 42:5,15;43:9,22;44:8, 10;45:1;46:1;47:12; 48:19;49:17;51:7; 54:10,17;56:1,3,16; 57:1;58:6,19;59:3, 11;60:17,20;61:7,15; 68:14;69:4,6,14;71:2, 14;72:3;73:13;75:7, 12,16,20,22;76:10, 13;77:17;78:2,22; 96:3;97:11;102:9,21; 103:2,11,14,18; 105:4;106:21;107:9, 16;108:3;109:22; 110:10;111:2; 121:15;122:15; 124:18;125:18; 128:10;133:17,20; 134:16,20;135:3,18, 21;136:2,6,15,18; 137:5;140:15,20; 141:9;142:7;145:11, 17;146:19,21;147:9; 150:16;153:3,20; 155:22;156:16; 163:17;166:3,6,15; 168:1;170:1,4,10,15; 171:13;172:1;174:4, 8,16;176:2,4,7,18; 177:21;178:10,10;</p>
---	--	---	--	---

<p>181:3;182:14,14; 183:5;190:6,13; 191:11;194:5,11,13; 195:4,14,22;196:11; 197:2,17;201:8; 204:1,7;206:15; 208:8,9;210:12,14; 211:1,9;212:11; 215:5,17;216:8; 230:2;232:21;237:9; 246:4,6,17;249:15; 253:10;255:7; 256:16;257:6,9,13, 17,22;258:4,6,7,11, 18;259:3,13,19; 260:19;261:6,18,21; 262:2,15,22;263:8, 12;264:7,15;265:19; 266:5,8,22;267:13, 21;268:1,7;269:4; 270:14;271:4;272:7, 21;273:1,10;274:14, 20;275:2,5,19,21; 276:10,12;277:10,17, 21;279:8,9;280:19; 281:2;283:15; 285:11,21;286:2,3,9, 13;289:11;291:7,13; 293:10;294:1,15,18; 295:22;296:4; 297:18;299:5,9; 300:18,20,22;303:5, 8,17,18;304:11,14; 305:2,9,10,14,14,21; 306:4,15,17,21; 307:4;308:10,12,15; 309:3,17;310:15,19; 311:3,11;312:4,12, 18;313:15,17,22; 314:2,5,10,21;317:7, 11,21;318:1,6,13,15; 320:5,19;321:6; 324:8,9,19;325:22; 326:2,17;327:15,16, 19,22</p> <p>biosimilar's (11) 106:5;107:4,20; 108:3,18;109:1,18; 112:15,19;199:19; 216:21</p> <p>biosimilars' (1) 315:15</p> <p>BIOTECanada (1) 178:11</p> <p>biotech (2) 131:2,9</p> <p>biotechnology (1) 16:11</p> <p>birth (1) 215:7</p> <p>bit (33) 33:19;35:10;36:2; 37:15;50:3;52:13;</p>	<p>57:6;61:5;64:17; 102:19;125:20; 130:16;135:11; 140:14;149:21; 154:3;157:7;158:6; 182:20;184:13; 187:21;189:3;190:8; 192:2;197:13; 201:15;210:16; 214:11;233:8; 240:10;245:17; 282:10;287:6</p> <p>bite-size (1) 207:17</p> <p>black (5) 87:7,9,17;256:22, 22</p> <p>bleeds (1) 51:10</p> <p>block (3) 280:6;309:3; 327:14</p> <p>blockage (1) 308:19</p> <p>blockbuster (2) 170:22;308:14</p> <p>blocked (1) 30:17</p> <p>blocker (1) 283:14</p> <p>blocking (1) 157:6</p> <p>blue (3) 129:7;135:11,16</p> <p>board (6) 44:18;204:7,9,11; 278:9;316:8</p> <p>board-certified (1) 300:10</p> <p>boat (1) 60:7</p> <p>body (5) 181:20;216:7; 244:2;247:17;294:8</p> <p>Boehringer (1) 32:16</p> <p>boil (1) 175:16</p> <p>bold (1) 88:7</p> <p>bombarded (1) 179:18</p> <p>bonnet (1) 227:17</p> <p>Book (5) 53:11,17;54:3; 176:18;314:16</p> <p>boost (1) 166:12</p> <p>booth (2) 90:2,4</p> <p>border (2) 177:16,19</p>	<p>both (67) 11:22;13:13;14:19; 15:1;29:12;36:7; 37:5,10;49:3,4; 50:20;51:1;52:16; 57:6,9;60:2;61:15; 63:14;70:22;76:1; 79:6,16;80:19;82:5; 86:19;94:13;98:9,15; 99:1;100:6,13;101:6; 103:14;106:8; 107:14;114:20; 125:22;127:10; 158:8;159:22;162:5, 12;163:7;166:19; 168:14;189:22; 191:7;194:3;195:8; 196:21;197:10; 206:13;212:5;214:6; 224:19;225:4;231:8; 241:12,19;275:15,16; 296:4;303:13; 305:22;313:7,16; 327:12</p> <p>bottom (5) 34:17;88:9;130:7; 184:15;204:18</p> <p>bottom-line (1) 236:7</p> <p>bouncing (1) 185:8</p> <p>bowel (1) 188:2</p> <p>box (3) 87:7,9,17</p> <p>BPCIA (6) 158:15;201:15; 285:17;312:13,16; 315:9</p> <p>branch (1) 241:3</p> <p>brand (17) 26:3,5,14;27:1; 28:18;78:16;140:10; 153:5,8;160:17; 182:1,10,11;299:19; 303:5,7,8</p> <p>brandcom (1) 299:20</p> <p>brand-connected (1) 299:18</p> <p>branded (12) 25:19;26:1;77:11; 132:22;148:14; 308:13;309:16; 311:5,6,8,12;317:6</p> <p>brand-on-brand (1) 154:7</p> <p>brands (3) 182:15;300:1; 319:8</p> <p>breadth (1) 310:6</p>	<p>break (2) 69:15;212:20</p> <p>bridging (2) 41:22;42:5</p> <p>brief (5) 17:10;23:3;32:3; 40:7;172:10</p> <p>briefings (1) 316:6</p> <p>briefly (4) 36:1;172:11;174:9; 180:21</p> <p>BRILL (8) 124:21,21;137:22; 152:19;156:1,12,13; 170:20</p> <p>bring (14) 7:8;8:7;11:10; 55:17;98:4;194:20; 215:15;218:16; 225:16;226:5; 254:13;258:17; 266:22;322:4</p> <p>bringing (9) 8:5;16:8;33:22; 192:20;268:1,20; 269:20;285:22; 286:21</p> <p>brings (2) 70:2;283:20</p> <p>British (1) 184:2</p> <p>broad (5) 25:7;43:4;157:2; 164:18;221:20</p> <p>broad-based (1) 55:17</p> <p>broaden (1) 57:5</p> <p>broader (4) 102:1;251:2;277:8; 321:4</p> <p>broadest (1) 157:8</p> <p>broadly (3) 205:12;214:16; 322:19</p> <p>broker (1) 179:20</p> <p>brought (3) 27:18;30:16; 225:12</p> <p>Brown (1) 23:7</p> <p>BsUFA (3) 313:19;326:8,9</p> <p>bucket (5) 230:14,16,17,19; 234:20</p> <p>buckets (4) 156:19;214:15; 230:14;268:9</p> <p>build (4)</p>	<p>73:17;134:2; 175:22;263:11</p> <p>building (2) 208:19;266:19</p> <p>built (1) 244:1</p> <p>bullet (1) 184:12</p> <p>bunch (6) 51:14;54:12; 214:19;225:21; 239:16;242:4</p> <p>bundled (1) 310:4</p> <p>bundling (4) 49:8;52:2;237:3,6</p> <p>burden (1) 219:9</p> <p>burdening (1) 281:5</p> <p>burdens (1) 160:11</p> <p>Bureau (5) 31:18;79:20;91:17; 125:3;256:21</p> <p>Burich (7) 32:15,15;46:10; 59:14;65:3;69:7; 72:11</p> <p>buried (1) 88:9</p> <p>business (5) 7:12;25:9;63:8; 171:2;231:1</p> <p>buy (2) 184:15;226:10</p> <p>buyers (2) 232:8;233:21</p> <p>buying (1) 270:2</p> <hr/> <p style="text-align: center;">C</p> <hr/> <p>caffeine (1) 185:7</p> <p>calculate (1) 143:8</p> <p>calculation (2) 135:19;143:16</p> <p>Caldwell (3) 278:3,5,6</p> <p>call (12) 43:18;89:3;126:15; 161:6;183:11;187:8; 192:9;193:9;195:19; 209:22;248:16; 286:16</p> <p>called (7) 14:8;51:11;53:19; 114:18,19;143:7; 247:1</p> <p>calling (2) 84:21;196:10</p>
--	---	---	--	---

<p>came (6) 11:5;15:14;42:10; 190:8;209:15;210:18</p> <p>campaign (2) 21:13;279:10</p> <p>campaigned (1) 271:9</p> <p>campus (1) 34:6</p> <p>can (225) 7:12;9:18;10:2,17; 12:18;14:19;17:1,22; 18:4;21:20;22:5; 24:4,21;27:7;33:20; 35:9,12;37:8,20; 40:16;41:10,20;43:5; 44:16;46:20;49:9,20; 55:1,14;56:5;57:21, 22;61:2;64:17;66:22; 68:16;69:17;70:9,21; 71:1,20;73:4,16,17; 74:11;75:7,21;76:4; 77:1;78:6;84:22; 85:16,18;88:3;97:2,3, 3,4;98:3,5;99:21; 100:4,7;105:21; 106:2;108:15;110:4, 11;115:13;118:14; 119:2;121:5,9,15; 124:15;125:13,18; 126:17,19;129:7; 131:6;133:2;134:15, 18;138:2,8;139:21, 21;140:5;141:3; 143:20;144:10,18; 145:1,7,16,20; 149:16,16;150:2; 157:13,14,14,20,21; 159:8,9,10,11; 160:14;161:1;162:2, 11,19;164:5,14,21, 22;165:7,12,22; 166:18;169:6,12; 171:6;172:4,22; 173:2,4,5,6,9;175:1, 5;176:17;177:10,11; 184:1,15,19;185:2, 12,22;186:20,21,21; 187:15;188:1;190:4; 191:13,18;196:21; 198:14,15;201:22; 202:15;203:3; 206:20;207:2,14,18; 214:9;215:14;218:4, 16;219:16;221:15,17, 18;223:10,16,19; 225:7,19;227:10; 228:8;229:2,11; 231:13,14;232:2; 233:5;234:19; 238:18;241:22; 244:2,3,16,19; 245:21;248:7,22;</p>	<p>254:1,6,12;255:17, 19;259:17;265:6,15; 266:22;273:11,15,15; 275:7;276:8;284:5; 287:1,5;295:21; 297:17;298:19; 299:8;300:1;301:9; 304:14;308:10; 309:12;310:8; 311:15;318:12,14; 319:6,20;321:20</p> <p>Canada (16) 172:17,21;173:11; 177:14;178:11,16; 181:2,5;183:9; 188:17;189:6; 195:11;200:4;207:8; 273:6;276:6</p> <p>Canadian (2) 183:13;184:17</p> <p>Cancer (7) 11:8;15:14;24:19; 130:14;272:12; 274:6,10</p> <p>capacity (1) 169:22</p> <p>capita (1) 129:19</p> <p>capitals (1) 169:8</p> <p>capitol (1) 164:3</p> <p>capture (1) 126:16</p> <p>cards (1) 143:19</p> <p>care (21) 12:12;15:15; 184:12,16,18;185:21; 186:2;204:5;215:13; 233:19;267:22; 275:6;278:4,13; 289:4,13;295:20; 296:14;302:8; 316:19;317:3</p> <p>career (1) 22:21</p> <p>carefully (3) 105:14;110:22; 122:7</p> <p>caregivers (1) 316:15</p> <p>Carrier (26) 213:11,12,20; 214:1,6,17,18;218:7; 225:22;229:2,5; 237:22;238:9;240:5; 243:1;245:2,10; 246:1,21;249:17; 250:14;251:5;252:1; 253:9,18;254:8</p> <p>carved-out (1) 148:22</p>	<p>cascade (1) 211:18</p> <p>case (40) 30:16;48:1;49:2; 54:16;66:10;85:2; 107:17;112:4;133:9; 145:12;146:16; 147:20;164:12; 165:22;219:1,9; 220:2;222:3,17; 223:1;227:3;230:4; 232:4,12;235:10,10; 237:1,20;239:6; 242:2;243:10;245:7; 246:2,12;248:12,14; 249:5;250:6;274:6; 313:6</p> <p>case-by-case (5) 230:18;234:21; 237:17;242:17;249:7</p> <p>cases (20) 68:9;79:1;148:14; 182:18;221:9,12; 223:6;224:5;227:20; 230:8;232:20,20; 237:6;241:19,20; 248:18;249:12,14; 270:4;279:16</p> <p>cash (2) 131:21;168:21</p> <p>catastrophic (3) 220:4,6,10</p> <p>catch (1) 16:15</p> <p>catch-if-can (1) 207:11</p> <p>categories (7) 41:12;52:3;59:11; 160:7;191:19; 214:20;254:3</p> <p>categorization (1) 217:20</p> <p>categorize (3) 156:18;214:19; 218:5</p> <p>category (9) 43:4,21;51:14; 57:5;214:20;215:19, 22;216:18;224:6</p> <p>Catherine (2) 120:10;328:6</p> <p>Caty (5) 100:10;101:11; 120:9;256:17;328:5</p> <p>cause (10) 218:15;219:5; 223:8;238:2;242:22; 244:6;248:21; 251:19;294:9;301:15</p> <p>causes (2) 164:9;244:6</p> <p>causing (1) 137:10</p>	<p>caution (3) 136:11;227:13; 281:18</p> <p>cautious (2) 44:2;265:2</p> <p>cautiously (1) 215:5</p> <p>CBE-0 (1) 327:2</p> <p>CBE-0's (1) 327:3</p> <p>CDC (1) 12:16</p> <p>CDER's (6) 6:10;102:6,8; 124:17;171:12; 256:15</p> <p>cell (2) 7:17;57:1</p> <p>Center (3) 11:8;102:10; 288:16</p> <p>Centers (3) 43:17;58:4;289:6</p> <p>central (2) 16:17;49:22</p> <p>CEO (1) 288:4</p> <p>certain (7) 9:14;79:6;164:16; 243:15;252:21; 290:16;314:14</p> <p>certainly (22) 17:2;18:3;45:17; 50:15;127:9;157:10; 184:8;214:18; 231:10,13,14;232:18; 234:5;236:1;238:12; 245:2;248:19;249:1, 20;250:19;251:15; 253:9</p> <p>certainty (2) 45:4;163:7</p> <p>cetera (3) 59:2;66:17;188:3</p> <p>CFL (3) 109:6,20;116:20</p> <p>CFR (1) 82:8</p> <p>chain (4) 63:14;69:16;73:1; 266:2</p> <p>chair (1) 260:6</p> <p>chaired (1) 275:8</p> <p>chairing (2) 274:3;275:11</p> <p>Chairman (4) 22:18,19;23:14; 31:8</p> <p>challenge (3) 55:10;193:22;</p>	<p>294:9</p> <p>challenged (1) 97:18</p> <p>challenger (1) 219:10</p> <p>challenges (11) 33:14;40:15;41:6, 8,12,13,19;153:18; 276:5;292:18;323:7</p> <p>chance (6) 63:13;97:13; 213:20;239:4; 241:16;248:10</p> <p>Change (9) 71:19;147:12; 196:2;208:5,6;254:6; 265:4;313:2;319:20</p> <p>changes (7) 10:9;52:15,22; 53:10;65:15;292:12; 301:18</p> <p>changing (2) 265:4,13</p> <p>channel (2) 131:6;154:16</p> <p>channels (1) 128:1</p> <p>character (1) 299:15</p> <p>characteristics (3) 59:10;128:5; 287:20</p> <p>characterization (1) 291:10</p> <p>characterize (2) 210:22;240:1</p> <p>charge (2) 72:1;173:21</p> <p>charitable (1) 316:3</p> <p>charities (1) 183:2</p> <p>chart (5) 90:3;130:7,8; 132:7;135:12</p> <p>charts (1) 127:1</p> <p>cheaper (1) 182:17</p> <p>checkbook (1) 319:14</p> <p>Cheryl (9) 172:19,22;173:10; 176:21;177:1,2; 185:4;202:14;207:6</p> <p>Cheryl's (1) 185:14</p> <p>chief (7) 11:7,15;12:5; 22:17,18;23:5;32:11</p> <p>child (1) 222:20</p> <p>children (2)</p>
--	---	--	--	---

<p>191:8;215:7 choice (10) 18:6;19:1;29:1; 200:15;304:16; 306:20;307:8,12; 313:4,12 choices (3) 7:3;311:16;321:20 choose (1) 29:2 chooses (1) 82:21 choosing (2) 187:2;297:15 Chopra (2) 251:1,1 chosen (4) 66:2,7,12;182:3 Christine (7) 32:4,17;39:2;44:6; 50:1;56:11;160:5 Christine's (1) 47:3 chronic (6) 56:2;59:16;283:18; 287:9;294:6;316:17 chronically (2) 316:14;318:10 chronicity (3) 56:7,13;59:10 circle (1) 28:15 circles (1) 159:5 circling (1) 38:12 Circuit (4) 222:3,10;227:4; 242:2 Circuits (4) 230:20;231:22; 234:22;242:16 circuit-split (1) 240:22 circulated (1) 206:10 Cirincione (10) 79:13;80:6,7,9; 98:22;100:18;114:9, 10,13;120:19 citizen (3) 216:3;239:8; 324:16 claim (24) 89:6,12;90:7;95:2; 97:3,4;115:3,13,18; 218:19;219:6,10,14, 15,17,20;220:16,18; 226:5;227:10; 239:21;242:8,12; 251:18 claimed (1) 230:5</p>	<p>claims (29) 87:2,12;88:7,14, 21;89:17;90:21;91:4, 5;94:14,14,17,17; 97:2,7;103:3;122:5,6, 8;126:10;152:9; 218:16;219:8,8; 223:2,6;226:14; 227:5;235:15 clarify (1) 285:10 clarifying (1) 295:3 clarity (6) 20:1;45:4,17; 281:8,17;290:1 class (7) 225:20;226:8,17; 239:20;240:7,8; 262:22 classes (3) 61:6;290:17; 322:19 classic (1) 154:7 classification (1) 260:19 class-specific (1) 46:5 cleaned (1) 54:3 clear (20) 48:4;78:8;164:16; 165:1,3;195:4; 205:17;219:3; 229:21;232:4,16; 234:14;250:18; 251:11,12;274:18; 281:3;284:19;285:6; 318:14 clearly (15) 53:5;105:19;117:1; 179:3;202:2;208:13; 223:3;232:6,6,7; 233:3,6,14;252:4; 262:16 Cleland (15) 79:18;91:16,18,19; 92:1;99:17;214:3; 225:10;226:21; 227:19;228:9; 244:19;245:8; 249:13;253:3 clicker (1) 125:13 clinic (1) 181:21 clinical (31) 36:17;38:5;41:21; 42:7;89:2,9;90:15; 107:7;115:21; 116:12;117:13,17; 127:16,17;188:12;</p>	<p>189:9;198:14,16; 201:11,17;211:8; 271:12;284:13; 290:5,8;292:9; 301:19;318:18; 325:7;326:10,15 clinically (18) 29:17;34:21;42:3; 76:15,19;97:8; 110:19,20;111:4,17; 113:15,16;116:3,14; 117:18;118:10; 200:22;215:18 clinicians (9) 179:14;186:2; 265:1;267:12; 279:10;281:7,10,18; 314:6 clinics (1) 60:22 clockwise (1) 131:13 close (4) 15:7;38:12;149:18; 184:16 closed (1) 161:14 closely (4) 53:1;197:6;205:15; 322:11 closing (6) 31:1;184:1;286:15; 297:9;328:6;329:8 CMS (3) 68:18;259:11; 278:10 Coalition (4) 263:20;300:8; 307:7,11 coast (2) 178:15,15 Coca-Cola (1) 168:2 co-chair (2) 174:7;197:16 cockeyed (3) 40:14;41:10;44:2 Code (1) 82:7 coding (1) 306:9 coffee (2) 8:14;54:3 cognitive (1) 301:9 Cohen (8) 174:2;197:12,14, 15,15;203:7;210:4; 258:1 cohort (1) 155:4 coinsurance (1) 309:15</p>	<p>co-insurance (1) 309:17 collaborate (3) 197:5;284:9; 322:11 collaboration (16) 13:16;14:16;21:14; 22:10;23:22;31:3,4, 11;45:7;98:17;99:1; 193:19;279:3; 280:12;321:2;324:7 collaborative (3) 6:15;13:1;196:17 collaboratively (1) 293:9 colleague (3) 188:6;214:4;258:1 collect (1) 147:15 collecting (1) 191:10 collectively (1) 269:13 College (2) 209:13;260:1 Collins (1) 53:19 Colon (1) 272:12 color (1) 88:4 colorectal (2) 274:6,9 colorful (1) 88:8 colorfully (1) 222:21 Columbia (1) 186:2 Columbia's (1) 184:2 combat (2) 42:14;164:14 combating (1) 26:20 combination (2) 239:5;250:6 combined (2) 14:18;222:20 comfortable (4) 48:14;190:15; 262:3,5 coming (15) 11:9;54:12;59:20; 70:3;127:12;129:10; 168:11;209:19; 250:12;259:17; 264:13;304:12; 307:3;312:20;323:11 commend (4) 53:10;279:4;291:2; 307:17 commends (1)</p>	<p>279:2 comment (28) 9:9;10:3;11:3; 45:19;48:22;58:13; 63:13;73:21;82:18; 118:20;120:5;126:1; 137:22;138:1,16; 151:9;169:16; 177:13;199:2;215:2; 247:22;255:2,4,8; 263:13;298:14; 300:5;320:18 commenter (1) 328:4 comments (19) 10:18,20,22;14:13; 49:21;120:1;121:10; 199:14,21;200:5,16; 261:2;272:8;282:9; 293:19;300:3; 307:17;328:19,21 Commerce (2) 28:3;94:3 commercial (15) 50:4,20;92:18,22; 93:17,21;131:14; 132:1,2;139:15; 154:22;223:10; 303:6,9;308:16 commercialization (1) 263:7 Commission (11) 11:14;12:6;24:1; 26:4,21;31:19;125:4; 213:4;214:4;247:2; 257:2 Commissioner (15) 11:5;21:17;23:13, 17;24:7,8;28:10,12; 39:21;69:8;75:4; 235:19,19;251:1,1 Commission's (1) 172:9 commit (1) 238:19 commitment (3) 83:19;280:5; 303:14 commitments (1) 11:12 committed (8) 21:7;30:7;257:19; 283:22;284:4; 304:19;307:3;322:13 Committee (7) 28:2;174:7;186:16; 197:17;260:7;291:8; 316:12 committees (2) 285:12,14 common (11) 15:20;52:4;63:21; 64:13;86:3,21;87:19;</p>
--	--	---	---	--

89:15;96:19;321:19; 323:7 common-law (1) 249:20 commonly (3) 56:10;85:10;86:9 communicate (3) 15:16;206:20; 222:21 communicating (2) 108:12;195:19 communication (17) 14:1;43:7;79:3; 81:6;82:14,16;92:11; 102:18;109:9,11; 195:20;197:7,9; 212:7;260:11; 284:19;294:13 communications (34) 6:17;20:3;30:9; 75:3;76:11,21;77:17; 78:4;79:8;80:14,22; 81:15;82:11,20;83:1, 5,7;91:10;92:13,15; 98:14;102:2,4;109:4; 110:3;171:11;255:6; 257:12;285:8,11,13; 287:3;314:4;324:18 communicative (1) 241:6 communities (3) 7:7;183:7;320:9 Community (14) 172:20;173:10,13; 174:5;178:6;179:20; 180:17;184:22; 208:20;274:2,21; 277:9;290:16;302:5 co-moderating (1) 172:6 companies (29) 26:6;71:22;92:5,6; 143:11;197:20; 199:6;210:5;234:1,1; 236:6,15;239:15; 247:7,12;248:8; 252:11;253:1,6,11; 268:13;275:12,14; 278:20;312:3,6; 316:4,7;320:1 company (13) 92:16;94:13;143:8, 10;199:6;217:9; 234:8;237:1;246:1; 267:21;268:2;283:8; 288:18 comparable (3) 88:1,13;161:13 comparative (12) 29:14;36:10;91:5; 112:3;115:21; 116:11;117:16; 279:18;290:8,17,21;	301:19 comparator (4) 106:15,17;116:13; 117:7 comparators (1) 138:14 compare (4) 111:1;147:4,7; 241:7 compared (6) 167:20;219:5; 245:18;291:14; 303:22;320:4 compares (1) 90:4 comparing (2) 90:10;110:13 comparison (3) 90:9;137:4;147:10 comparisons (7) 89:17;103:5;110:9; 121:14;122:14; 138:19;149:11 compelling (1) 244:22 compete (6) 153:20;154:9,10; 277:6;305:13;318:18 competing (5) 290:12;304:16; 305:18;309:3;312:19 Competition (108) 17:9;18:6,8;19:2; 20:8,17,19;21:4; 22:21;24:4;25:5,8,11, 14,22;26:19;28:7,16, 17;29:4,5;30:2,6,18; 31:18;39:22;49:2,8; 72:2;74:1,8;75:8; 78:10,15,20;94:2; 98:19;99:2,8,19; 102:5;124:5;128:17, 18;129:16;133:17; 139:11;141:12,22; 142:1;144:20;145:3, 16;150:17,18;151:1; 154:6,8;159:12; 161:22;162:4,11; 167:6,8;170:4,13,21; 171:6;186:20; 230:22;231:3; 240:14;241:4,5,10, 14;245:16,20; 246:19;268:22; 271:4;276:13,22; 279:3;280:7;285:22; 288:22;296:1; 304:10;305:1,4,9,10; 306:11;307:1,19; 311:16;312:11,17; 313:11;314:9;315:4, 8,11;316:22;321:8; 322:18;324:10	Competitive (20) 6:8;7:11;13:18; 21:22;24:2;41:13; 99:15;245:20; 257:15;280:21; 281:20;286:20; 289:17;293:10; 303:19;306:12; 312:3;320:18; 321:10;322:1 competitiveness (1) 286:8 competitor (7) 90:8;145:13;162:8; 218:15;227:21; 228:4;305:16 competitors (11) 30:1;84:13;134:20; 146:1;147:2;162:9; 170:16;225:13; 242:6;246:9;251:22 competitor's (3) 90:6;93:3;220:3 compilation (1) 148:17 complaints (1) 84:12 complementary (2) 98:13;238:13 complete (6) 90:22;202:3; 257:20;284:19; 285:6;318:2 completely (7) 67:7;71:15;227:12, 16;236:4;247:10; 265:21 complex (4) 69:13;294:6; 297:16;312:15 complexities (1) 121:21 complexity (2) 49:2,6 compliance (11) 79:16;81:5,6;84:4, 4;85:12,15,21;86:11; 102:17;187:6 complicated (10) 49:14;50:15;57:3, 11;128:2;158:6; 169:10,11;192:3; 222:16 complicates (1) 62:20 complication (1) 62:10 complications (1) 63:8 comply (1) 119:16 component (2) 58:7;268:20	components (2) 110:19;113:15 composed (1) 300:13 comprehensive (4) 81:4;102:16;144:5; 279:10 compromising (4) 184:18;266:20; 276:2;326:3 concept (1) 13:8 concepts (4) 69:13;175:17; 225:7;291:4 concern (1) 192:1 concerned (9) 103:3;110:8; 139:13;155:13; 189:3;222:22;258:2; 296:17;327:7 concerning (6) 13:2;81:11;85:22; 104:16;291:16; 324:18 concerns (8) 85:13;99:5;181:11; 191:17;194:10; 237:16;291:21;292:2 concessions (2) 126:21;267:5 conclude (1) 200:6 concluded (4) 9:10;25:20;255:22; 329:13 conclusion (3) 90:12;91:7;118:13 concretely (1) 31:5 concur (1) 313:22 condition (4) 56:7,14;310:2; 326:6 conditioned (1) 327:18 conditions (9) 16:13;56:2,3,9; 57:6,7;107:18,22; 297:16 conduct (19) 26:21;30:11;32:2; 229:10;230:13; 231:2,10;238:14; 239:5,8,13;240:8; 244:3,10;247:9,14; 251:13;252:2;295:4 conducted (6) 22:7;84:1;90:14; 108:8,19;261:9 conducting (2)	25:15;206:8 conference (3) 71:11;90:1;275:9 conferences (1) 84:6 confidence (13) 21:2;110:11;261:6, 7;262:17;267:13; 274:20;275:18; 294:17;295:13; 296:6;306:14,17 confident (1) 261:18 confidential (1) 143:3 confirmatory (1) 41:22 conflict (1) 281:16 conflicts (1) 205:16 confused (1) 221:19 confusing (4) 48:16;184:14; 191:14;296:4 confusion (2) 130:17;281:17 conglomerates (1) 302:22 congratulate (1) 22:12 Congress (5) 17:7;27:21;28:1,6; 259:11 Congress' (1) 19:2 connected (1) 60:13 connection (1) 327:10 consensus (1) 194:7 consequences (5) 75:21;157:16; 161:16,19,20 conservative (1) 265:2 consider (16) 36:22;94:18;96:9; 110:13;117:11; 122:7;237:8,14; 239:4;262:1;268:17; 272:6;284:8;287:20; 295:16;326:21 considerable (1) 304:8 consideration (5) 122:1;212:18; 266:8;280:15;326:11 Considerations (20) 14:9;48:6;100:20; 101:14;103:9,17;
---	--	--	--	---

105:1;106:20; 114:16;119:9;120:6, 15,20,22;121:4,5; 172:1;282:6;290:6; 299:1 considered (6) 88:19;89:20;93:17; 115:13;184:8,9 considered' (1) 215:9 considering (3) 122:9;166:10; 266:14 consistency (2) 109:8;197:9 consistent (7) 109:1,4,11;116:19; 312:9;314:14;327:1 consistently (2) 60:14;167:18 consolidate (1) 126:12 consolidated (2) 51:4;302:2 consortium (3) 196:1,11,17 constant (1) 153:10 constantly (2) 44:21;55:10 constituents (1) 175:7 constitute (4) 29:19;30:6;86:8; 235:5 constitutional (1) 223:8 constitutionally (1) 223:11 constraints (1) 194:12 consult (1) 179:13 consultant (1) 32:10 consultation (1) 102:8 consume (1) 69:17 consumer (34) 21:8;25:5;29:12, 13;79:20;83:14; 91:17;96:12,14,18; 99:20;158:9;176:21; 219:6;221:1,7,15; 222:13;225:15,16,19; 226:7,12;228:1,3; 238:7,10;239:21; 246:20;252:20,22; 307:13,15;313:12 consumer-level (1) 181:14 consumers (31)	25:8,21;29:2,5; 31:5;44:14;84:13; 93:12;94:18;95:12, 21;96:19;221:2,4,10, 14,16,20;222:22; 226:1,4,6,15;228:7; 241:18;244:5;246:9; 251:21;280:10; 308:11;309:10 consumer's (2) 218:22;228:2 consumers' (1) 224:17 Contact (5) 8:17;9:1;85:1; 91:13;329:6 contained (2) 14:12;93:1 containing (1) 275:7 contains (1) 89:6 contemplate (1) 54:5 contemplating (2) 120:22;183:18 content (8) 86:19;92:22;96:1; 103:20;173:17,18; 175:11;292:8 contents (1) 142:8 context (16) 47:6;93:15;105:11; 112:3;118:5;125:19; 159:4;213:5,8; 218:11;235:2;238:7; 239:21;240:1; 247:21;317:8 contextual (2) 104:22;117:2 continually (1) 298:7 continue (34) 17:2;30:19;38:17; 42:12;45:12;55:6; 72:2,5,10;86:12; 124:15;127:18; 130:10;136:5; 140:19;163:1; 263:11;267:6;277:2, 6;284:10;285:12,18; 290:13,19;293:3; 302:11;314:9; 315:13,15;320:4,8; 323:2,10 continued (7) 17:6;145:18;195:5; 232:9;258:7;305:5; 314:3 continues (6) 47:7;144:19;258:3; 264:8;286:12;292:22	continuing (4) 24:9;31:11;131:22; 138:4 continuity (1) 215:12 continuously (1) 321:3 contract (2) 63:16;147:22 contracted (2) 52:16;63:1 contracting (13) 42:17;50:20;51:3, 6,7,19;52:1,6;53:6; 160:15;186:17; 309:2;327:8 contracts (3) 226:10;327:14,17 contrary (2) 273:19;275:1 contribute (2) 112:1;122:6 contributing (1) 137:1 contributions (1) 316:3 control (3) 221:4;284:13; 302:2 controversial (1) 158:12 convene (1) 323:3 convener (1) 323:2 convening (2) 323:10;328:1 convention (1) 90:3 conversation (19) 23:3;100:16;136:5; 177:22;178:10; 179:6,11,11;180:7; 181:8;192:8,21; 194:12,13;195:21; 196:6;197:2;253:20; 293:6 conversations (2) 188:19;193:22 convert (1) 129:18 convey (4) 94:19;104:7;106:7; 121:6 conveying (1) 109:13 conveys (2) 96:4;117:21 cookie-cutter (1) 294:10 cooperation (1) 102:9 coordinated (1)	211:13 coordinating (1) 11:13 co-pay (1) 318:22 co-payment (1) 154:11 co-payments (1) 151:17 copies (5) 8:15;9:18;328:22; 329:5,7 copy (2) 94:22;182:16 copyright (1) 213:17 core (3) 105:10;106:6; 301:15 Corey (4) 288:7;293:15; 315:18;316:9 coronavirus (2) 12:11;291:21 corporate (2) 205:15;257:8 correcting (1) 260:10 correctly (6) 105:17,19;138:16; 240:20;241:4;244:20 correlation (1) 149:22 Cosmetic (7) 81:10,18,21;85:6, 18,22;119:13 cost (30) 13:14;18:17;42:4; 53:6;65:17;140:5; 153:16;162:16; 171:2;192:2;236:13; 253:5;258:10; 259:14,15;265:14; 266:8;267:1;271:5; 274:13;281:1;304:8, 13;305:4;306:2; 309:5,13,14,17; 310:17 cost-containment (1) 296:12 costing (2) 24:22;25:1 costly (3) 42:1;158:4;159:16 costs (26) 15:21;17:17;21:3; 25:21;30:3;162:3,6; 164:5;165:10,17; 176:5;235:7;253:8; 275:7;280:10,18; 284:4;285:17;286:6, 21;301:21;302:10; 309:17;311:17;	318:19;324:12 Council (2) 32:18;43:9 counsel (4) 79:13;80:10;101:2; 124:16 counseling (2) 79:15;317:16 counter (2) 21:10;30:4 counteract (2) 69:5;254:16 counter-productive (1) 21:16 counterproductively (1) 277:20 countries (9) 72:14,15,19; 261:10;262:10,12,18; 276:9;320:5 countries' (1) 276:8 country (13) 12:21;177:15; 178:14;183:18,22; 184:10;208:21; 259:13;260:14; 261:22;264:14; 276:5;316:15 country's (2) 262:19;312:5 couple (18) 39:20;41:11;47:13; 50:8;53:7;70:20; 128:14;141:8;167:2; 174:18;199:4;201:6, 6;215:1;219:4; 221:13;250:4;264:7 coupon (1) 143:19 course (25) 37:11;40:3;43:12; 48:17;53:14;54:19; 55:19;82:9;135:2,10; 159:15,22;160:2; 162:3;165:11; 167:21;203:21; 208:3;214:3;233:15; 239:13;249:3,10; 277:9;296:14 Court (13) 27:6;98:6;220:12; 222:19;223:12; 227:10;231:17; 235:1;236:20; 239:10;242:7,11; 252:14 courteous (1) 256:6 courts (22) 27:10;219:14,18; 223:6,21;224:3,9,21; 226:14;227:14,17;
---	---	--	--	---

<p>230:13,21;231:19; 235:4,6;236:10; 240:6,20;243:20; 244:17;251:7 cover (6) 99:21;100:4; 120:15;124:10; 268:8;311:6 coverage (10) 9:12;192:2,5; 194:17;270:21; 278:19;293:1;304:6; 327:15,15 covered (6) 52:1;59:18;142:15; 147:19;155:12; 194:18 covers (1) 103:13 cows (2) 168:21;222:6 crack (1) 136:9 crafting (1) 242:21 crazy (1) 190:3 create (15) 20:21;27:7;74:1, 14;112:6;182:3,18; 195:20;198:13; 203:22;254:6;270:6; 318:4,16;320:9 created (5) 158:15;201:14; 207:11;209:9;287:17 creates (6) 29:16;30:3;148:7; 163:6;305:3;314:19 creating (5) 77:13;113:1,5; 159:6;181:19 creation (2) 21:11;278:11 credible (1) 180:3 credit (1) 266:18 critical (16) 25:11;31:9;38:18; 75:9,17;193:2;194:2; 195:15;203:2; 268:20;270:15,16,21; 284:10;303:11;314:2 critically (2) 42:14;313:18 Crohn's (1) 24:19 cross (1) 238:19 cross-benefit (1) 49:10 crosses (1)</p>	<p>79:3 crosstalk (1) 159:8 crucial (3) 240:16;246:7; 306:19 CSRO (1) 300:13 cumulative (3) 132:20;133:3; 156:21 cure (2) 16:12;294:9 cures (2) 21:6;22:6 curious (1) 247:20 current (16) 11:13;43:9;68:19; 83:8;118:19;210:2; 229:3;262:7;302:21; 304:5,5;305:8;306:8; 313:5;317:19;327:12 currently (9) 115:16;196:11; 248:14;283:15; 298:19;304:1; 305:11;314:15; 322:18 curricula (1) 205:8 curve (3) 57:16;67:8,8 curves (4) 56:18,19;57:1;59:5 cut (2) 78:8;158:17 CVS/Aetna (1) 32:12 cycle (2) 323:1,9 cycles (1) 19:17</p>	<p>126:1,2,6,8,10; 136:22;143:9;144:3, 6,21,22;147:1,4,4,6; 149:11,12;151:22; 152:9;189:14; 196:21;200:5; 201:11;269:15,16; 285:1;313:5;326:10, 16 data-driven (1) 22:2 date (4) 183:13;257:18; 259:1;300:16 Dave's (2) 138:1,16 David (3) 125:2;307:7,10 day (13) 6:13;8:9,12;9:9; 10:4;31:14;37:11; 39:1;174:12;177:5; 233:4;283:2;328:7 daylight (2) 91:20;100:14 days (9) 9:20;73:10;89:7, 10;136:18,19;250:4; 275:8;329:4 DC (4) 12:4;227:4;234:22; 235:1 de (7) 230:17;231:20; 232:2;233:2;234:18; 243:22;270:3 deal (8) 92:6;98:3;99:22; 168:10,17;186:18; 239:2;250:19 dealing (3) 194:15;237:3; 239:18 deals (3) 49:7;216:18; 233:15 debate (3) 28:7;159:9,10 debilitating (1) 307:22 decade (5) 18:8;162:22; 312:13;315:9;321:15 decades (4) 236:6;247:2;278:7; 283:9 decades-long (1) 23:22 deceive (3) 221:14;244:5; 246:15 deceived (1) 221:16</p>	<p>deceives (1) 244:5 deceiving (1) 29:22 December (2) 11:6;141:22 deception (9) 29:11;30:5,5; 78:18;225:1;227:7; 234:16;245:21; 251:13 deceptive (18) 25:9;29:20;30:11; 94:3;96:1;97:5; 227:2,2,5,8,11;233:5, 9,12;240:14;244:10; 300:21;301:17 deceptiveness (1) 225:4 decide (1) 284:3 decided (1) 254:4 deciding (1) 285:2 decision (16) 27:6;53:2;167:14; 186:17;188:18; 196:4;200:13; 218:22;228:2,6,11; 247:6;252:9;290:5,7; 297:20 decision-making (3) 208:16;235:8,15 decisions (15) 22:3;58:19;110:6; 169:20;192:11,14; 247:20;284:12,16; 286:18;289:18; 290:14;292:19; 297:14,19 decline (1) 170:3 deconcentrated (1) 252:18 decrease (11) 144:13,19;145:4,8, 18,21;146:10,11,15, 17;290:11 decreased (3) 147:3;300:18; 313:9 decreases (1) 145:15 decreasing (2) 20:10;151:12 dedicated (2) 312:10;320:20 deep (1) 303:14 deepest (1) 288:20 deeply (1)</p>	<p>283:22 defects (1) 215:7 defendant (2) 220:3;244:9 defer (1) 224:10 deference (2) 224:20;225:2 deferring (1) 224:12 defined (3) 37:6;94:6;319:2 definitely (5) 19:21;64:1;188:20; 252:11;253:2 definition (4) 34:15;215:17; 223:9;313:2 definitive (1) 165:3 degree (7) 57:16;163:6;164:2; 167:6;202:15; 281:11;301:4 degree-ish (1) 126:11 degrees (1) 319:15 delay (3) 20:18;269:20; 280:18 delayed (1) 293:1 Delays (2) 271:5;326:16 delighted (3) 12:2;23:13;101:6 deliver (3) 63:20;180:13; 182:15 delivered (1) 181:15 deliverer (1) 178:7 delivering (2) 285:16;304:20 delivery (2) 58:2;304:16 delved (1) 204:12 demand (1) 93:2 demanding (1) 302:4 demonstrate (4) 36:9;166:14;292:7; 306:8 demonstrated (4) 34:19;38:4;46:2; 89:14 demonstrates (2) 176:5;305:7</p>
	D			
	<p>dairy (1) 223:1 damage (1) 244:16 damages (1) 239:3 dark (2) 129:7;135:11 data (58) 22:4;35:5;36:1,7,9, 10,16;37:1,3,15;38:1; 56:17;57:19;58:20; 89:1,11;104:21; 106:1,22;107:5,7; 108:7,12;115:21; 116:16;117:4,6; 118:12;125:21;</p>			

<p>demonstrating (3) 36:2;37:19;269:3</p> <p>demonstration (12) 34:4;35:2,22;36:7, 12;108:8,20;109:17; 111:20;116:3,14; 117:17</p> <p>denial (1) 239:10</p> <p>denials (1) 239:9</p> <p>denied (1) 250:5</p> <p>denigrating (1) 93:3</p> <p>denominator (2) 135:3;143:13</p> <p>deny (1) 310:2</p> <p>Department (2) 85:16;98:2</p> <p>depend (2) 22:9;36:18</p> <p>dependent (1) 235:2</p> <p>depending (6) 69:15;93:18;95:8; 105:11;226:11; 261:22</p> <p>depends (5) 46:13,14;122:4; 162:3;306:12</p> <p>deploys (1) 77:2</p> <p>depressed (1) 261:7</p> <p>deputy (2) 311:19,22</p> <p>dermatology (1) 261:14</p> <p>describe (3) 112:20;118:4; 141:10</p> <p>described (6) 13:21;105:12; 109:3;116:9;160:5; 302:8</p> <p>describes (4) 109:7;114:21; 116:7;117:7</p> <p>describing (1) 247:18</p> <p>deserve (1) 284:19</p> <p>deserves (1) 266:18</p> <p>design (6) 34:11;117:2;118:4; 162:4;301:16;302:21</p> <p>designation (12) 42:2;43:11;46:1,7, 11;65:10,21;67:5,10; 70:11;195:2;305:19</p>	<p>designed (9) 15:8;20:20;22:11; 72:8;83:12;203:9,13; 279:17;301:12</p> <p>designs (1) 90:16</p> <p>desire (1) 291:17</p> <p>desired (2) 153:19;289:17</p> <p>Despite (2) 268:12;316:21</p> <p>detail (4) 146:7;202:16; 204:13,16</p> <p>detailed (2) 194:13;291:9</p> <p>details (6) 10:18;86:18; 175:12;190:18; 204:8;328:21</p> <p>detain (1) 218:17</p> <p>detaining (1) 310:19</p> <p>deter (3) 15:11;30:12; 257:13</p> <p>determination (5) 48:2;104:19;111:9; 247:4;271:20</p> <p>determinations (1) 224:16</p> <p>determine (5) 83:22;92:21;192:4, 20;219:16</p> <p>determined (6) 110:16;113:21; 156:2;227:4;296:21; 297:3</p> <p>determines (1) 109:10</p> <p>determining (2) 46:9;94:20</p> <p>deterred (1) 225:20</p> <p>deterring (1) 6:18</p> <p>detriment (1) 302:6</p> <p>develop (12) 7:4;30:13;42:4; 126:12;175:1; 208:15;212:19; 241:16;290:11; 297:7;314:4;323:7</p> <p>developed (5) 27:21;69:12,22; 180:22;322:6</p> <p>developers (4) 7:3;14:6;19:15; 20:1</p> <p>developing (17) 101:18;105:13; 108:2;122:15; 174:19;176:9,15; 180:18;197:18; 202:20;203:13; 295:11;301:6,11; 312:7;322:15,18</p> <p>development (43) 15:6;16:2;19:11; 20:16;21:12;22:6; 31:21;38:20;41:12, 20;42:16;44:8,19,20; 45:5,6;53:22;101:5; 127:16;160:18; 169:3;173:19; 179:16;201:18; 236:13;245:15; 254:18;257:19; 263:6;271:10; 279:20;280:4; 283:10;286:12,13; 304:3,18;312:14,16; 320:21;321:18; 322:9;323:4</p> <p>develops (1) 116:19</p> <p>device (2) 220:5,7</p> <p>devices (3) 7:17;295:17; 304:16</p> <p>devoted (1) 312:7</p> <p>diabetes (2) 24:19;95:10</p> <p>diabetic (1) 95:10</p> <p>diagnose (1) 16:12</p> <p>diagnosed (2) 283:19;298:5</p> <p>dialogue (2) 72:21;297:4</p> <p>Dickinson (1) 242:4</p> <p>dictate (1) 59:5</p> <p>dictionary (2) 220:5,13</p> <p>Diego (1) 275:9</p> <p>dietary (2) 92:5;320:22</p> <p>differ (5) 35:8,15;219:22; 220:1;224:21</p> <p>difference (18) 40:13;59:9;65:7; 67:10;72:9;74:7; 111:5,17;118:2,11; 137:7;143:22;147:7; 187:20;189:20; 210:20;219:7;227:1</p>	<p>differences (26) 29:17;34:21;42:3; 55:22;71:6;76:16,20; 97:9;110:18,20; 113:15,16;116:4,15; 117:18;118:6; 138:18;139:6,17; 153:2;198:16; 200:22;215:18; 262:19,20;291:12</p> <p>different (61) 8:7,8;17:5;34:11; 40:17;41:11;48:15; 49:11;51:15,16; 52:12;61:12;64:2; 67:8;72:17;73:2,9, 18;74:11;90:10,11, 14,15;95:8;98:12; 127:10;128:7; 132:10,11,13,13; 139:12,14;140:15; 153:7,11;154:18,19, 20,22,22;162:18; 170:16;174:18; 198:1;201:10,11; 208:12;210:6;211:9; 217:19;219:22,22; 220:11;231:1; 236:11;250:17; 261:12;264:11; 265:21;276:6</p> <p>differential (1) 148:7</p> <p>differentiation (2) 140:18;141:1</p> <p>differentiator (1) 187:2</p> <p>differently (6) 74:12;97:13; 160:10;216:2,6,10</p> <p>difficult (6) 167:22;168:1,17; 201:1;225:19;236:18</p> <p>difficulty (1) 40:21</p> <p>digital (1) 298:20</p> <p>diminish (2) 295:10,21</p> <p>direct (7) 83:14;126:6; 145:12;146:1; 221:16;223:13; 229:17</p> <p>directed (2) 203:10;266:9</p> <p>direction (5) 73:6;137:16; 192:17;209:19;281:4</p> <p>directional (1) 132:8</p> <p>directly (8) 98:6;148:5;152:8;</p>	<p>229:12;248:8,9; 299:20;318:7</p> <p>director (17) 6:9;23:6;32:15,18; 33:1;79:19;91:16; 125:3,6,9;173:16,20; 174:2;256:15; 272:15;324:1,4</p> <p>disagreement (1) 159:4</p> <p>disarm (1) 159:10</p> <p>disclose (7) 97:5,19;118:2; 205:15;285:8;287:4; 315:22</p> <p>disclosed (2) 286:19;292:8</p> <p>disclosing (1) 179:10</p> <p>disclosure (4) 104:22;205:21; 223:17;240:18</p> <p>disclosures (3) 178:18;293:18; 316:1</p> <p>disconnect (1) 247:2</p> <p>discount (5) 143:21;144:16; 150:18;262:22; 276:20</p> <p>discounted (1) 308:14</p> <p>discounting (2) 162:12;245:14</p> <p>discounts (20) 126:18,20;140:8; 142:6;143:1,2,8,18, 19;144:1,15;146:12, 22;148:10;154:10; 276:14;277:7,7; 309:8;327:19</p> <p>discourage (3) 20:21;257:12; 271:3</p> <p>discouraging (2) 6:17;160:18</p> <p>discovering (1) 312:7</p> <p>discretion (1) 252:17</p> <p>discrimination (1) 311:10</p> <p>discuss (16) 6:15;13:1;31:20; 44:3;86:7;100:18; 101:12;103:9,17; 114:7;171:13,22; 212:16;224:8;323:6, 18</p> <p>discussed (12) 13:17;110:1;</p>
--	---	---	---

<p>114:16;155:10; 156:4;160:4,20; 162:1;166:10;207:4; 215:1;292:17 discusses (1) 109:10 discussing (1) 75:6 discussion (11) 35:10;44:5;64:21; 98:8;120:10;132:16; 133:8;135:10; 167:10;206:2;225:9 discussions (3) 196:3;202:10; 323:19 disease (10) 24:20;127:21; 130:22;188:3;189:2; 215:15;283:19; 284:14;294:7;316:17 diseases (9) 16:12,19;24:19,21; 191:9;288:5;293:19; 294:5;308:1 disentangle (1) 51:9 Disincentivize (1) 270:11 disincentivized (1) 271:7 dislike (1) 100:14 dismiss (1) 250:5 disparagement (17) 198:2;205:3;210:7; 213:5,7;214:12; 218:11;219:19; 222:14;225:17,20; 229:4;230:16;232:2; 238:2;240:21;249:14 disparaging (4) 231:12;232:21; 247:22;300:22 disparities (1) 139:4 dispense (2) 140:5;142:17 dispensed (7) 60:21;71:12,13; 128:20;134:9;135:5; 137:13 dispensing (4) 137:7,10,18;139:7 display (1) 94:9 disproportionate (1) 18:13 disregard (1) 301:11 disrupts (1) 215:12</p>	<p>disseminate (1) 175:4 disseminated (5) 75:19;77:12;81:8; 93:18;327:4 disseminating (2) 76:8;93:14 dissemination (2) 118:18;320:21 dissipated (1) 167:1 distinct (1) 224:6 distinction (11) 56:6,11;154:14,15; 223:14,18;224:4; 240:2;251:17;269:9; 270:5 distinguish (1) 219:21 distinguishable (1) 260:18 distinguished (1) 213:12 distinguishing (1) 219:12 distortions (1) 301:10 distribution (2) 30:17;126:5 distributor (2) 81:2,17 distributors (2) 91:11;104:2 distributor's (1) 92:14 district (2) 98:6;186:1 division (5) 31:18;32:19;79:19, 21;257:1 docket (9) 9:19;10:17,19; 120:2;272:9;282:9; 300:4;328:19,22 doctor (5) 176:8;204:4; 212:10;228:15; 284:16 doctor-patient (1) 297:11 doctors (17) 61:1;187:11;188:4; 203:4;211:7;220:9, 13;228:17;233:18; 247:5,9;266:12; 284:3,19,22;285:6; 311:1 doctrinal (1) 219:7 doctrine (1) 223:12 document (2)</p>	<p>43:7;210:18 documents (8) 71:9;83:9;203:8,8, 14;289:22;291:7; 299:13 dollar (4) 74:3;125:22; 126:15;128:16 dollars (12) 18:10;25:1;129:4, 11;130:2;171:3,4; 179:12;185:22; 252:12;258:17; 310:14 Dom (8) 80:4;98:21;100:13, 17;101:1;114:7; 120:11,14 domain (2) 83:2;84:14 dominant (1) 310:8 Dominic (5) 79:12;80:6,9; 101:11;114:9 Dom's (1) 121:9 Done (23) 7:12;21:18;22:13; 24:4,13;54:20;68:16; 141:8;151:7;156:17; 161:10;164:4,4; 174:11;204:10; 221:1;223:21; 225:22;246:8;249:4; 259:10;260:8;275:20 door (1) 259:10 dosage (3) 115:1,4,11 dosing (1) 271:15 dots (1) 60:14 doubt (1) 76:12 down (17) 8:14;19:18,19; 29:4;69:15;70:19; 74:9,12;135:2;174:2; 175:16;211:18; 276:14;285:22; 286:21;307:3;309:18 downstream (1) 183:1 downtown (1) 12:3 Dr (65) 11:5,10,15,20; 13:6;32:9;48:22; 49:20;56:5;58:12; 61:2;65:18;73:20; 124:19;139:22;</p>	<p>141:6;151:9;152:13; 155:10;185:17; 197:15;203:4,7; 209:7;210:4;214:1, 18;218:13;225:14, 18;226:6;227:12,22; 228:13;229:5;238:9; 240:5;241:2;243:1; 245:2,10;246:1,21; 248:2,19;249:17; 250:14;251:5;252:1, 8;253:9,19;254:8; 260:2;263:17; 267:18;283:5,6; 287:7;288:13;299:3, 6;300:9;320:14; 324:3 draft (29) 14:7,13;43:18; 46:2;82:18,20; 100:18;101:12,17,22; 102:6,20;103:8; 105:2;106:19;109:6; 114:8,14;118:14,19; 119:21;120:4,14; 121:13,22;268:10,11; 298:21;325:1 dramatically (3) 245:5,12;286:21 draw (3) 46:18;166:18; 223:17 drawing (1) 126:2 drawn (1) 33:12 draws (1) 56:8 drive (4) 64:15;72:17;74:9, 12 driven (5) 51:14;59:4;144:14; 146:12;269:3 driver (2) 299:6;302:9 drives (3) 29:4;276:13;305:4 driving (1) 306:20 dropped (2) 27:15;68:21 drug (121) 17:11,16;18:20; 26:5,14;27:1;28:7; 30:18;57:8;60:5; 61:22;62:18;63:1,4,6, 9,17,20;75:19;79:8, 14;80:11,14,18,21, 22;81:2,9,11,15,17, 21;82:2,5,6,12;83:15; 84:18;85:6,8,18,21; 86:1,5,22;87:5,6,9,</p>	<p>13,21;88:15,18,21, 22;89:5,10,13,16,17, 18,19,20;90:2,12,22; 91:5,11;92:5,14,16; 94:5;99:6;100:12; 101:5;102:7,13; 104:9;119:6,13,15; 127:11;137:13; 142:15,16,17;148:16, 22;149:1,3,5,8,9,12, 20;150:7,8,13; 186:13;217:9; 225:21;234:1,1; 236:6;265:14; 278:17;280:10; 291:20;296:18; 298:16;308:4,6; 309:4,16,22;310:8, 21,22;312:15; 314:16;317:20;320:3 drugs (60) 18:15,16,18;25:19; 26:1;28:18;33:14; 51:4;62:15;64:12; 65:17;67:6;71:12,13; 77:11,11,14,22; 87:17;90:11;104:2, 15;119:2;122:17; 127:12;130:10,12; 132:21;133:1,6; 137:5;139:20; 140:16;143:11; 147:15;148:1,3,4,8, 11,17;150:10,11,13; 155:20;161:15; 257:15;271:15; 289:15;294:9; 307:21;308:3,9; 309:6;310:3,17; 311:8,12;317:7; 319:4 drug's (4) 81:16;87:3;90:5; 104:8 drugs@FDA (1) 176:18 DTC (1) 83:14 dual (3) 14:19;57:3,12 due (6) 54:13;269:22; 275:19;291:19; 293:1;302:15 Duke (1) 158:18 duplication (1) 198:6 duration (2) 89:12;165:4 during (5) 7:1;45:19;73:10; 89:3;298:9</p>
---	---	---	--	---

<p>DUTTA (2) 256:20,20</p> <p>dynamic (11) 52:18;127:19; 133:11;135:9;153:7; 154:4,12;164:8; 192:10,12,14</p> <p>dynamics (9) 60:11;125:20; 127:10;128:6,11; 133:20;139:12; 286:20;287:8</p>	<p>279:10;291:11</p> <p>educated (3) 204:19,20;207:9</p> <p>educating (2) 169:7;292:10</p> <p>education (39) 21:13;69:21,22; 75:16;78:7;81:5; 97:22;102:17; 161:10;165:17; 169:2;171:19; 172:13;173:19; 174:7,10,13;179:7; 180:19;189:12,13; 194:1;196:5;197:10, 16;204:3,18;205:8; 207:10;209:17; 289:18;291:3; 294:17;299:4,5; 314:1;317:3,16; 318:13</p> <p>educational (11) 69:3,5;72:21; 73:14;175:13;209:9; 267:7;292:20;301:1; 306:18,19</p> <p>educator (1) 178:7</p> <p>educators (1) 183:1</p> <p>effect (17) 13:12;20:9;156:21; 181:8,18,19;182:4,5, 8;188:21;193:3; 228:4,8,22;231:14; 243:4;251:15</p> <p>effective (34) 20:3;24:20;28:19; 29:10;31:6;34:5; 35:17;76:14;89:20; 90:12;97:14,16; 111:11,12;112:8,13; 113:7;114:4;170:17; 182:20;185:2; 206:16;217:7;218:4; 246:17;252:7;270:8; 289:1;290:17; 294:18;314:4; 324:11;325:5,18</p> <p>effectively (2) 327:14,18</p> <p>effectiveness (12) 35:1;38:8;88:17, 21;103:7;107:8; 122:11;198:15; 210:10;290:22; 324:19;325:12</p> <p>effects (7) 152:21;206:18; 232:1;238:22;249:8; 254:5;300:17</p> <p>efficacy (28) 19:21;87:3,9,13;</p>	<p>88:2,7,14,22;104:8; 159:17;176:6; 181:11;182:21; 191:20;199:1,8,9,11, 12;211:11;217:1; 225:3;266:20;276:3; 281:14;295:3,10; 300:18</p> <p>efficiencies (1) 290:10</p> <p>efficiency (5) 19:10,22;45:5; 166:14;313:20</p> <p>efficient (2) 19:14;55:14</p> <p>effort (6) 24:8;102:1;190:9; 211:13,15;321:6</p> <p>efforts (24) 6:15;13:2;14:19; 20:18;21:3,15;24:16; 69:3,5;71:17;75:17; 78:7;85:15;174:10; 176:6;207:3;257:14; 279:14;288:21; 289:20;307:18; 313:14;314:3;327:9</p> <p>egregious (2) 296:9;302:14</p> <p>eight (2) 186:1;266:6</p> <p>Eighth (1) 234:22</p> <p>Eighty-nine (1) 50:10</p> <p>either (18) 38:7;62:15;98:4; 103:7;151:7;164:2,2; 207:3;213:8;228:15, 19;229:12;240:21; 251:21;269:22; 274:20;293:5;302:17</p> <p>elaborate (3) 50:3;51:13;300:1</p> <p>elbow (1) 92:2</p> <p>electric (1) 222:8</p> <p>electronic (5) 9:12,13;188:8; 295:14,17</p> <p>electronically (3) 53:12;189:22; 190:4</p> <p>element (1) 218:19</p> <p>elements (3) 244:7;248:22; 249:3</p> <p>Eleventh (1) 231:22</p> <p>Eli (2) 222:3,4</p>	<p>eliminated (1) 163:21</p> <p>eliminating (1) 290:21</p> <p>Elizabeth (3) 101:9;172:6;206:3</p> <p>else (6) 65:8;73:11;139:21; 242:10;263:9;319:14</p> <p>EMA (1) 210:17</p> <p>email (1) 84:20</p> <p>emerge (1) 318:10</p> <p>emergency (2) 215:13;273:13</p> <p>emerging (2) 70:16;322:16</p> <p>emphasis (1) 233:22</p> <p>emphasize (1) 168:5</p> <p>emphasized (1) 217:4</p> <p>emphasizing (1) 320:6</p> <p>empirical (2) 221:7;254:5</p> <p>empirics (1) 254:2</p> <p>employ (1) 280:16</p> <p>employed (1) 178:20</p> <p>Employees (2) 278:22;288:14</p> <p>employers (1) 280:10</p> <p>employs (1) 84:3</p> <p>empowering (2) 21:7;295:20</p> <p>EMR (1) 66:17</p> <p>enable (1) 312:8</p> <p>enabling (1) 110:5</p> <p>enacted (1) 313:2</p> <p>enacting (2) 315:9,14</p> <p>enactment (1) 314:18</p> <p>encountered (2) 199:5;202:1</p> <p>encourage (15) 10:16,21;79:7; 85:1;122:7,20;164:6; 207:16;208:5; 270:16;282:7; 290:13;314:9;</p>	<p>325:14;328:18</p> <p>encouraged (5) 270:19;271:18; 275:1,14;279:13</p> <p>encourages (2) 118:15;305:1</p> <p>encouraging (4) 78:3;279:21;280:4; 306:10</p> <p>end (15) 9:9;10:12;15:3; 19:16;21:15;164:2; 173:15;176:20; 185:3;187:1;215:6, 13;256:1;272:22; 302:20</p> <p>endeavor (1) 36:4</p> <p>endorse (1) 188:1</p> <p>endorsements (1) 205:7</p> <p>endorsing (1) 210:3</p> <p>endpoint (1) 89:8</p> <p>ends (1) 270:5</p> <p>endure (1) 284:12</p> <p>enduring (1) 288:21</p> <p>Energy (1) 28:3</p> <p>enforcement (18) 25:6;26:22;27:18; 30:8,10;85:17;92:9; 98:1;213:6,8;218:9; 224:9;238:6;240:3; 251:7;252:7,9;309:2</p> <p>enforces (1) 93:22</p> <p>enforcing (1) 251:15</p> <p>engage (2) 82:22;231:10</p> <p>engaged (8) 15:7;160:15;167:5; 177:22;204:5;259:5, 9;278:10</p> <p>engagement (7) 75:17;171:19; 174:22;187:3;196:9; 213:19;294:16</p> <p>engaging (6) 31:13;73:15; 174:19;231:11; 243:5;295:19</p> <p>engine (1) 298:20</p> <p>engineering (1) 220:5</p> <p>enhance (5)</p>
E				
<p>eager (1) 255:3</p> <p>earlier (21) 46:18;54:17;69:8; 116:21;129:20; 160:20;166:18; 193:22;194:17; 195:9;196:8;198:11; 213:4;214:5,11; 218:8;239:19; 246:13;287:7;299:3; 302:8</p> <p>earliest (1) 20:15</p> <p>early (7) 17:6;73:10;136:18, 19;205:6;255:11; 321:18</p> <p>earn (1) 154:2</p> <p>ease (1) 62:6</p> <p>easier (3) 19:15,16;190:16</p> <p>easily (3) 53:11;202:22; 203:22</p> <p>easy (3) 202:19;203:9; 207:8</p> <p>echo (1) 121:9</p> <p>economic (5) 62:6;93:13;164:7; 313:10;318:14</p> <p>economics (6) 59:4;125:4,6; 158:19;256:21;317:4</p> <p>economist (2) 169:11;256:21</p> <p>economists (1) 136:20</p> <p>ecosystem (1) 158:14</p> <p>editorial (1) 173:16</p> <p>educate (5) 164:15;190:9,10;</p>	<p>207:10;209:17; 289:18;291:3; 294:17;299:4,5; 314:1;317:3,16; 318:13</p> <p>educational (11) 69:3,5;72:21; 73:14;175:13;209:9; 267:7;292:20;301:1; 306:18,19</p> <p>educator (1) 178:7</p> <p>educators (1) 183:1</p> <p>effect (17) 13:12;20:9;156:21; 181:8,18,19;182:4,5, 8;188:21;193:3; 228:4,8,22;231:14; 243:4;251:15</p> <p>effective (34) 20:3;24:20;28:19; 29:10;31:6;34:5; 35:17;76:14;89:20; 90:12;97:14,16; 111:11,12;112:8,13; 113:7;114:4;170:17; 182:20;185:2; 206:16;217:7;218:4; 246:17;252:7;270:8; 289:1;290:17; 294:18;314:4; 324:11;325:5,18</p> <p>effectively (2) 327:14,18</p> <p>effectiveness (12) 35:1;38:8;88:17, 21;103:7;107:8; 122:11;198:15; 210:10;290:22; 324:19;325:12</p> <p>effects (7) 152:21;206:18; 232:1;238:22;249:8; 254:5;300:17</p> <p>efficacy (28) 19:21;87:3,9,13;</p>	<p>24:8;102:1;190:9; 211:13,15;321:6</p> <p>efforts (24) 6:15;13:2;14:19; 20:18;21:3,15;24:16; 69:3,5;71:17;75:17; 78:7;85:15;174:10; 176:6;207:3;257:14; 279:14;288:21; 289:20;307:18; 313:14;314:3;327:9</p> <p>egregious (2) 296:9;302:14</p> <p>eight (2) 186:1;266:6</p> <p>Eighth (1) 234:22</p> <p>Eighty-nine (1) 50:10</p> <p>either (18) 38:7;62:15;98:4; 103:7;151:7;164:2,2; 207:3;213:8;228:15, 19;229:12;240:21; 251:21;269:22; 274:20;293:5;302:17</p> <p>elaborate (3) 50:3;51:13;300:1</p> <p>elbow (1) 92:2</p> <p>electric (1) 222:8</p> <p>electronic (5) 9:12,13;188:8; 295:14,17</p> <p>electronically (3) 53:12;189:22; 190:4</p> <p>element (1) 218:19</p> <p>elements (3) 244:7;248:22; 249:3</p> <p>Eleventh (1) 231:22</p> <p>Eli (2) 222:3,4</p>	<p>empirical (2) 221:7;254:5</p> <p>empirics (1) 254:2</p> <p>employ (1) 280:16</p> <p>employed (1) 178:20</p> <p>Employees (2) 278:22;288:14</p> <p>employers (1) 280:10</p> <p>employs (1) 84:3</p> <p>empowering (2) 21:7;295:20</p> <p>EMR (1) 66:17</p> <p>enable (1) 312:8</p> <p>enabling (1) 110:5</p> <p>enacted (1) 313:2</p> <p>enacting (2) 315:9,14</p> <p>enactment (1) 314:18</p> <p>encountered (2) 199:5;202:1</p> <p>encourage (15) 10:16,21;79:7; 85:1;122:7,20;164:6; 207:16;208:5; 270:16;282:7; 290:13;314:9;</p>	<p>284:12</p> <p>288:21</p> <p>28:3</p> <p>25:6;26:22;27:18; 30:8,10;85:17;92:9; 98:1;213:6,8;218:9; 224:9;238:6;240:3; 251:7;252:7,9;309:2</p> <p>93:22</p> <p>251:15</p> <p>82:22;231:10</p> <p>15:7;160:15;167:5; 177:22;204:5;259:5, 9;278:10</p> <p>75:17;171:19; 174:22;187:3;196:9; 213:19;294:16</p> <p>31:13;73:15; 174:19;231:11; 243:5;295:19</p> <p>298:20</p> <p>220:5</p>

<p>15:21;38:15; 230:22;279:3;288:22 enhanced (1) 20:8 enjoins (1) 222:12 enjoy (2) 122:21;276:10 enormous (1) 16:13 enough (10) 56:17;128:4;133:7; 146:22;147:11; 184:19;200:5; 245:21;252:22; 308:22 enrolled (1) 304:2 ensure (33) 15:9;21:19;22:11; 53:21;54:20;75:1; 80:13,17;82:10; 85:21;91:9;98:13,17; 99:11;101:21; 102:12;103:9; 105:15;119:10,16,18; 165:13;176:6; 211:11;270:16; 285:5;286:18; 294:17;313:18; 321:13;324:18; 325:16;327:3 ensures (2) 244:14;313:16 ensuring (7) 15:18;110:2; 257:19;316:17; 322:13;323:12,13 enter (7) 54:13;55:7;153:10; 237:12;245:3; 253:13,13 entered (3) 245:4;308:12; 313:7 entering (6) 27:3,11;134:16,17; 184:3;314:21 Enterprise (1) 125:1 enthusiasm (3) 74:13;275:18; 277:11 enthusiastic (3) 38:13;263:7; 266:21 entire (2) 264:13;294:12 entities (4) 51:22;285:14; 291:14;301:22 entitled (2) 107:2;205:19</p>	<p>entity (1) 307:12 entrant (1) 249:10 entry (28) 26:5;30:3;78:17; 124:11,12;129:16; 135:2;144:20,22; 145:9;146:11,15; 147:5;151:4;155:8; 157:21;158:2,5,10; 161:18,19;229:16; 236:12;237:10; 271:3;280:6;310:8; 316:20 enumerate (1) 235:3 environment (5) 21:19;164:20; 165:21;241:6;318:4 epoetin (1) 262:13 Epogen (1) 305:13 equation (1) 227:9 equilibrium (2) 138:3,7 equipped (1) 250:19 equivalency (1) 217:21 equivalent (1) 77:15 ER (2) 234:10,11 erected (1) 309:20 erects (1) 30:2 erode (1) 21:2 especially (11) 12:2;51:3;52:14; 103:3;140:16;180:6; 204:13;228:20; 249:9;291:5;317:8 essence (1) 159:14 essential (3) 290:1;307:21; 325:11 essentially (7) 33:21;36:5,6; 37:21;97:2;129:9; 264:10 establish (6) 95:1;219:14; 220:17;245:19; 257:14;296:22 established (7) 76:19;168:10; 220:9;237:4,6;</p>	<p>303:22;322:7 establishing (2) 208:20;295:14 esteemed (1) 288:14 estimate (5) 126:20;131:7; 143:13,14;144:1 estimated (3) 129:3;143:21; 308:10 estimates (4) 18:7,17;132:8; 150:21 et (3) 59:2;66:17;188:3 etanercept (1) 135:17 ethical (1) 296:12 EU (3) 72:15;276:6,9 Europe (16) 68:8;72:14;73:2; 170:3,19;187:12; 189:7;195:11;263:4; 266:15,16;276:11; 292:7;304:1;308:12; 317:1 European (8) 71:2;72:12,13; 169:19;187:10; 261:10,19;290:15 Eva (13) 6:3,8;11:20;32:4, 22;33:3,6;39:3;44:6; 46:17;69:20;256:13, 14 evaluate (6) 36:14;105:14; 110:22;210:22; 269:6;290:19 evaluated (2) 116:11;240:20 evaluating (4) 37:2;122:13;229:4; 290:13 Evaluation (5) 102:10;117:4; 121:13;289:10; 325:21 even (34) 43:10;49:13;53:14; 74:6,7,10;76:22; 94:18;96:6;159:20; 189:3;192:20,21; 194:20;208:3;210:2; 215:15;217:1;225:4; 229:22;233:6; 234:17;237:7; 241:11;262:7; 265:20;291:7,9; 301:20;305:18;</p>	<p>310:9,12;317:9; 326:12 event (3) 7:22;24:13;206:8 events (5) 24:14;84:7;177:5, 20;295:19 ever-increasing (1) 302:4 everybody (4) 66:14;124:21; 207:8;242:10 everybody's (1) 228:5 everyday (1) 204:5 everyone (26) 14:3;23:12;39:4; 63:3;64:11;80:8; 99:16;156:14; 172:12;181:17; 183:19;185:1,11; 191:5;201:5;205:19; 206:4;212:11,17; 213:2;256:22;257:4; 264:16;266:13; 319:14;328:9 everyone's (1) 24:16 evidence (23) 9:2;37:1,22;89:11; 94:21;136:14; 178:17;180:12,13,15; 182:20;187:10,11; 210:12;221:7,15; 222:13;228:16; 269:2,9,12;271:11; 309:4 evidence-based (2) 178:7;182:7 evolution (1) 315:15 evolve (5) 138:5;163:15; 196:2;271:21;315:14 evolved (1) 171:5 evolves (1) 322:14 evolving (2) 129:1;138:12 exacerbate (1) 215:14 exact (1) 202:5 exactly (3) 24:14;53:4;152:10 exaggerate (1) 88:20 examine (2) 42:12;56:18 examining (1) 109:8</p>	<p>example (48) 13:20;25:17;30:15; 35:11,14;50:9;54:9; 56:22;76:2,11;77:2, 13;84:6;85:19;87:6; 88:4,6,19;90:1,13; 93:15;95:7;97:8; 106:13;107:17; 111:15;112:4,21; 114:21;116:7,9; 117:10;214:15; 217:1,10;220:2; 227:3;230:4;235:1; 239:6;262:13; 271:16;288:1; 290:15;299:16; 306:9;321:13;326:4 examples (10) 16:3;76:6;114:8, 15,17;121:12;199:4; 214:12,19;306:8 exceedingly (1) 184:11 Excellence (1) 288:17 excellent (1) 212:9 except (1) 149:18 exceptions (1) 221:13 exchange (1) 327:19 excited (1) 38:14 exciting (4) 6:12;39:1,9;40:4 exclude (1) 55:11 excluded (1) 270:20 exclusion (1) 327:14 exclusionary (5) 42:17;53:6;229:10; 230:12;232:1 exclusive (2) 237:3;270:1 exclusivity (7) 78:12;127:11; 129:17;158:15,18,20; 165:2 excuse (1) 40:10 executing (1) 24:12 executive (5) 11:7;32:18;125:9; 174:2;272:15 exemption (1) 184:5 exercise (1) 205:1</p>
--	--	--	--	---

exerting (1) 150:16	190:5;254:12	214:21	factually (2) 198:9,21	241:17;251:12
exhaustive (1) 86:8	experiment (1) 266:1	extremely (7) 202:11;236:13,17; 237:16;275:2;294:6; 308:5	faculty (2) 124:20;260:5	familiar (10) 26:2;43:1,1; 185:19;191:6;253:4; 261:18;262:2,2; 297:12
exist (7) 55:3;73:2;121:4; 161:13;165:18; 171:1;326:1	expert (7) 94:22;195:5; 213:13,19,21;219:21; 322:10	extrinsic (1) 94:21	fail (2) 64:4;311:4	families (1) 322:19
existed (1) 72:14	expertise (5) 79:22;188:6; 224:13;238:14;289:9	F	fail-first (3) 310:20;311:3,9	family (1) 173:22
existence (1) 43:10	experts (8) 31:20;101:6; 172:20;173:10; 176:21;214:7;322:8, 8	fabulous (1) 181:1	fails (1) 97:5	famously (1) 247:1
existing (3) 60:10;302:17; 309:21	expire (2) 129:16,17	face (6) 40:16;95:2;133:16; 163:1;164:22;173:8	failure (10) 94:8;97:19;136:15; 220:4,6,6,10,10; 317:2,4	far (12) 12:3;28:13;56:12; 69:22;72:4;170:21; 227:14;233:5;263:9; 275:3,16;301:16
exists (3) 111:6;248:14; 302:15	explain (3) 49:18;174:4; 206:14	faced (5) 141:11,21;162:22; 305:10;308:15	fair (13) 7:11;20:13;21:22; 22:7;36:2;80:19; 98:18;102:14; 147:10;161:5; 243:11;268:6;303:1	fashion (1) 13:21
expand (5) 233:8;274:14; 286:12;287:5;305:6	explained (2) 214:22;287:7	facilitate (9) 156:9;273:4;279:6; 280:21;295:13; 314:20,21;321:7; 323:19	fairly (1) 219:3	fast (1) 195:2
expanded (1) 304:20	explanation (3) 224:12;311:10; 317:16	facilitated (1) 99:15	faith (1) 297:17	faster (2) 89:13;268:21
expect (7) 115:6;116:5,8; 117:9;225:2;249:1; 276:16	explicit (3) 43:5;219:15,16	facilitates (1) 313:16	FALB (12) 124:3,16;125:11; 136:4;139:16;141:3; 151:2;155:7;156:10; 167:10,11;171:8	fastest (1) 308:6
expectancy (2) 274:9,11	exposed (4) 12:13;151:16,19; 152:3	facilitating (3) 38:18;297:4;321:4	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	favor (5) 148:17;160:16; 209:16;281:4;317:22
expectation (4) 78:8,13;308:7; 322:3	exposure (1) 194:22	facing (1) 293:3	fallen (4) 129:8;130:5; 230:13;286:4	favorable (2) 27:8;318:21
expectations (1) 321:16	express (6) 94:13,14,17,17; 198:17;288:19	fact (20) 16:19;27:17;46:14; 76:4,17;86:18;97:6; 164:5;165:14; 175:10;200:21; 201:9,12;204:11; 207:22;213:18; 241:20;246:8;248:7; 292:5	falls (1) 92:11	favorite (1) 220:2
expected (4) 34:12;35:16;38:5; 268:12	expressed (3) 8:9;198:18;281:7	fact-finder (1) 227:7	false (69) 6:17;13:22;29:19; 30:8;76:22;77:1,13; 79:4;81:22;84:18; 86:6;88:19;89:21; 90:21;91:4;94:4,6; 97:3,18;99:5;102:1; 103:4;110:8;111:13; 119:19;218:14; 219:7,8,11,14,17; 220:16,19;222:11; 223:7,9;226:18; 230:21;231:2,5; 232:6,15,17;233:4,7; 235:4,6;241:4,10,12, 13,15;242:4,8,12; 243:5,10,18;244:1,4, 7,10,14,15;252:4; 253:20;254:3,5; 257:12	FD&C (2) 81:18;104:5
expecting (2) 14:13;68:21	extend (2) 30:11;167:8	factor (8) 57:1;61:15,20; 195:15;233:7,14; 234:2,13	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FDA (174) 6:15;8:6,9;11;11:5, 6,10,10,13;12:16; 15:4;21:6;22:1;24:1, 6,9,10;31:3,9;38:17; 39:8;40:22;42:2,7; 43:6;44:12;46:3,8; 48:2;53:10;69:20,21; 70:3,14,18;74:22; 75:5,15;79:6;80:12; 81:3,20;82:4,8;83:3; 84:9,19;85:16;86:3,8, 14,91;3,8;94:11; 98:17;99:1,10;100:2; 101:17;102:15,19; 103:21;106:5;107:3; 108:5;109:5,10; 110:3,8,22;112:22; 113:20;115:6;116:4, 8,11;117:8,11; 118:14,15,20;119:1, 4;120:21;121:20; 127:13;161:10; 163:3;169:6;174:11, 14;175:1;177:6; 195:4;196:14;202:5, 20;203:8,8,14,22; 205:1;206:7,12; 207:17;209:11;
expenditures (1) 289:12	extended (2) 68:9;171:16	facto (1) 270:3	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FD&C (2) 81:18;104:5
expense (2) 54:7;290:11	extending (2) 161:4,21	factoring (1) 270:3	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FD&C (2) 81:18;104:5
expenses (2) 185:22;235:12	extends (2) 27:17;92:18	factor (8) 57:1;61:15,20; 195:15;233:7,14; 234:2,13	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FD&C (2) 81:18;104:5
expensive (10) 24:22;29:3;55:15; 139:19;229:22; 245:14;308:5;311:5, 8;312:15	extensive (2) 14:18;168:9	factors (17) 6:22;51:15;58:9; 59:19;88:3;92:21; 104:19;145:10; 146:4,18;233:3; 234:17,19;235:11; 262:16,18;263:2	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FD&C (2) 81:18;104:5
experience (23) 27:16;70:22;71:2, 4;72:12;117:14; 163:19;187:18; 200:3;210:14,17; 212:10;261:20; 267:13;272:6;278:7; 283:10;285:22; 292:16;300:11; 304:22;305:7;314:1	extensively (1) 64:11	facts (7) 17:18;104:9;122:1; 198:10;224:3,16,19	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FD&C (2) 81:18;104:5
experienced (2) 35:18;300:17	extent (19) 36:18,20;132:12; 133:8,10,12;152:9; 157:1;158:8;165:9; 169:12;170:17; 192:13,19;195:14; 212:2;245:3;282:8; 314:17	fact-specific (2) 104:18;111:8	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FD&C (2) 81:18;104:5
experiences (2)	external (1) 186:6	factual (3) 198:12;219:17; 224:10	fall (6) 92:1;160:6;191:18; 245:5,12;268:8	FD&C (2) 81:18;104:5

210:6;211:13;213:5; 216:5,11;217:15,15; 218:9;235:18,19; 236:1;238:12;251:9; 254:9,11;258:22; 259:8;260:16; 263:10;266:18; 267:7;273:1,5; 275:20;276:1;279:2, 5;280:13,14,22; 281:3,14;284:8; 285:10,13;286:15; 287:17;288:15; 289:19;290:13,19; 291:2,5,15;292:11; 295:7;298:7,18; 299:10;302:12; 303:20;304:19; 312:20;314:1,7,15; 318:12;320:6;321:3; 322:12;323:17; 324:17,22;325:14,21; 326:4;327:22;328:8, 15	81:17;82:7;120:2; 125:4;143:20;172:8; 213:4;214:4;247:1; 257:2;278:21;297:6; 316:4;325:9;328:22	168:20 figure (1) 248:6 figured (3) 185:11;250:2,9 figures (1) 186:7 figuring (1) 224:22 file (1) 98:6 filed (4) 43:2;50:10;216:4; 324:16 filgrastim (3) 61:16;144:10; 147:2 filing (1) 268:18 fill (1) 161:11 film (1) 9:15 final (6) 37:19;253:18; 279:8,15;299:13; 328:5 finalize (1) 268:14 finalized (1) 295:1 finalizes (1) 280:1 finally (19) 8:15;43:14;93:13; 145:19;149:4; 159:13;162:18; 165:17;205:13; 211:5;217:8;234:7, 20;237:4;265:11; 266:13;283:20; 315:5;327:7 financial (11) 58:7;65:11;78:16; 140:3;141:14,17; 180:2;268:16; 313:19;319:11;320:2 financing (3) 235:7,12,14 find (8) 91:12;138:14,16; 184:19;185:2; 186:18;221:18; 222:17 finding (5) 107:8;113:20; 183:9;283:20;315:12 findings (4) 26:1;224:11;225:2, 3 finds (2) 222:10;227:7 fine (3)	185:9;205:19; 241:11 finger (1) 185:7 finishes (1) 255:11 finite (1) 57:13 firm (10) 107:10,15;108:1; 114:22;115:12; 116:16,18;117:1,6; 143:7 firmly (1) 179:22 firms (22) 84:9;101:18;103:1; 105:2,7,14;108:11; 109:19;110:13,22; 118:14,15,21;119:2, 8,16;121:17;122:2,7, 13,15;298:19 First (67) 7:2,16;27:18; 30:16;31:19;32:7; 44:7;50:3;54:10; 61:3;64:4;76:18; 86:21;87:19;97:22; 114:21;124:15; 136:9;138:1;141:9, 19;157:4;160:5; 167:17;178:2,9; 180:11;181:1;184:3; 185:10;190:8,16; 191:11;193:9;198:3, 4;209:14;211:22; 213:16;214:20; 215:19;223:5; 224:14;226:21; 227:5,7;229:11; 230:14,19;233:3; 234:13;235:12; 242:7;257:5;260:9; 264:8;269:14; 274:16;283:12; 284:8;289:19; 297:14;303:21; 305:20;311:9; 314:13;321:12 fit (3) 70:7;75:12;194:13 fits (2) 39:6;64:22 five (7) 44:9;62:1;63:22; 64:10;90:20;155:6; 268:9 five-year (1) 39:17 fix (3) 231:13;238:4; 298:19 fixed-cost (1)	154:2 flare (2) 191:20;215:14 flexibility (5) 42:11;46:4;98:3; 235:11;321:20 flexible (1) 42:9 Flip (2) 66:18;76:6 floating (1) 193:10 flow (3) 65:8;126:4;202:4 flyer (1) 89:6 focus (13) 12:22;14:19;20:6; 24:3;34:16;41:9; 56:8;60:6;159:11; 193:13;260:17; 293:4;298:19 focused (8) 70:15;101:4; 103:15;106:20; 195:18;196:18; 204:22;289:9 focuses (2) 213:17;238:22 focusing (2) 99:20;118:6 folks (12) 10:21;12:13;45:14; 67:20;153:15; 184:14;186:3; 209:18;245:22; 246:16;255:3;328:15 follow (10) 85:2;118:18; 120:12;149:3; 180:12;188:11; 226:21;244:19; 282:10;296:13 followed (5) 106:7;131:19; 132:4;231:21;234:21 Following (7) 26:15;58:13; 139:16;177:13; 231:19;237:17; 314:12 follow-on (3) 28:6;78:15,17 follow-up (1) 64:18 font (3) 88:4,7,10 Food (8) 81:9,17,21;85:6,18, 21;94:5;119:13 Foods (2) 222:3;320:22 footnote (1)
FDA/FTC (1) 6:7 FDA-administered (1) 84:5 FDA-approved (12) 107:4,6;108:6,18; 109:2,9,12,18; 116:17;117:5; 119:18;206:15 FDA-FTC (4) 69:1;110:1;180:22; 324:6 FDA-regulated (8) 101:19;103:10,20; 104:14;110:10; 119:11;121:5;122:16 FDA's (36) 9:19;13:1;39:17; 79:13;81:14;83:8,17; 85:20;86:17;92:11; 100:18;107:7;109:3, 7;110:15;119:13; 125:6;172:13; 216:12;217:5; 224:10,13;260:13; 279:13;281:13; 286:13;290:4;293:8; 296:6;303:15;304:2; 306:16;307:18; 313:14,21;321:5 FDCA (2) 81:18;82:2 fear (1) 269:13 February (1) 101:13 Federal (21) 10:17;11:14;12:6; 24:1;27:9;31:19;	feedback (3) 82:19;118:16; 121:10 fee-for-service (5) 131:20;132:4; 148:21;149:2;154:20 feel (7) 23:3;179:19; 193:12;200:11; 260:20;262:3;318:8 feeling (1) 38:22 feelings (1) 264:22 fees (2) 239:3;301:13 Feldman (3) 263:15,17,18 fellow (3) 124:22;177:8; 256:6 felt (2) 190:15;264:14 FEMALE (1) 288:8 few (26) 7:15;11:9;17:18; 23:21;51:22;70:15, 15;94:18;120:12; 125:16;140:2;143:6; 145:8,17;156:18; 160:14;163:13; 198:18;204:3;230:9; 237:14;263:10; 268:13;275:8;294:8; 310:11 fewer (5) 35:13;107:18; 112:5,10;308:2 fictional (2) 114:18,19 field (7) 14:4;16:14;22:7; 31:20;99:14;285:19; 304:22 fields (1) 214:7 fierce (1) 273:19 fifth (5) 191:16;211:5; 230:19;234:3;242:2 fig (1) 251:11 fight (3) 184:20;252:14; 259:5 fighting (1)	figure (1) 248:6 figured (3) 185:11;250:2,9 figures (1) 186:7 figuring (1) 224:22 file (1) 98:6 filed (4) 43:2;50:10;216:4; 324:16 filgrastim (3) 61:16;144:10; 147:2 filing (1) 268:18 fill (1) 161:11 film (1) 9:15 final (6) 37:19;253:18; 279:8,15;299:13; 328:5 finalize (1) 268:14 finalized (1) 295:1 finalizes (1) 280:1 finally (19) 8:15;43:14;93:13; 145:19;149:4; 159:13;162:18; 165:17;205:13; 211:5;217:8;234:7, 20;237:4;265:11; 266:13;283:20; 315:5;327:7 financial (11) 58:7;65:11;78:16; 140:3;141:14,17; 180:2;268:16; 313:19;319:11;320:2 financing (3) 235:7,12,14 find (8) 91:12;138:14,16; 184:19;185:2; 186:18;221:18; 222:17 finding (5) 107:8;113:20; 183:9;283:20;315:12 findings (4) 26:1;224:11;225:2, 3 finds (2) 222:10;227:7 fine (3)	finishes (1) 255:11 finite (1) 57:13 firm (10) 107:10,15;108:1; 114:22;115:12; 116:16,18;117:1,6; 143:7 firmly (1) 179:22 firms (22) 84:9;101:18;103:1; 105:2,7,14;108:11; 109:19;110:13,22; 118:14,15,21;119:2, 8,16;121:17;122:2,7, 13,15;298:19 First (67) 7:2,16;27:18; 30:16;31:19;32:7; 44:7;50:3;54:10; 61:3;64:4;76:18; 86:21;87:19;97:22; 114:21;124:15; 136:9;138:1;141:9, 19;157:4;160:5; 167:17;178:2,9; 180:11;181:1;184:3; 185:10;190:8,16; 191:11;193:9;198:3, 4;209:14;211:22; 213:16;214:20; 215:19;223:5; 224:14;226:21; 227:5,7;229:11; 230:14,19;233:3; 234:13;235:12; 242:7;257:5;260:9; 264:8;269:14; 274:16;283:12; 284:8;289:19; 297:14;303:21; 305:20;311:9; 314:13;321:12 fit (3) 70:7;75:12;194:13 fits (2) 39:6;64:22 five (7) 44:9;62:1;63:22; 64:10;90:20;155:6; 268:9 five-year (1) 39:17 fix (3) 231:13;238:4; 298:19 fixed-cost (1)	flare (2) 191:20;215:14 flexibility (5) 42:11;46:4;98:3; 235:11;321:20 flexible (1) 42:9 Flip (2) 66:18;76:6 floating (1) 193:10 flow (3) 65:8;126:4;202:4 flyer (1) 89:6 focus (13) 12:22;14:19;20:6; 24:3;34:16;41:9; 56:8;60:6;159:11; 193:13;260:17; 293:4;298:19 focused (8) 70:15;101:4; 103:15;106:20; 195:18;196:18; 204:22;289:9 focuses (2) 213:17;238:22 focusing (2) 99:20;118:6 folks (12) 10:21;12:13;45:14; 67:20;153:15; 184:14;186:3; 209:18;245:22; 246:16;255:3;328:15 follow (10) 85:2;118:18; 120:12;149:3; 180:12;188:11; 226:21;244:19; 282:10;296:13 followed (5) 106:7;131:19; 132:4;231:21;234:21 Following (7) 26:15;58:13; 139:16;177:13; 231:19;237:17; 314:12 follow-on (3) 28:6;78:15,17 follow-up (1) 64:18 font (3) 88:4,7,10 Food (8) 81:9,17,21;85:6,18, 21;94:5;119:13 Foods (2) 222:3;320:22 footnote (1)

<p>95:15 forced (2) 310:21;319:10 foreclose (1) 311:15 foremost (3) 274:17;297:15; 321:12 Forget (1) 66:5 forgive (2) 64:19;253:3 forgot (1) 152:13 form (5) 115:1,4,11;119:2; 185:1 format (1) 88:12 former (2) 24:6;32:11 forms (4) 52:12;79:1;126:21; 129:17 formularies (4) 265:13;305:18; 309:4;318:22 formulary (17) 42:20;43:14;49:9; 57:10;142:22;186:8; 265:15;266:3;270:1; 285:12,14;301:16,18; 302:21;309:22; 310:2,16 forth (4) 38:9;180:9;265:18; 285:1 forthcoming (3) 231:6,8;240:19 Fortune (1) 278:19 Forum (14) 174:8;197:17; 202:10;203:21; 205:6;211:16;257:6, 10,10,16,19;258:16; 259:19;288:20 forums (1) 235:2 forward (12) 14:4;31:11;44:3; 48:2;119:22;121:2, 10;133:13;135:11; 177:8;246:15;279:22 foster (5) 53:22;296:6;314:9; 321:6;322:1 fostering (4) 25:12;268:22; 314:2;321:10 Fouad (2) 320:13,15 found (15)</p>	<p>37:21;113:13; 143:6;187:13,20; 189:8,20;191:13; 192:9;204:20;214:9; 220:12;227:11; 261:17;292:4 foundation (13) 36:12;173:17; 175:22;183:3;191:6; 193:6;195:17; 204:14,15;208:18; 315:20;316:2,11 foundational (2) 175:20;291:4 foundations (2) 193:6;316:5 founder (3) 263:21;298:15; 307:11 founding (2) 272:19;273:11 four (10) 44:9;142:3;148:20; 199:5;210:5;214:20; 278:7;283:15;284:8; 304:19 fourth (4) 89:15;134:4; 233:21;285:15 frame (4) 57:20;125:17; 268:17;326:8 framework (5) 33:20;229:2,3; 232:13;238:6 frameworks (2) 98:12,13 framing (2) 198:12;202:14 France (1) 261:11 Frank (1) 213:15 frankly (3) 130:11;131:5; 132:8 free (7) 13:4;20:7,13,14; 163:11;180:18; 310:11 frequent (2) 269:2;271:15 frequently (5) 48:12;81:20; 267:10;287:9,12 friction (1) 156:7 frictions (1) 166:8 frighten (1) 76:8 frivolous (1) 271:5</p>	<p>front (3) 29:13;127:11; 161:9 fronts (1) 14:20 FTC (89) 8:6;11:10;15:8; 19:4;20:6;21:7,14; 22:10,12,15,17,19, 22;23:14;24:10,14; 25:7,13,15,17,20; 26:9,12,16,19;27:6, 18,20;28:3,5;29:14; 30:7,11,15,18;31:3,8; 43:6;45:7;54:19; 74:22;79:6;93:22,22; 94:9;97:2,20;98:17; 99:1,10,22;177:6; 198:10;205:1;206:9; 207:16;213:6;218:9; 219:5;236:2;238:13; 240:12,16;251:1,2,4, 10;252:7;254:9,11; 256:21;259:2,8; 263:11;279:2; 280:13;284:8; 286:15;288:15; 302:12;307:17; 311:13;313:10; 314:7;320:6;323:17; 327:22;328:8,15 FTC's (17) 6:15;11:15;13:1; 25:4;27:16;30:10; 31:9;79:20;91:17; 92:17;94:21;252:16; 280:4;293:8;303:15; 306:16;321:5 fulfill (2) 21:20;252:20 full (5) 28:15;100:4; 205:21;255:15; 317:19 full-time (1) 178:20 fully (9) 75:9;138:1;146:19; 199:9,19;204:7; 267:20;307:3;325:20 fund (1) 29:8 fundamental (2) 241:2;291:12 funding (3) 152:17;179:10; 205:16 fur (1) 222:8 further (18) 20:12;32:6;62:20; 80:4;144:18;149:21; 151:5;167:8;271:21;</p>	<p>280:15,21;292:13; 293:6;314:10;326:1, 12,18;327:17 Furthermore (3) 269:8;321:8,22 future (8) 38:20;164:14; 207:3;259:16; 275:17;298:4; 303:11;327:13</p> <p style="text-align: center;">G</p> <p>gain (2) 27:2;267:13 gained (2) 269:18;276:22 gaining (2) 202:13;306:4 gains (1) 166:14 gainsharing (2) 68:7;72:20 gainsmanship (1) 78:19 gambit (1) 94:16 game (3) 65:11;204:14; 250:18 games (3) 236:7;254:15,17 gaming (2) 11:12;280:14 gap (1) 161:14 gaps (5) 161:12,12;165:18; 166:13;292:4 gastroenterologic (1) 57:7 gastroenterologists (1) 204:21 Gastroenterology (2) 209:13;261:14 gather (3) 126:2,6,8 gathering (1) 136:21 GCCA (1) 272:15 Genentech (1) 216:10 general (18) 9:3;94:10;96:9; 103:19;109:12; 112:7;114:16;119:5; 122:1;146:8;192:11; 198:22;202:1; 207:20;219:19; 224:13;271:13;299:9 generally (15) 29:14;36:22;60:18;</p>	<p>81:3;102:15;107:20; 108:6;110:1;113:22; 126:15;153:9;154:9; 223:7;229:22;265:2 generate (3) 37:3;60:4;73:7 generating (2) 36:7;306:2 generation (2) 36:16;38:2 generic (34) 17:11,19;18:8; 20:11;26:1,3,5,6,14; 27:1;28:18;33:13; 70:22;71:4;77:11,19, 21;128:17,20;134:7, 8;139:1;140:6;153:5; 161:15;182:17; 245:4,10,11;268:19; 312:15;317:6; 318:15;320:3 generic-like (1) 318:7 generics (30) 17:12,14,16,22; 25:19;30:13;32:20; 71:6,11,12,17;72:7; 73:10;74:5;77:13; 133:20;134:2; 136:17;139:2,4; 140:4,9,12,22; 153:10;169:4;186:6; 245:18;311:7;320:5 genomics (1) 323:15 gentlemen (1) 23:8 Germany (1) 261:11 get-go (1) 266:6 gets (7) 66:5;130:11; 143:17;159:7;187:3; 192:2;317:17 GHLF (4) 316:12,13,16; 318:12 GI (3) 57:6;188:4;209:15 Gilead (1) 250:5 given (16) 28:22;38:6;143:15; 162:11,16;177:4; 179:12;215:16; 222:6;228:9,20; 245:14;262:22; 276:13;291:17; 326:11 gives (3) 74:9;98:3;240:15 giving (3)</p>
--	---	---	--	--

<p>153:10;250:1; 270:6 glad (1) 216:16 glamorous (1) 8:12 glargine (3) 149:4,9,15 glasses (1) 71:10 global (12) 169:18;170:8; 257:8;267:19; 272:12;273:9;303:5, 8;315:19;316:2,11; 320:15 globally (2) 269:4;323:13 gloss (1) 94:10 goal (13) 15:20;19:2;33:7; 83:17;103:8;197:19; 267:21;273:7; 302:13;303:15; 306:16;322:22; 324:13 goals (6) 13:17;74:14;99:9; 284:5;326:8,9 goes (9) 19:17,19;24:14; 28:14;71:18;135:2,6; 255:22;276:15 gold (2) 19:20;281:13 gold-standard (1) 184:11 Good (53) 6:4;11:20;22:4; 23:12;31:16;38:22; 39:4;44:3;65:19; 74:21;77:20;80:8; 91:19;94:12;100:9; 101:11;125:2,8; 130:15;132:9; 136:21;137:4; 151:11,13,22;157:9, 12,20;158:10;159:21, 22,22;160:22; 167:18;177:5; 186:18;189:11; 199:13;200:18; 224:22;226:4; 236:19;241:11; 253:21;257:7; 272:14;278:5;283:5; 293:21;303:7;307:9; 316:9;320:14 goodness (1) 176:4 Google (5) 203:4;299:3,6,12,</p>	<p>16 Gottlieb (3) 13:6;24:7;235:20 governed (1) 285:12 government (16) 12:17;13:20;79:1, 6;178:12;213:9; 223:13;240:12; 251:20;252:2,10; 253:2;254:16;316:4; 317:22;322:12 governments (1) 207:13 grab (1) 239:7 Grabowski (1) 158:19 gradual (1) 129:14 graduate (1) 23:7 grant (1) 152:16 grants (1) 316:2 graphical (1) 90:18 graphics (1) 88:8 grasping (1) 253:21 grateful (3) 24:16;258:22; 259:2 gratifying (1) 302:12 GRAY (11) 100:9,10;120:10, 11;121:9,12;122:18; 256:17,17;328:6,7 great (28) 11:4;13:12;19:4; 22:16;36:4;39:3; 53:3;71:22;98:3; 114:10;137:1,16; 161:11;168:15,16; 169:4;173:3;177:11, 12;204:12;209:6; 218:13;221:17; 228:11;252:22; 253:19;265:22; 275:18 greater (6) 39:22;58:3;219:10; 279:6;296:1;310:10 greatest (1) 167:13 greatly (3) 301:13;320:12; 328:12 green (4) 134:8,21;135:12;</p>	<p>191:3 GREENBLATT (8) 288:6,7,11;293:15, 16;315:18,21;316:10 Greenspan (4) 283:3,5,6;287:7 Gregory (2) 300:7,10 ground (1) 181:10 groundbreaking (1) 15:6 group (11) 62:11;101:4;141:9; 173:21;197:18; 208:20;211:6; 228:19;264:13,20; 317:22 groups (14) 29:8;137:4;174:6; 194:8;202:7,9; 204:12;205:14; 206:22;211:15; 219:22;264:2; 307:14;318:12 grow (3) 17:2,3;130:10 growing (5) 25:2;29:22;127:8; 277:21;308:6 growth (10) 57:1;61:14,20; 127:19;129:9,21; 130:6,7;289:14; 320:3 guarantee (1) 295:12 guess (5) 45:2;64:7;73:20; 74:5;238:3 guessing (1) 223:21 guidance (75) 14:7,13;36:3; 37:19;42:9,10;43:7; 44:13,19;45:9;46:3, 6;47:22;83:3,5,6,9; 100:18;101:4,12,17, 22;102:6,20;103:8, 13,16;105:2;106:19; 107:2;109:3,6,7,20; 114:8,14;116:20; 119:10,21;120:4,4, 14,17,19;121:13,22; 164:17;167:3; 216:13;217:5,15; 251:9,10;268:9,10, 11,14;279:8,15; 280:2;282:6;285:13; 289:22;293:5;295:2; 298:18,21;299:13,14, 17;300:2;324:17; 325:2;326:19</p>	<p>guide (2) 192:16;255:19 guy (2) 253:12;282:16</p> <p style="text-align: center;">H</p> <p>Ha! (1) 41:15 Hahn (11) 11:5,5,10,15,19,20; 23:13,17;24:8;39:21; 235:19 half (4) 147:4;212:15; 275:22;286:6 hall (1) 8:18 hallway (1) 8:14 hand (2) 212:11;238:3 handle (1) 318:13 happen (8) 24:11;52:14;53:1; 135:22;215:8; 273:16;276:17;298:6 happened (8) 62:2,3;77:19; 141:10;142:5; 190:14;214:7;265:21 happening (5) 126:11;128:9; 133:19;164:11;276:1 happens (12) 12:12;34:10;51:6; 53:21;127:11; 150:18,20;161:22; 188:14;207:22; 220:6;242:3 happy (4) 36:3;141:20; 175:19;323:19 hard (14) 42:8;51:8;71:20; 145:13;168:1,20; 226:17;234:8; 235:13;237:11,16; 239:22;240:6;246:14 harder (2) 237:8;241:6 hardware (1) 213:21 harm (13) 219:1,2;230:17; 242:13;243:22; 244:6;245:20,20; 246:19;249:8,10,11; 252:22 harmed (5) 242:5,10;246:9,10; 296:16</p>	<p>harmful (1) 77:6 harmonized (1) 273:7 harms (4) 220:10;241:5,13; 254:7 harped (1) 74:6 Harvard (2) 23:7;213:16 Hatch-Waxman (4) 26:7;27:2;28:4; 77:9 hate (2) 69:19;91:19 HCP (3) 193:15,19;196:9 head (3) 8:2;267:19;274:17 headings (1) 88:10 headlines (1) 95:14 headroom (2) 74:1,14 heads-I-win/tails-you-lose (1) 242:1 head-to-head (1) 305:4 Health (56) 34:1;37:7;49:11; 52:6;57:14;58:1; 74:11;76:1;77:7; 80:17;81:13;83:19; 85:9;93:8;98:18; 99:2,7;101:3;102:4, 12;104:13;110:5,12; 142:19,22;143:7,14; 172:8;173:17,22; 178:7,11;180:2; 183:2;184:16;186:7; 233:16;267:3,22; 268:4;273:6,6;276:4; 277:13;278:19,20,22, 22;289:7,10;302:8; 311:2,11;317:3; 320:21;321:4 healthcare (56) 7:6;15:9;18:9; 20:22;21:3,5;22:20; 31:17;37:9;44:14; 75:10,11;76:9,13; 77:20;84:12;96:15; 99:11;108:13;110:6; 162:17;172:2;174:5, 17;175:2,9;176:10, 16;184:17;192:11; 202:5,11;203:11; 206:14,21;257:1; 258:5,8;259:15; 263:3;267:8;275:4,7; 284:4;288:18;</p>
---	---	---	---	--

<p>294:20;299:4; 303:12;304:7;307:5; 317:9,17;319:7; 324:12,14;327:5 healthier (1) 312:9 health-related (1) 80:2 healthy (4) 284:1;315:19; 316:2,11 hear (14) 33:12;45:14,19; 48:7;51:17;172:22; 173:2,6;177:10,11; 179:2;215:22; 235:18;302:12 heard (21) 44:17;48:13;52:11; 78:1;94:15;98:11; 100:13;108:11; 127:7;128:2;182:12; 200:3;208:6;214:18, 21;216:19;237:4; 250:20;284:17; 299:3;316:18 hearing (6) 45:18;177:8;249:8; 256:7;291:8;323:16 heart (3) 19:2;137:2;276:4 heated (1) 170:4 held (1) 273:5 Hello (7) 125:5;293:15; 298:13;300:9; 311:21;315:21;324:3 help (40) 12:20;15:9;19:5; 21:19;22:11;28:4; 45:4;53:14;55:3; 74:9;75:1;85:20; 91:8;99:11;101:21; 103:9;105:2,21; 106:2;110:4;114:15; 121:5;166:8,11,13, 13,18;167:8;169:12; 174:16;259:3;274:8, 14;295:12,21; 321:13;322:1; 324:17;325:16;327:3 helped (4) 11:10;26:1;163:4; 274:5 helpful (16) 10:21;35:11;42:8, 11;44:13;47:21;56:7; 69:9;70:1;86:2; 100:6;169:15; 207:16;251:9; 254:13;292:1</p>	<p>helping (11) 15:21;20:10;80:17; 85:21;98:13,17; 102:12;188:12,13; 189:10;283:22 helps (7) 80:12;82:10;174:3; 187:22;188:7; 192:20;322:4 Henry (1) 158:19 hep (1) 150:12 Herceptin (2) 39:21;190:7 Here's (1) 134:12 HERNANDEZ (8) 124:19,19;139:22; 141:5,6;151:9; 152:13;155:10 heroes (1) 12:20 hesitancy (2) 264:18,19 hesitant (1) 265:3 Heterogeneity (1) 34:11 HHS (1) 12:16 Hi (13) 32:9,15,17,22; 124:21;171:10; 191:5;256:14,22; 267:18;288:6;307:9; 315:20 hide (1) 251:11 high (14) 139:1;159:19; 168:8;210:13; 229:18;232:11; 234:14;235:12; 236:13;238:1; 246:10;262:17; 268:16;316:21 high-deductible (1) 151:18 higher (15) 117:14,22;140:11; 146:21;148:9;156:9; 162:5,6;189:6;201:4; 265:13;266:4;277:7; 309:11,12 highest (1) 216:22 high-fixed (1) 171:2 highlight (4) 34:17;136:8; 202:16;308:21 highlighted (2)</p>	<p>137:17;209:8 highlights (3) 91:8;176:1,3 high-list (1) 140:10 highly (11) 29:1;34:20;97:11; 110:17;111:3; 113:13;200:20; 215:17;216:9,11; 287:15 high-quality (1) 268:1 hilarious (1) 222:2 Hillel (5) 174:2;197:12,14, 15;258:1 hindrance (1) 296:4 hire (1) 266:3 historically (1) 311:7 history (3) 31:2;291:20; 297:13 hold (7) 28:20;46:8,12; 78:15;137:11;294:1; 323:11 holders (1) 7:8 holding (4) 14:15;27:7;153:9; 263:6 home (2) 185:12;329:10 honest (2) 158:6;179:19 hope (13) 17:2;37:16;44:20; 74:4;91:7,19;125:13; 184:14;224:7; 253:22;254:21; 296:2;318:3 hoped (1) 277:16 hopefully (10) 13:11;38:19;55:1; 98:12;176:5,12; 225:7;242:16;254:6; 307:19 hopes (1) 9:5 hoping (3) 18:2;197:5;274:14 Hopkins (1) 58:5 hopping (2) 239:9;250:7 hormone (1) 222:6</p>	<p>horrible (1) 265:20 hospitalized (1) 215:14 hospitals (5) 52:6;60:22;132:1; 246:16;289:7 host (1) 160:6 hosted (1) 323:5 hosting (2) 24:10;206:7 hour (1) 212:16 hours (1) 233:10 house (2) 18:20;28:2 Hovenkamp (1) 232:14 hub (1) 181:3 huge (3) 53:12;63:10;137:7 Humira (3) 54:9;55:4;308:14 hundred (2) 17:15;50:9 hundreds (2) 171:2;258:16 hurdle (3) 166:2,12;293:6 hurdles (2) 250:17;293:3</p>	<p>301:11 II (2) 326:8,9 IKENBERRY (41) 171:10,11,18; 173:3,7;177:11; 185:4,9;190:20,22; 197:11;206:3,4; 212:14;255:3,5; 256:4;257:3;259:21; 263:14;267:16; 272:11;277:22; 278:2;282:2,5,14; 283:1;288:3,10,12; 293:12;298:10; 300:6;303:4;307:6; 311:18;315:17; 320:13;323:22;328:3 ill (2) 316:14;318:10 illustrate (2) 61:19;114:15 illustrates (2) 117:10;153:2 image (1) 222:4 imagery (1) 222:19 images (1) 222:5 imagine (5) 87:6;88:6;90:1; 225:19;252:3 immunogenic (3) 200:1;287:15,21 immunogenicity (8) 46:3;269:15; 271:12,13,19;290:5, 8;295:3 immunology (4) 59:17;283:4,7; 287:14 immunosuppressant (1) 271:14 impact (25) 56:12;60:20;65:1; 69:2;88:3;124:11; 129:15;135:8; 139:20;151:3;155:7; 167:13;172:4; 180:16;209:3,6; 212:7;228:11,17; 258:8;270:9;292:19; 296:12;299:21; 301:16 impacting (1) 291:22 impacts (5) 65:7;67:21;99:7; 102:4;151:4 impaired (1) 301:4 impartiality (1)</p>
I				
			<p>Ian (2) 298:11,14 idea (6) 50:5;58:17;63:14; 64:4;221:21;242:18 ideal (1) 252:7 identical (14) 76:3;113:10,22; 114:5;181:12; 200:21;201:12,13; 216:1,6,11,16; 233:11;240:9 identified (4) 105:9;106:17; 193:21;290:16 identify (12) 105:7,17;106:2; 152:10;156:18; 160:3;193:18; 196:20;197:20; 298:17;319:17;323:3 identifying (2) 105:19;209:4 ignore (1)</p>	

70:3 impede (2) 281:19;301:14 impedes (1) 30:12 impediments (2) 165:21;296:7 impeding (1) 156:22 implement (1) 313:14 implemented (2) 183:14;266:7 implementing (12) 72:19;73:5;75:15; 81:10;85:6,22;104:5; 119:13;148:16; 150:8,12;183:18 implication (2) 200:7;201:7 implications (3) 157:16;162:2; 163:16 implicit (2) 43:8;243:12 implied (3) 94:14;95:1,1 implies (2) 118:8,10 Implying (1) 285:3 importance (10) 31:2;37:12;73:14, 15;128:7;159:19; 194:7;298:8;299:4; 303:11 important (104) 7:13;12:2,8,22; 13:4,7;14:12,16; 15:15,22;28:17; 42:14;43:16;47:6,21; 48:10;59:15;60:13; 65:3;69:9;70:10,16; 72:13;73:3;77:4; 86:20;87:4,11,15; 88:12;96:2;100:16; 101:7;128:8;132:11; 136:7;137:18,19,21; 139:17;140:9,17; 141:1;142:10; 150:19;155:11,19; 157:13;158:14; 159:3;162:7,9;164:7, 20;165:20;167:16; 168:5;169:3,7; 171:14;175:16,17; 177:7;178:22;179:1, 5;180:11;181:6,17; 182:2,6,22;193:2,7; 197:8;198:10; 202:12,19;203:2,5, 16;205:21;206:9; 208:5,9,15;216:16;	219:20;220:14; 236:3;254:10,19; 267:6;275:6;279:5; 280:20;286:11; 287:22;299:21; 309:7;313:18; 321:10;324:22;327:4 importantly (2) 179:15;292:20 impose (1) 164:5 imposed (1) 25:20 imposing (1) 160:11 impossible (1) 319:16 impression (11) 29:16;77:14;95:5, 7,16;112:7;113:2,6; 122:6,10;218:2 impressive (1) 22:22 improve (11) 6:20;19:10;73:7; 174:16;273:9; 289:12;291:4; 294:16;304:16; 314:4;316:16 improved (3) 19:10;304:15; 316:18 improvement (4) 90:7;155:16; 288:18;323:4 improving (4) 171:18;288:22; 289:20;320:20 inaccurate (3) 105:22;263:5; 325:11 inadequate (1) 77:16 inadvertently (1) 298:18 inappropriate (1) 235:15 inaugural (1) 213:15 incentive (6) 62:6,21;65:1,15; 166:11;270:14 incentives (24) 60:17;61:4;62:4,5; 63:7;65:8;67:15; 68:3;72:22;73:16; 78:17;132:13;140:3; 141:14,18;148:7; 166:3;251:19;266:2, 7,10;270:21;309:11; 319:22 incentivized (2) 148:8,11	incentivizes (1) 78:11 incentivizing (1) 166:1 inception (1) 61:14 incidence (1) 152:10 include (17) 27:5;35:5;81:7; 85:19;87:2,3;106:14; 107:20;108:7,19; 109:20;118:4; 135:19;142:1; 163:22;198:4;262:19 included (12) 37:14;58:22;93:6; 107:13;109:18; 115:22;116:12,17; 149:9;256:10; 275:11;278:8 includes (18) 13:5;43:9;45:7,8; 80:19,21;81:4;82:14, 16;90:6;92:12; 102:14,17;107:6; 115:3,12;135:17; 264:3 including (32) 14:22;23:2;33:15; 75:20;79:9;82:1; 86:19;91:5;93:8; 94:8;104:2;111:9; 115:20;116:21; 126:3;130:20; 150:10;260:16,17; 261:13;279:7,15; 289:5;290:21; 291:19;297:5; 303:17;304:18; 306:15;308:19; 325:1,22 inclusion (1) 106:22 incomplete (2) 198:8;324:14 inconsistency (1) 194:4 incorporate (1) 107:4 incorporated (2) 26:10;205:12 incorporating (2) 107:7;205:7 incorrect (4) 75:18;198:21; 261:3;270:7 increase (15) 19:4;20:17;67:15, 18;68:2,13;144:11, 17;151:14;222:6; 276:14;309:14; 314:13;315:3;324:10	increased (15) 20:9;38:7;40:2; 145:2;163:7;176:3; 230:5;239:1;245:6; 276:21;291:17; 307:20;313:12; 315:10;321:7 increases (2) 102:21;229:18 increasing (12) 28:21;44:10; 144:18;145:6; 146:12;267:4;280:7; 291:3,6;301:8;307:2; 309:4 increasingly (3) 16:17;62:13; 150:12 incredible (5) 24:11;165:5; 179:13;259:1,2 incredibly (5) 12:8;136:13; 137:21;169:14;236:2 incumbent (5) 63:17;168:15,16; 309:20;310:8 incumbents (2) 168:10,13 indeed (3) 23:18;303:2; 313:11 independent (6) 32:10;179:14; 194:11;316:7; 320:19;322:8 independently (3) 179:9;195:18; 196:19 indicate (1) 321:22 indicated (2) 133:4;326:4 indicates (2) 39:15;313:11 indication (5) 112:14,16;115:15, 17;199:17 indications (8) 35:13;112:5,10; 217:16;272:4;310:5; 325:7;326:13 Indirectly (2) 229:12,12 individual (8) 8:10;52:5;111:22; 122:8;184:19; 192:17;284:11; 296:16 individuals (2) 294:4;316:5 individual's (1) 297:12	induce (2) 232:7;233:17 industry (21) 14:8;25:16;27:17; 30:11;31:10;45:15; 70:22;74:5;83:4; 84:7;100:19;158:17; 203:10;214:13; 246:6;249:22; 254:14;280:2; 298:16;302:2;306:12 industry's (1) 82:17 ineffective (1) 244:10 inequalities (1) 318:14 inexpensive (1) 182:13 infer (1) 248:7 inferences (1) 219:19 inferior (4) 264:15,17;273:18; 300:20 inferiority (1) 189:21 inflammatory (2) 188:2;294:7 inflated (2) 235:7;309:15 inflation (1) 129:20 Inflectra (3) 187:9,16;209:14 Inflectra-Remicade (1) 189:19 infiximab (12) 49:3;57:2;61:8; 62:3;145:5;146:16; 283:14;284:22; 285:21;286:3; 287:10,15 influence (4) 49:8;193:14;209:3; 319:18 influenced (1) 208:16 influencer (1) 208:15 influencers (1) 193:3 influences (1) 209:4 influencing (2) 58:10,18 infographic (2) 175:10,15 inform (1) 28:7 information (120) 8:17;14:5,12;
---	--	--	--	--

<p>15:11,17;19:15;29:6; 35:6;50:7;58:18; 69:17;75:19;76:8; 77:5;79:4;80:18,20, 20,21;85:2,3;87:1,3, 8,11,20,22;88:2,8,12, 13;91:1,13;93:6,8; 94:9;97:19;99:13; 102:13,15;104:7,20; 105:3,15,18;106:1, 14,22;107:5,10,13, 16,21;108:4,7,12,15, 19,22;109:14,16,20; 110:7;112:1;115:9, 18;117:2;119:3,5; 121:7;137:20;143:3; 163:4;165:18;166:7, 13;175:6;176:8,14, 19;178:8;179:6; 180:18;181:3,4,15; 182:7,8;183:5; 191:14;192:18; 195:8;198:8,9;202:3, 4;203:5,17;204:1; 206:20;212:19; 214:8;257:21;258:4, 7,12;269:18;284:14; 285:6;291:9,16; 292:8,12;300:22; 321:17;324:15; 326:20;327:1,4; 329:6</p> <p>information-related (1) 161:7</p> <p>informative (3) 6:13;136:13;292:9</p> <p>informed (2) 83:10;284:15</p> <p>infringe (1) 298:18</p> <p>Ingelheim (1) 32:16</p> <p>inherent (2) 137:9;302:20</p> <p>inherently (4) 65:15;223:14,22; 227:1</p> <p>inhibit (1) 158:3</p> <p>inhibiting (1) 160:17</p> <p>initial (1) 166:12</p> <p>initially (2) 153:6;187:16</p> <p>initiating (2) 24:7;211:16</p> <p>initiative (2) 196:10;205:5</p> <p>initiatives (3) 172:14;306:19; 321:7</p> <p>injunctions (2)</p>	<p>85:19;239:4</p> <p>injured (1) 246:4</p> <p>Inma (3) 124:19;141:5; 156:5</p> <p>Inma's (2) 152:20;162:10</p> <p>innovation (24) 15:5;16:8,16;17:9; 20:9,12;21:2;22:5; 25:12;71:21;78:10, 12,20;259:16,17; 268:3;271:10;305:5; 312:1,11,17;313:13; 316:22;322:17</p> <p>innovative (10) 24:5,17;74:2; 130:13,18;268:2; 279:12;296:8;298:3; 312:6</p> <p>innovator (12) 51:1;137:11;158:8; 286:5,7;303:13; 305:2,11,12;312:19; 313:9;315:4</p> <p>innovators (1) 20:4</p> <p>input (6) 120:5;121:3; 281:21;298:21; 322:10;325:9</p> <p>inquiries (1) 8:19</p> <p>insert (3) 89:8;90:5,6</p> <p>insight (1) 240:19</p> <p>insights (3) 191:10;212:9; 289:16</p> <p>insignificant (1) 170:8</p> <p>instance (7) 89:3;105:16;106:5; 143:12;147:1; 232:17;243:10</p> <p>instances (5) 29:7;181:15; 182:18;232:19; 270:18</p> <p>instantaneous (1) 277:14</p> <p>instead (4) 23:16;96:13; 223:17;317:12</p> <p>Institute (2) 125:1,10</p> <p>instituted (1) 311:3</p> <p>institutional (1) 270:2</p> <p>instructed (1)</p>	<p>317:12</p> <p>insulin (15) 42:10;46:2;48:1; 145:22;146:3;149:4, 6,9,14,14;268:9,11, 15,21;290:7</p> <p>insulins (3) 48:5;321:14; 323:14</p> <p>insurance (12) 74:4;126:10; 142:18;151:19; 192:5;194:17;247:7, 12;270:20;279:1; 302:14;319:21</p> <p>insurer (4) 63:13;142:19; 301:22;319:5</p> <p>insurers (12) 60:19;62:12,12; 64:3,14;142:22; 278:20;302:21; 317:9,13;319:12; 327:13</p> <p>integrated (3) 58:2;267:21;289:6</p> <p>intellectual (1) 213:14</p> <p>intend (5) 13:22;255:15; 268:3;282:8;326:4</p> <p>intended (4) 105:2;182:18; 271:3;324:10</p> <p>intent (1) 221:14</p> <p>inter (2) 55:8,12</p> <p>interaction (4) 46:21;47:2,17; 65:14</p> <p>interactive (1) 11:2</p> <p>interchangeability (41) 37:4,5,13,20; 43:11;46:12,19,22; 47:7,10,16,22;48:9; 64:21,22;65:10,13; 66:9;72:6;195:1; 200:12,13;201:2,4, 216:19;260:19; 269:1,7,17;270:3; 279:15;281:15; 284:18,20;285:7,9; 286:18;287:4,16,19; 305:19</p> <p>interchangeable (59) 15:1;18:4,12,22; 19:11;34:8;37:6; 38:3,10;46:1;47:15; 48:3,19;65:21;66:19; 67:4,9;70:11;72:9; 96:11,20;103:18;</p>	<p>113:1,3,8;120:6,16, 18;121:3;140:21; 155:14,21,21;156:3, 8;169:9;172:4; 181:13;201:9;204:2; 216:21;217:3,6; 233:11;269:10,21; 279:7,8;280:9;281:1, 9;285:4;290:6;295:2, 9;296:21;325:8,15,19</p> <p>interchangeables (11) 13:11;37:18;38:14, 19;48:7;69:14;70:6; 120:21;121:7;155:8; 325:10</p> <p>interconnectedness (1) 170:11</p> <p>interdependencies (1) 52:4</p> <p>interest (12) 93:14;159:18; 193:5,9;205:17; 236:7;252:19,20; 297:19;304:4; 307:11;328:12</p> <p>interested (14) 8:22;10:14;16:7; 25:13;32:13;108:11, 14;152:17;159:5,6; 192:22;209:20; 212:17;323:16</p> <p>interesting (4) 33:11;68:1;153:14; 154:12</p> <p>interests (1) 252:21</p> <p>interfere (3) 7:18;257:14; 277:20</p> <p>internal (1) 185:18</p> <p>international (5) 264:6;273:8;274:1, 2,18</p> <p>internet (1) 299:14</p> <p>internist (1) 32:11</p> <p>interpret (2) 96:20;136:14</p> <p>interpretation (6) 95:18,19;96:6,7, 17;218:3</p> <p>interpretations (1) 27:9</p> <p>interpreted (1) 95:4</p> <p>interpreting (1) 46:4</p> <p>interrelated (1) 50:18</p> <p>interrupt (1) 9:6</p>	<p>intervention (2) 37:9;79:2</p> <p>intimations (2) 216:20;252:5</p> <p>into (37) 9:22;24:12,14; 26:10;27:3,11;29:9; 39:1;50:14;51:10; 54:13;55:8;56:8; 75:13;104:19;124:6; 127:13;130:9; 146:21;157:10; 168:11;175:11; 178:9;180:16; 191:18;194:13; 204:12;212:10,18; 214:14,20;227:9; 230:13;240:19; 242:1;299:13;322:9</p> <p>intricate (1) 294:11</p> <p>introduce (9) 11:5;17:16,21; 22:17;32:2;124:14; 172:11;256:9,12</p> <p>introduced (7) 17:19;53:18;68:19, 20;71:6;135:13; 142:8</p> <p>introduces (1) 49:5</p> <p>introduction (6) 11:21;61:15;73:22; 101:10;286:2;324:9</p> <p>introductions (1) 32:7</p> <p>introductory (1) 54:19</p> <p>invaluable (1) 291:11</p> <p>inventory (5) 63:1,9;66:1,4,12</p> <p>inventorying (2) 62:7;65:16</p> <p>invest (1) 169:21</p> <p>invested (1) 208:19</p> <p>investigate (1) 83:13</p> <p>investigates (1) 84:11</p> <p>investigations (2) 31:10;311:14</p> <p>investing (1) 133:11</p> <p>investment (2) 143:7;290:11</p> <p>investments (1) 154:3</p> <p>invite (1) 83:20</p> <p>invited (1)</p>
--	---	--	--	---

178:9 invoice (5) 126:15;131:4,8; 132:19,20 invoiced (1) 52:17 involve (1) 265:18 involved (4) 51:1;99:16;186:12; 260:15 involvement (2) 28:14;61:13 involves (3) 44:7;104:18;111:8 involving (7) 26:17;27:19;30:9, 20;103:14;239:6; 242:3 IQVIA (4) 61:18;125:9,21; 126:2 isolation (2) 77:4;122:5 issue (21) 13:9;46:5;51:10; 52:8,18;62:20;63:10, 19;64:3;72:7;73:21; 86:21;87:19;88:16; 89:15;194:21;224:7; 226:22;227:6;233:7; 324:17 issued (4) 101:17;102:6,20; 299:11 issues (36) 23:18;28:14;32:13; 43:15;50:5,20;51:18; 53:5;55:13,16,19; 57:6;65:22;73:13; 83:13;86:3,7,11; 103:1,13;194:15; 217:22;223:8; 226:19,19;227:15; 254:10,20;264:7; 291:22;292:20; 297:8;301:6;314:17; 318:13;321:19 issuing (2) 81:7;268:10 Italy (1) 261:11 items (1) 164:19	January (3) 30:15;214:22; 286:14 Jex (4) 172:7;206:3,7; 212:8 Jim (2) 8:19;9:1 job (5) 15:14;161:11; 180:13;318:16;328:7 Jocelyn (2) 311:19,22 Johns (1) 58:4 Johnson (3) 249:15;283:8,8 Johnson-Pfizer (1) 249:16 join (3) 23:13;254:22; 259:5 joined (2) 79:21;100:17 joining (4) 11:22;100:15; 177:1;213:11 joint (7) 11:11;13:15;24:8; 110:1;206:8;207:3; 273:5 joke (1) 215:19 journal (2) 190:1;301:2 journey (1) 284:2 journeys (1) 284:13 judge (1) 250:4 judgment (1) 296:15 Juliana (1) 257:5 Julie (1) 257:7 jump (3) 6:6;32:6;44:16 jumping (1) 184:13 junction (1) 270:15 JUNEXANT (15) 114:19,20;115:8, 11,16,20;116:1,4,11, 15;117:12,13,15,19; 118:9 jurisdiction (4) 45:22;92:12,18; 100:2 jurisdictions (1) 205:3	Justice (2) 85:16;98:2 justifiable (1) 237:18 justification (1) 326:14 justified (2) 165:22;291:1	knows (1) 254:14 Koehn (11) 172:20;173:2,4; 176:21;177:2,3,12, 18;185:7;202:14; 207:6 Koslov (8) 11:15;12:5;22:17, 18;23:5,8,11,12	153:10;154:2,15; 155:2,4;180:20; 204:6;270:4;301:22; 302:21 largely (1) 223:21 larger (4) 183:2;193:3;267:3; 310:12 largest (8) 91:2;178:13; 183:17;189:18; 191:6;275:12,13; 288:17 last (31) 11:6;13:15;17:3; 18:8;20:5;39:18; 50:6;52:21;62:1; 63:12;70:19;90:20; 144:3;146:6;156:18; 162:2,22;163:3; 167:2;173:12; 184:12;190:13; 194:21;235:11; 249:18;261:9;276:1; 286:14;299:11; 328:4,14 lasting (1) 234:3 lastly (2) 183:8;272:5 late (2) 42:18;161:11 later (6) 99:19;127:18; 135:22;145:17; 202:15;273:15 late-stage (2) 127:16;130:22 latter (1) 49:15 Laugher (15) 40:18;41:18;91:22; 125:14;171:17; 177:17;185:6; 190:21;203:6; 213:22;250:13; 256:3;282:1,18,22 launch (4) 50:11;133:5;139:3; 142:7 launched (15) 47:12,13;49:1; 50:19;52:10;59:12, 22;60:10;132:21; 181:2;266:7;276:12, 19;304:12;305:20 Laura (4) 303:5,8;324:1,4 laurels (1) 247:15 Law (21) 23:7;213:13,14,16,
J		K	L	
J&J (3) 230:5,5;253:11 JAMA (2) 50:6;144:4 Janssen (5) 217:1,10;283:3,7,9		Kaiser (6) 58:1,22;185:20; 187:14;189:16; 204:10 Kathleen (4) 288:3,6;293:14,16 keep (10) 100:7;114:13; 122:2;136:7;152:4; 168:21;196:3;236:8; 271:21;297:20 keeping (2) 137:19;248:11 keeps (1) 310:18 kept (2) 84:22;185:8 key (14) 6:22;11:12;13:21; 81:19;191:17;193:8, 14;206:12;210:5,21; 218:19;219:6;280:9; 289:16 kick (3) 6:11;33:4,18 Kim (2) 278:3,5 kind (17) 11:21;28:14;57:19; 108:15;115:6;116:5; 117:9;158:11;168:5; 172:10;188:10; 192:13;193:10; 214:14,15;219:1; 227:9 kinds (2) 86:10;248:18 king (1) 242:19 Knowing (1) 179:8 knowledge (6) 172:2;179:19; 180:14;195:6;232:8; 233:21 knowledge- (1) 161:6 knowledgeable (4) 96:12;204:8,17,21 known (4) 34:5;68:7;294:9; 310:20	labeled (1) 281:16 Labeling (44) 14:8;35:5,6,7,8,15; 81:1,22;82:1,5;85:7; 86:5;100:19;101:14; 103:10,22;106:6; 107:2,4,6,9,14,15,16, 20;108:4,6,18;109:2, 5,10,12,18;116:17; 117:5;119:7,18,19; 280:3;282:7;298:22; 325:15;326:22;327:2 labels (1) 326:20 labor (1) 278:20 lack (5) 87:11;91:6;165:5; 246:11;295:21 LADA (1) 293:17 Ladies (1) 23:8 lagging (1) 136:16 lags (1) 266:14 landmark (1) 27:5 landscape (2) 289:17;293:10 language (12) 175:15;180:16; 181:21;182:7; 193:21;194:1,8; 197:1;208:4,6; 222:20;296:5 Lanham (14) 218:14,19;219:5,9; 223:6,7;224:5; 225:12;226:19; 227:20;241:19; 248:3,19,21 Lantus (5) 141:15;145:19; 146:2,16;149:10 large (17) 54:7;58:3,22;59:1; 88:7;128:13,18;	

16,18,19;218:16; 226:4;232:4,14; 238:21;240:16; 241:4,10,13,15; 243:19;244:2; 248:14;253:20	leeway (1) 240:15	liable (2) 95:22;96:6	279:16	233:8;240:15; 245:17;250:8; 253:12;271:12; 277:15;282:9;287:6; 317:15;319:18
laws (12) 25:17,20;26:2; 29:12,12;48:17,18, 20;84:5;169:6; 242:21;251:16	left (1) 124:15	License (1) 7:8	limits (2) 162:4;311:16	live (7) 8:3;11:1;169:18; 207:9,12;294:10; 312:8
lawsuits (1) 43:2	legacy (1) 31:11	licensed (20) 37:17;76:18; 104:12;106:15,16; 107:18,19;108:1; 112:5,9,22;113:2,8, 11;115:15;116:13; 117:8;217:17;325:7, 19	line (7) 79:3;134:21; 135:12;173:1; 184:15;189:6;238:19	lives (6) 12:11;52:1;173:11; 267:22;277:13;312:9
lay (4) 182:7;207:5; 219:21;243:2	legal (1) 14:20	licensing (1) 291:5	lingering (3) 59:7;291:20;292:2	living (8) 16:11;178:4;185:1; 294:4;315:19;316:2, 11,17
layout (1) 88:5	legally (1) 265:15	licensure (17) 31:21;34:7,35;12; 107:11;110:15; 112:15,19;113:12; 115:8,20;116:10; 280:2;282:7;313:1; 325:13;326:5,13	link (1) 299:20	Liz (2) 206:5;207:6
lays (1) 33:21	legislation (3) 28:8;53:18;68:20	lie (1) 226:2	linked (2) 205:15;261:5	lobby (2) 8:13;205:14
lead (4) 235:7;287:8;303:6, 9	legislative (3) 67:14;68:18;164:1	lieu (1) 96:22	list (33) 44:19,21;56:10; 69:19;86:8;126:17; 140:12;142:6,8,12; 144:10,17;145:2,3,6; 146:9;148:6,9,11; 149:12;150:20; 151:10,16,17,19; 152:4,5,11;154:9; 266:4;305:22; 309:11,15	local (1) 137:13
leader (2) 173:13;278:10	legislators (1) 169:13	life (7) 11:11;274:9,10; 316:16;320:9;323:1, 9	listed (4) 53:16;54:2,5;142:4	located (1) 8:13
leaders (1) 58:21	legislatures (1) 273:2	life-altering (1) 294:4	listening (1) 185:3	location (2) 137:18;139:7
leadership (2) 274:1;293:8	length (2) 36:4;262:20	life-saving (2) 6:21;15:22	lists (10) 148:16;149:4,5,8, 10,20;150:7,9,10,14	lock (1) 235:8
leading (8) 196:10;232:12,13; 258:10;289:6;312:5; 313:11;315:12	lengths (1) 71:22	life-threatening (4) 16:18,21;24:18; 308:1	literacy (1) 184:20	locked (1) 235:16
leads (1) 224:7	less (26) 29:2;55:15;60:9; 76:13,14;77:14; 97:14;112:8,8,13,13; 113:6,6;155:13; 158:4;192:4;204:21; 244:22;245:6,17; 271:15;286:6;311:8; 312:13;325:5,18	light (6) 55:17;135:15; 251:8;255:22; 267:10;287:2	literal (3) 220:12;221:8,9	logic (1) 166:5
leaf (1) 251:12	lesser (1) 193:2	lightning (1) 225:6	literally (3) 219:11;222:11; 244:4	logical (2) 227:13,14
learn (9) 70:21;71:1;77:10, 21;83:21;195:10; 267:12;276:8;299:8	lessons (5) 28:4;70:21;73:4; 138:18;195:12	lights (1) 255:19	literature (2) 164:7;292:9	long (17) 15:18;23:17;25:13; 26:22;32:13;168:22; 173:6;174:15;178:1; 202:12;210:11; 212:4;218:18;228:6; 284:12;285:18; 316:21
learned (6) 28:4;70:21;138:19; 195:12;213:18;233:4	letter (8) 43:19;85:11;86:9, 15;299:11;317:17; 326:8,9	likelihood (2) 218:22;219:2	litigants (1) 213:9	long-acting (1) 145:22
learning (3) 163:7;177:8; 243:18	letters (6) 81:7;86:13,14; 90:20;91:3;97:21	likely (17) 17:2;29:18;30:5; 65:13;71:15;111:13; 133:13;220:14; 221:5;226:10;228:1, 7;232:7;244:5,6; 262:18;304:10	litigate (2) 253:8,15	longer (5) 68:4;72:14;114:15; 265:11;312:8
learns (1) 26:12	level (15) 14:4;46:20;131:5, 6,7;133:19;140:7; 184:21;224:20; 229:18;238:2;264:6; 285:18;291:3;304:22	limit (1) 310:2	litigating (1) 54:5	longitudinal (1) 295:14
least (19) 61:10;128:6;135:8; 151:14;153:6;166:1; 210:15;212:15; 226:9;228:11; 229:14;242:16,17; 246:15,19;249:3,7; 264:20,22	leveled (1) 99:13	limitations (3) 9:14;117:6;299:16	litigation (9) 26:7;53:7,9;54:7; 55:15;71:17;180:8; 224:10;271:6	long-standing (1) 321:2
leave (1) 85:1	leveling (1) 87:1	Lilly (2) 222:3,4	little (42) 33:19;35:10;37:15; 47:18;50:3;57:5; 61:5;64:17;89:7; 125:20;130:16; 135:11;140:14; 149:21;154:3;158:6; 177:15;185:10; 187:21;189:3,6; 190:8;192:2;197:13; 201:15;202:4; 207:15,17;214:11; 215:20;217:12;	long-term (4) 74:14;271:4; 306:11;313:18
led (1) 283:16	levels (5) 132:14;170:13; 195:6;217:19;261:6	limited (6) 68:2;78:13;244:15; 252:10,17;326:9	look (49) 6:21;31:10;37:16, 17;42:4,16;44:3; 48:1;61:17;73:2; 92:10,21;108:3; 127:15;128:11,14; 129:22;132:20; 135:11;137:4;138:7, 17;139:5;142:5;	
leery (1) 265:22	leverage (3) 62:13;196:7;209:5	limiting (1)		

<p>146:6;148:19; 150:19;151:21; 152:7;155:1;177:7; 180:4;186:14; 187:10;195:4; 196:22;197:4;216:4, 7,14;217:16;222:14; 230:4;233:3;243:3,8; 262:9;276:16;286:15</p> <p>looked (7) 56:12,19;141:20; 149:7;152:14; 187:18;235:6</p> <p>looking (23) 19:9,13;36:10; 42:8;69:20;77:19; 93:20;97:7;119:22; 121:2,10;127:3; 130:9;132:17; 137:20;152:16; 186:11;193:4; 209:18;211:8;212:5; 227:13;228:5</p> <p>looks (3) 147:13;185:15; 275:17</p> <p>lose (2) 310:15,16</p> <p>loses (1) 127:11</p> <p>losing (2) 252:12,15</p> <p>loss (1) 310:13</p> <p>lost (5) 12:11;158:20; 242:9;244:11;258:10</p> <p>lot (73) 12:9;34:15;37:10; 38:11;42:18;44:2; 45:7,10;47:1;48:18; 50:15;52:1,19,21; 53:3,4;54:20;57:4; 58:20,21;60:1;61:4, 12;62:4;63:7;72:16; 74:4,12;92:2,6;146:2, 4;151:16;161:9; 162:22;168:13; 174:13;175:21; 181:10;184:16; 186:2;188:20; 190:16;191:14; 192:7,8,10,15; 194:15;198:18; 203:17;206:10; 208:19;209:2; 210:17;216:3;224:2, 11;226:8;230:11; 233:19,22;235:10; 241:16;244:16; 247:8,13;251:12,14; 253:14;256:4; 264:11;282:16</p>	<p>lots (2) 210:14;232:19</p> <p>Louisiana (1) 263:22</p> <p>love (3) 70:15;182:1,11</p> <p>low (3) 261:6;276:20; 277:7</p> <p>Lowell (5) 75:3;80:8;98:8; 100:13;101:1</p> <p>lower (18) 21:3;31:7;60:2; 140:11;148:10,11; 171:7;201:8;229:15; 280:18;281:1; 289:11;305:22; 308:9;309:17; 310:17;313:12;318:7</p> <p>lowered (1) 285:17</p> <p>lowering (4) 176:5;246:7;280:9; 319:22</p> <p>lowest (1) 286:5</p> <p>Lucio (4) 288:8,12,13,15</p> <p>lucrative (2) 168:7,21</p> <p>lunch (2) 122:21;123:3</p> <p>Lupus (3) 288:4;293:19; 294:6</p> <p>lymphoma (2) 186:14,14</p>	<p>majority (7) 85:13;95:19;241:3, 9;257:17;276:22; 300:19</p> <p>makes (8) 17:4;49:13;122:10; 215:19;237:7;241:6; 244:16,21</p> <p>making (18) 13:5;17:13;19:7; 31:6;33:7;48:2; 53:11;59:20;76:22; 78:8;155:19;161:8; 182:13;202:21; 228:10;247:5; 297:13;318:1</p> <p>manage (3) 66:13;182:5,8</p> <p>managed (1) 131:18</p> <p>managed-care (7) 147:16,21;148:22; 149:19;150:1,6; 154:21</p> <p>management (8) 57:9,10,10;64:5; 79:17;278:4,13; 296:10</p> <p>manager (3) 142:20;315:18; 316:10</p> <p>managers (2) 142:21;278:16</p> <p>managing (1) 65:16</p> <p>manipulations (1) 301:12</p> <p>manner (2) 104:9;327:6</p> <p>manufacture (1) 167:22</p> <p>manufactured (1) 143:11</p> <p>manufacturer (18) 54:1;76:2;81:2,16; 82:21;83:1;127:5; 165:7;166:20; 167:14;210:22; 280:5;285:13; 303:13;304:4; 309:20;310:7;327:9</p> <p>manufacturers (47) 14:2;20:18;26:14; 27:1,11;29:8;30:4; 32:21;44:14;50:21, 22;52:13,22;53:13; 54:8;55:7;76:7; 77:11;78:8,16;81:8; 91:10;100:1;104:1; 126:6;127:4;133:15; 142:13;143:1;164:6, 21;168:14;169:21; 181:16;270:13;</p>	<p>271:9;277:5;279:18; 280:16;290:1;295:4; 302:5;304:14;318:1; 321:15,17;322:4</p> <p>manufacturer's (1) 92:13</p> <p>manufacturing (6) 167:18;236:14; 283:11;291:18; 292:5,12</p> <p>many (54) 11:22;12:16;16:18; 24:10;25:6;33:14; 39:10,11,11,11,11; 63:11;68:3;78:11; 83:9;84:8;88:2; 136:22;145:10; 150:11;153:15; 156:21;157:10; 160:4,22;161:18,20; 163:10;166:22; 168:19;174:1,11; 180:8;181:15; 182:17,18;192:3; 200:21;203:4; 204:12;235:2; 237:13;250:17; 254:3;275:21;279:5; 281:9;284:12,17; 289:14;298:4; 313:21;317:9;328:14</p> <p>margin (1) 265:15</p> <p>markedly (1) 305:22</p> <p>market (205) 7:8;13:5,11;14:22; 20:7,13,13,16;21:21; 34:1;39:16,20;40:20; 41:14;42:15,16,21; 47:15;50:17;51:5,20; 52:12,17;54:11,13, 17;55:18;56:17;59:3; 60:4,14;61:7;72:18; 73:4,5,15;78:2,12; 125:18,19,20,22; 126:9,13,14;127:9, 22;128:5,8,13,14,17, 19;129:1,4,10;131:4, 7,10,12,14,16;132:1, 12,18;133:1,19,21; 134:1,7,11,14,16,17, 19;135:9,20;136:2,6, 6;137:11;138:4,11; 139:5,14,15;144:14; 145:10,18;146:1,18, 21;149:17;150:17; 151:4;152:22;153:3, 4,11,17,19;154:12; 155:5,9;156:8,22; 160:1,13;163:2,11; 164:9,12,14;166:2,4, 19;167:7,20,21;</p>	<p>168:7,8;170:1,7,9,14, 16,22;171:7;186:22; 190:12;228:8,10,20; 229:13,14;230:6; 231:3,15;236:22; 241:21;242:6,10,13; 243:14;244:11,22; 245:3,4,11;246:11; 247:3;248:5,11,11; 249:9,9,11;253:13, 13,22;254:7;258:18, 19;262:10,13,21; 263:12;266:4,19; 270:14;275:15; 276:10,15;277:1,5, 21;281:20;286:20; 287:8,14;293:3; 295:13;303:1,18; 304:5,10,15;306:6; 307:2;308:8,13; 309:21;312:18,21; 313:6,17;314:10,11, 21;315:13;316:21; 317:2;318:10,16; 319:17</p> <p>market-based (2) 160:8;319:22</p> <p>marketed (10) 40:5,10;41:2,16; 49:18,19;76:18; 135:15;257:17; 281:16</p> <p>marketing (5) 80:1;298:20; 299:15;300:21; 301:17</p> <p>market-leading (1) 310:14</p> <p>Marketplace (51) 6:8,19;7:11;13:2,4; 15:12;40:1;49:6,10; 50:4,14,22;78:5; 98:19;99:3,15; 126:22;127:14; 138:9,20;156:16; 160:19;162:21; 164:15;165:18; 166:9;167:9;237:12; 257:15;258:15; 268:6;269:3;272:7; 274:16;279:4; 280:22;301:6,10; 303:16;304:10; 305:3;306:13,22; 307:5;312:4,12; 313:7;320:18; 321:11;322:2,5</p> <p>marketplaces (1) 279:1</p> <p>markets (15) 13:19;24:2,3; 25:14;26:20;124:10; 132:10;136:21;</p>
	M			
	<p>macro (2) 61:5;73:21</p> <p>Madelaine (2) 263:15,18</p> <p>magnitude (1) 126:20</p> <p>mail (8) 131:8,14,16,17,18, 19,21;317:17</p> <p>main (3) 90:6;196:18;303:1</p> <p>maintain (3) 231:11;289:12; 327:10</p> <p>maintained (1) 229:18</p> <p>maintaining (4) 19:20;29:22;83:18; 184:11</p> <p>major (5) 27:10;45:22;51:22; 52:8;302:9</p>			

139:20;160:11; 169:17,20;230:22; 246:21;252:17 market's (1) 286:5 market-wide (1) 238:22 matched (1) 310:6 material (13) 76:22;92:10;94:8, 9;97:5,19;104:9; 117:5;203:18;232:6; 233:14,16;244:4 materiality (6) 218:21;227:20,21, 22;228:3,12 materials (83) 20:20;69:7,11; 77:12;81:9;82:18; 83:16;84:8,14;87:2, 21;88:17,18;89:16, 19;101:19,21; 102:22;103:18,20; 104:6,11,14;105:4,8, 11,13,15,17,21; 106:11,13,18;107:1, 12;108:2,16;109:14, 21;110:10,15; 112:21;113:4;114:1; 115:2,12;117:12; 118:1,12,15,17,20; 119:1,4,11;120:16, 21;121:1,6,18; 122:16;173:19; 174:20;175:2,5,9,14; 176:10,12,16;179:16; 180:22;195:20; 196:5;207:14;208:6; 209:9;212:19;217:4; 322:21;325:3,10,16 mathematical (1) 272:3 matrimonial (1) 213:21 matrix (2) 192:2,7 matter (7) 86:20;92:17;225:1; 232:8;233:22; 238:17;248:4 matters (7) 22:21;66:19;67:7; 79:16;83:9;93:15; 173:6 maturing (3) 160:18;303:19; 314:10 maturity (1) 153:19 maximize (2) 19:22;301:12 maximum (1)	140:4 may (69) 7:18;8:7;10:11; 16:10;22:20;29:8; 33:14;35:7,15;43:15; 48:20;51:12,14;53:1; 75:19;76:15,21;77:3; 79:2,5;84:17,20; 90:14;93:17,17;95:8, 14;96:14;97:11,13; 101:18;105:9;114:5; 149:13;153:18; 156:22;160:12,16; 161:7;164:11;166:5; 181:7;186:9;199:13; 200:1,8,18;204:7,22; 211:22;212:6;216:9, 9;217:10;219:22,22; 220:13;224:14,21,21; 226:15;240:19; 249:10;280:14; 281:11;287:8,12; 301:14;314:19 maybe (14) 39:19;60:8;98:10; 148:9;203:4;204:21; 216:21;223:19; 229:15;234:10; 238:1;241:11; 245:17;252:5 Mayo (1) 58:4 McKinley (3) 324:1,3,4 McKinney (1) 8:19 MCO (3) 148:2,5;154:21 MCOs (5) 148:10,15;149:2,3, 5 MD (1) 11:8 mean (10) 35:22;63:10;96:13, 21;120:17;147:18; 162:5;209:20;217:3, 7 meaning (8) 94:20;96:4,19; 149:1;219:15,16; 220:12;311:4 meaningful (23) 29:17;34:21;42:3; 46:17;76:16,19;97:9; 110:20;111:5,18; 113:16;116:3,14; 117:18;118:11; 187:20;189:20; 198:16;215:18; 270:9;301:4;305:4; 315:6 meanings (1)	220:19 means (14) 14:18,20;26:12; 37:12;40:5;93:9; 110:16;113:12,20; 151:13;174:22; 195:2;246:9;292:15 meant (2) 14:2;220:10 meanwhile (1) 141:7 measure (1) 126:14 measurement (1) 125:21 measures (1) 296:12 measuring (1) 133:22 mechanism (2) 139:7;292:22 mechanisms (2) 225:5;295:8 media (5) 8:18,20;9:12,13; 196:7 Medicaid (23) 43:17;131:18,20; 132:6;139:14; 141:14;144:1,15,16; 146:13;147:14,16,20, 21,22;148:15,21; 149:12,19;150:5; 154:20,21;278:21 medical (41) 11:7;16:4,13,22; 32:11;46:15;49:3,13; 51:16,20;52:7;57:14; 58:4;61:1,11,22;64:7, 9,13;65:5,12;66:11; 67:11;74:8;109:4; 171:15;173:21; 188:9;205:8;206:21; 220:5;224:16;275:6; 283:4,7;289:6; 295:14;297:13,16; 311:22;316:7 medical-benefit (1) 47:5 Medicare (15) 26:11,15;43:17; 52:21;68:11;131:16, 17;132:3,5;139:15; 155:1;271:2;278:11, 21;315:3 medication (12) 50:11,14;57:15; 192:1,11;194:16; 212:1;226:11; 260:14;302:10; 303:2;317:15 medications (6) 56:20;57:13;	188:15;290:3;301:9; 303:2 medication's (1) 299:7 medicine (7) 129:4;173:22; 185:18;228:18; 262:8;265:10;322:4 Medicines (20) 32:20;126:4,5; 130:3,18;215:4; 216:6;260:8;263:16; 265:17;272:18; 274:5,8;277:17; 312:8;320:22;321:5, 13;322:2;323:15 meet (3) 92:20;216:22; 321:15 meeting (10) 7:21;10:14;12:22; 22:13;177:7;185:13; 264:12;328:16; 329:1,2 meetings (6) 39:12;196:13; 220:13;273:5;301:1; 320:8 member (7) 199:6;210:5; 272:19;273:11,12; 278:9;312:2 member-driven (1) 288:17 members (8) 8:20;178:15; 255:12;257:16; 258:16;259:19; 274:7;288:13 membership (1) 179:15 mental (1) 173:22 mention (4) 193:16;222:1; 236:12;299:19 mentioned (28) 20:8;22:1,11,13; 23:17;39:7,22;62:11; 101:1;106:16; 116:21;157:17; 166:18;168:19; 174:13;188:21; 193:13;194:17; 195:9;196:8;207:2; 227:1;235:12; 239:20;246:14; 247:17;258:1;282:5 mentioning (1) 163:13 Meredyth (2) 31:17;44:5 merely (2)	161:4;267:3 mergers (1) 229:8 merits (1) 30:2 message (11) 77:5;93:1;94:16, 19;95:1,21;210:21; 211:20;220:22; 221:5;222:21 messages (13) 199:2,5,8;201:6; 202:1,20,21;203:7, 12;210:5,9;224:17; 292:21 met (2) 244:7;249:3 method (1) 30:6 methodologies (3) 90:16;271:21; 295:4 methodology (3) 117:3;186:4; 291:13 methods (6) 94:2;210:21; 211:10,11;240:13; 295:17 metrics (1) 128:22 mic (1) 173:1 Michael (3) 213:11,12;214:17 Michele (5) 173:16;190:22; 191:2;197:11;198:18 microphone (3) 9:22;255:18;256:9 middle (1) 41:5 middlemen (2) 265:15;302:3 middlemen-pocketed-fees (1) 267:4 might (26) 8:2;29:11;36:15; 48:6,13;49:18;54:18; 55:4;56:4;68:4;92:9; 96:12,20;139:20; 152:9;153:17; 158:11;161:17; 168:19;190:22; 226:10,12;236:4; 238:5;245:17;251:4 milk (1) 222:6 million (5) 54:6;185:21; 210:15;274:5;278:18 millions (7) 25:1;171:3,3;
--	--	---	---	--

252:12;258:17; 294:4;298:2 mind (9) 99:9;122:2;136:7; 138:14;139:13; 152:5;200:21;284:7; 287:5 mindful (3) 40:15;256:5; 277:19 minds (1) 274:20 minimis (6) 230:17;231:20; 232:2;233:2;234:18; 243:22 minimization (2) 87:20;91:1 minimize (2) 151:7;165:10 minimizes (1) 88:14 minor (2) 110:18;113:14 minute (2) 36:5;193:17 minutes (10) 6:5;10:6;70:20; 125:17;163:13; 194:14,14,14;208:7; 255:11 mire (1) 71:17 mischaracterize (2) 247:18;248:16 misinformation (14) 43:3,4,5,8;58:17; 69:6;71:16;75:21; 78:5;198:2;205:4; 264:8;271:8;325:1 mislead (2) 29:8;76:5 misleading (60) 6:17;14:1;29:16, 19;30:8;58:18;75:18; 77:2,6;79:5;81:22; 84:18;86:6;87:14; 88:19;89:17,21;90:9, 21;91:4;94:7;96:5,6; 97:1;99:5;102:2; 103:4;110:8;111:14, 21;112:2,11,17; 117:11;119:19; 191:14;198:7;219:8, 8,11;220:17;222:12; 223:10,15,15;224:1, 2;227:8;233:6,9,13; 234:16;244:4; 251:13;257:12; 258:7,12;260:10; 285:5;324:15 misleadingly (3) 89:13;118:8,10	misleadingness (6) 218:20;219:13; 221:12;223:18; 224:3,5 misled (1) 245:22 misnomer (1) 55:1 misperception (1) 260:10 misperceptions (1) 260:22 misrepresent (1) 89:1 misrepresentations (2) 95:22;216:14 misrepresents (1) 103:6 mission (6) 25:7;40:3;80:16; 87:1;102:11;312:10 mitigate (2) 160:14;163:22 mitigates (1) 183:5 mix (2) 59:18;127:12 mixed (1) 158:10 mix-up (1) 293:13 mobile (1) 7:17 mobilize (1) 320:8 models (2) 272:3;315:2 Modernization (2) 26:11,16 modernizing (1) 45:10 mole (1) 250:3 molecular (1) 291:14 molecule (31) 28:18;30:18;34:10; 128:12,13;129:7; 130:18;133:21; 134:1,2,3,7,11;135:1; 136:16;137:12; 138:17;139:1,11,19; 140:9;153:4,8; 154:14,15;155:3,3; 161:15;167:21; 169:4;287:15 molecules (22) 127:9;128:18,22; 130:5,13,15;133:10; 134:2,19;135:14; 140:18;142:2; 145:22;154:8;155:4; 167:22;268:15;	287:21;288:1;289:2; 290:12,16 Molly (2) 32:15;48:9 moment (9) 12:7,10,14;17:10; 20:7;39:10;138:3,10; 162:1 moments (1) 198:19 momentum (1) 17:7 Monday (2) 39:5;100:14 monetarily (1) 266:10 money (5) 148:12;230:3; 252:13,15;319:6 monitor (3) 84:4;295:18; 298:16 monitoring (2) 292:14;295:9 monoclonal (1) 283:13 monopolies (2) 234:4,4 monopolist (1) 243:5 monopolists (2) 243:7,13 monopolization (7) 229:6,9;232:18,19; 243:3,11;244:8 monopoly (13) 72:1;161:4,21; 229:10,11,17;230:10; 231:11;232:22; 236:9;243:15;246:2; 327:10 monster (2) 222:8,19 month (3) 13:15;299:11; 323:11 months (13) 11:9;17:6;143:6; 150:9;190:11;265:6, 7,17;267:11;271:16; 274:11;287:9;306:6 morally (2) 179:21;182:19 more (148) 7:13;13:10;17:12; 18:4,9,21;19:8,14; 21:9;25:16;27:19; 31:2,6,35;10:43;16; 48:2,7,10,12;49:13; 50:15;51:21;52:4; 53:11,14;55:14; 56:12;57:3,11;60:9; 61:16,20;63:21;64:6,	7,13;69:21;70:15; 74:8;78:2;80:12; 81:19;83:21,22;85:3; 86:3,3;89:19;90:8, 12;92:4;96:4;97:16; 99:15,18;111:11,12; 119:3;121:16;133:3, 13;134:1,20;137:11; 138:11;140:13; 144:20;146:6,20; 147:6;150:8,10,13; 154:7,15,19;158:6; 160:8;162:10,12; 163:4,19;164:10,13; 166:7;167:3;170:14; 175:21;176:8;192:2, 7,8;200:1,19;202:5; 204:3,3,20;209:22; 210:16;214:8,16; 215:21;217:12; 221:3;225:2;233:16; 235:10;240:15; 244:17,21;245:16; 264:1;265:2,14; 272:19;274:5; 276:12,12,13;277:9; 278:6,8,18;279:13; 283:9;287:21,22; 289:3,7,13;291:9; 293:9;295:20;296:2, 5,6;298:4;300:2; 303:20;304:11; 305:15;307:20; 311:4;312:9,14; 313:3;322:1 morning (28) 6:4;11:20;23:12; 31:12,16;39:4,7,22; 74:21;75:6;80:8; 91:19,20;92:3,8; 94:15;100:9;101:11; 122:20;128:3; 155:11;156:4;160:4; 166:11;174:12; 180:10;216:20; 287:18 most (42) 8:12;15:17;31:5; 39:19;43:18;60:20; 61:17;72:12;83:5; 85:9;86:8;96:18; 135:7;136:7;152:3; 175:13,16,17;177:18; 179:1,14;180:11; 181:6;183:14; 192:18;196:14; 200:11;203:3;208:1; 214:21;217:8; 237:18;241:8; 244:16;250:5;253:7; 267:6;274:9;292:19; 293:2;297:15;311:2 mostly (3)	155:12;219:4; 248:3 Mother (1) 186:9 motion (1) 250:5 motivate (1) 251:20 motivated (3) 133:16;192:14,22 motivation (1) 93:14 mouth (1) 252:14 mouthful (2) 14:11;201:1 move (8) 36:16;67:12; 138:11;185:11; 186:22;195:16; 241:21;255:15 moved (2) 41:16;183:21 movement (2) 129:14,14 moving (8) 9:5;14:4;60:14,19; 73:6;131:13;215:5; 248:11 much (47) 12:12;14:5;15:3; 16:7;17:1;18:1; 19:22;22:12;51:20; 52:4;55:3;61:16; 64:6,7,13;74:16; 91:13,20;114:11; 120:8;122:18,22; 136:11;139:2; 151:21;152:15; 154:14;156:13; 171:8;176:22;177:3; 205:22;208:16; 212:12;219:10; 220:20;230:1;234:2; 263:8,14;268:21; 275:16;278:1; 282:13;302:15; 303:3;323:16 multidisciplinary (1) 58:22 multiple (14) 40:1;64:9;87:8; 127:22;208:7;235:3; 258:14;269:6,18; 270:18;284:21; 295:5;305:13;310:4 multistakeholder (1) 174:22 multistakeholders (1) 297:5 murky (1) 159:7 Murray (7)
--	--	---	---	--

<p>125:8,12,15; 136:13;142:8; 150:21;168:5 Murray's (1) 170:20 muscle (1) 309:2 musculoskeletal (1) 191:8 must (16) 21:9;22:3,7;29:15; 87:3,22;104:6; 179:13;223:17; 269:11,13;284:5; 297:14;302:20; 311:4;315:5 myriad (1) 203:13 myself (2) 173:4;261:1 myth (1) 180:7</p>	<p>191:13;194:18 nature (3) 36:17;60:3;238:15 Navigating (2) 7:10;192:7 nearly (1) 319:16 near-term (1) 160:16 necessarily (6) 86:18;133:15; 139:9;163:21;199:6; 270:8 necessary (6) 42:2,6;94:22; 203:20;221:8;280:20 need (52) 6:21;7:7,8,9;16:22; 18:10;21:21;45:14; 69:21;70:4;85:2; 96:14;120:15;152:1, 4;154:18;157:7; 160:3;170:14;171:5; 175:2;193:12;195:7; 200:12;204:18,19,19; 215:4;238:2;242:15; 251:16;253:14; 254:15;257:11; 259:4,8,10;268:16; 269:6,9;271:16,21; 272:7;281:7;284:14; 290:21;294:17; 298:5;302:16;309:1; 318:17;319:20 needed (6) 30:13;69:5;71:9; 204:4;268:21;302:18 Needless (1) 269:13 needs (16) 10:1;45:15;154:1; 161:10;180:4;184:7; 194:21;196:2; 205:11;207:9; 235:14;249:4; 311:13;319:2; 322:15;323:3 negative (14) 75:21;99:7;102:3; 151:7;157:18; 159:11;181:20; 198:12,13;228:4; 258:3,8;263:5; 264:22 negatively (2) 110:12;181:20 negatives (1) 317:11 negotiate (2) 142:22;309:11 net (37) 95:5,7,16;112:7; 122:5;127:2,2,4;</p>	<p>129:3,18;131:5,7; 142:6,10;143:13,16, 18,21;144:11,12,19; 145:2,4,6,7,20; 146:11,14;147:2,8; 148:10;150:22; 151:10,12,21;218:2; 221:4 network (2) 62:18;208:21 networks (1) 58:2 Neulasta (1) 305:13 Neupogen (4) 305:12,14,16,17 neurology (1) 261:15 neutralization (1) 232:10 neutralize (2) 234:7,8 nevertheless (1) 276:7 new (33) 22:6;24:5;28:5; 51:7;74:2;84:2; 115:14;116:1; 127:12;129:16; 130:10,12;135:3; 164:3;187:17;237:7, 8,14;250:6;262:4; 263:19;265:3; 269:17;274:12; 281:11;291:14; 310:7,11;311:3; 315:12;321:18; 322:4,4 newer (1) 212:4 newly (1) 310:9 news (2) 42:18;77:20 NEXSYMEO (13) 114:18,20;115:1,2, 3,10,13;116:1,4,15; 117:15,20;118:9 NEXSYMEO's (6) 115:8,19;116:10, 16,17;117:5 next (37) 14:15;21:14;22:14; 36:16;47:13;74:17; 140:2;185:5,15; 190:16,19;191:1,4; 250:16;255:16; 259:22;267:17; 272:12;278:3; 280:20;283:3;288:3, 8;293:14;298:11; 300:7;303:5;307:7; 311:19;312:21;</p>	<p>315:18;320:13; 323:11 next-generation (2) 133:9,12 nice (2) 28:15;283:2 nine (2) 178:11;303:21 Ninth (1) 231:22 nocebo (8) 181:7,18,19;182:3, 5,8,19;188:21 no-go (1) 167:13 noise (2) 181:10,11 nomenclature (1) 106:12 nominal (1) 129:4 non-controversial (1) 159:14 none (2) 47:12;54:11 Nonetheless (1) 231:17 non-medical (5) 265:9;296:11,18; 319:2,10 non-medically (1) 319:4 non-misleading (25) 15:10;75:2;78:4; 79:8;80:13,19;82:11; 91:9;96:7,98:14; 99:12;101:22; 102:14;103:12; 104:7,18;105:6; 109:3,15;110:4; 121:7,15;122:3; 257:21;324:20 non-preferred (1) 43:20 nonprofit (1) 191:7 non-profit (1) 320:20 non-proprietary (1) 260:18 non-retail (6) 131:10,22;132:1,3, 4,5 non-US (4) 106:15,16;116:13; 117:8 normal (1) 191:22 normative (1) 240:3 north (2) 177:15;179:22 Notably (2)</p>	<p>26:21;35:7 note (11) 8:8;9:20;22:16; 35:11;87:15;100:5; 122:12;286:11; 290:4;299:10;329:8 noted (9) 46:18;47:3;82:13; 90:19;120:2;121:22; 156:5;174:11;313:9 notes (1) 325:2 noteworthy (1) 311:7 notice (7) 10:17;85:11;86:10; 120:3;130:16;325:9; 329:1 noticeable (1) 300:21 notification (1) 281:6 notion (1) 154:16 notwithstanding (2) 110:18;113:14 novel (1) 292:15 November (1) 210:19 nuance (1) 239:11 nuanced (6) 121:16;240:9,10; 252:3,6;254:11 number (34) 19:17;21:11;27:14; 47:3;54:4;59:21,22; 82:4;84:21;92:21; 95:20;102:20;130:1, 15,19;133:4;162:9; 163:5;181:19; 210:12;217:16; 221:10;228:6,21; 230:2;262:21;268:9; 269:1;270:4,11; 274:1;275:9;299:6; 308:17 numbers (3) 44:10;129:5,20 numeric (1) 117:22 numerical (1) 118:6 numerically (1) 117:14 numerous (3) 87:12;272:22; 308:16 nursing (1) 205:9</p>
N				
<p>naive (3) 35:20;211:22; 298:1 name (33) 26:5;31:16;48:3, 14;80:9;92:14;100:9; 105:10,10,10;106:6; 124:16,19;171:10; 172:19;190:18; 213:3;255:5;256:10; 260:3;263:18; 267:18;272:14; 283:5;288:7,15; 293:15;298:14; 300:9;303:7;311:21; 316:9;320:14 named (1) 158:19 namely (1) 261:4 names (3) 57:22;140:10; 260:18 naming (3) 43:10;272:5;273:8 nation (1) 273:2 national (7) 173:13;204:14; 209:12;264:6,12; 278:15;300:13 nation's (3) 289:4,5;303:11 Native (1) 250:10 natural (4) 163:10,10;166:3,5 naturally (2)</p>				

<p>O</p> <p>Oak (1) 12:3</p> <p>object (5) 115:6;116:5,8; 117:9;319:7</p> <p>objective (1) 171:21</p> <p>objectives (1) 13:17</p> <p>objectivity (1) 264:9</p> <p>obligating (1) 119:17</p> <p>obligations (1) 296:13</p> <p>observation (2) 85:11;86:10</p> <p>observe (2) 84:7;170:2</p> <p>observed (8) 52:11;90:18;91:2; 97:8;111:19;116:18; 118:1;300:21</p> <p>observes (1) 86:4</p> <p>obstacles (2) 20:17;308:16</p> <p>obtain (1) 85:15</p> <p>obtained (1) 305:16</p> <p>obtaining (1) 308:16</p> <p>obtains (1) 26:16</p> <p>obvious (2) 160:21;222:15</p> <p>obviously (17) 40:5;41:8;42:13; 52:19;78:16;80:2; 137:17;144:16; 156:3;169:5;191:20; 198:6;205:1;207:10; 210:6;253:5;317:20</p> <p>occasion (2) 97:21;198:19</p> <p>occur (2) 18:11;46:20</p> <p>occurrence (1) 111:18</p> <p>occurrences (1) 300:17</p> <p>occurs (1) 319:10</p> <p>o'clock (2) 10:15;131:13</p> <p>October (1) 196:14</p> <p>off (10) 6:12;33:4,18;</p>	<p>53:21;64:18;78:17; 233:2;234:17; 236:22;237:2</p> <p>offer (5) 13:12;75:7;251:10; 253:17;289:15</p> <p>offered (3) 16:4;251:9;310:10</p> <p>offering (3) 304:15;309:22; 321:20</p> <p>offerings (2) 30:1;267:1</p> <p>offers (6) 16:2;239:2,3,3,4; 319:11</p> <p>Office (18) 6:10;23:6;33:1; 44:18;79:14;80:10; 100:12;102:7,8; 124:17;125:6;132:2; 171:12;172:9;210:1; 250:12;255:6;256:15</p> <p>officer (2) 8:19;32:12</p> <p>offices (2) 61:1;301:1</p> <p>Often (15) 24:20;33:12;86:21; 88:16;89:15;142:18, 21;164:11,11; 198:19;200:19; 218:16;252:17; 265:13;299:6</p> <p>oftentimes (1) 159:4</p> <p>Ohio (2) 260:1,4</p> <p>ok (1) 177:10</p> <p>old (4) 77:18,18;133:5; 312:13</p> <p>omission (2) 87:14,16</p> <p>omissions (1) 91:1</p> <p>omits (2) 77:4;198:10</p> <p>omnipresent (1) 64:7</p> <p>ON/R (1) 269:5</p> <p>once (16) 9:9;35:4;54:3; 57:18;145:3;147:6; 158:2;187:17; 189:12;190:15; 197:4;219:15;234:8; 250:8;266:6;268:18</p> <p>oncology (6) 59:1,17;186:13; 261:14;271:13;</p>	<p>305:21</p> <p>one (98) 10:5;13:1;16:2; 17:19;21:22;25:15; 36:5,5;41:4;48:22; 50:3,21;58:12;70:20; 71:8;72:7;73:20; 78:6;88:20;90:12; 96:4,4,5;98:10; 101:22;113:22; 124:7;128:16;134:1, 20;138:15,22;141:9, 19;144:9,21;147:4,9; 153:2;156:19,20; 167:17;168:18; 169:1,3,16;170:14; 172:17;181:4,6,19; 185:10;188:16; 190:16;197:7;199:6; 208:1,18;210:12; 211:19;218:2;224:6; 225:19;226:22; 227:2;230:4,13; 234:5,15;237:1; 238:3;239:15,17; 241:3;242:20; 244:19;247:4; 249:10;250:21; 264:15,19;268:9; 275:11,13;276:11; 287:1;292:4;293:2; 296:7;299:6;302:8; 304:13;311:10; 317:4,22;318:5; 319:13;328:14</p> <p>ones (10) 41:15;85:9;130:20; 148:2;149:19;152:3; 155:11;190:16; 232:22;266:4</p> <p>ongoing (2) 56:2;258:10</p> <p>online (3) 196:6;207:14; 208:19</p> <p>only (54) 16:20;20:10;24:20; 29:5;45:21;49:17; 54:13;62:14;66:21, 22;92:18;96:4,4; 103:15;122:4,13; 127:19;128:9;131:6; 143:10,18;144:21; 147:4;148:21;150:4, 19;156:5;186:5; 189:22;200:20,20; 201:19;203:11; 223:9;224:1;227:13; 243:6,12;252:5; 258:13;259:8; 269:19;272:16; 273:16;274:12; 288:20;297:3,11;</p>	<p>301:9;305:1;318:9; 319:5,12,13</p> <p>Ontario (1) 183:17</p> <p>onto (1) 54:12</p> <p>opacity (1) 318:2</p> <p>OPDP (20) 79:14,16,17;80:12; 81:3;82:8,10,19,22; 83:3;84:3,6,11,19; 86:4,21;100:12; 101:2;102:16;256:19</p> <p>OPDP'S (11) 80:16;82:16;83:10, 12,17,20;84:16; 90:19;91:8;102:11; 119:3</p> <p>open (11) 9:8;10:3;45:19; 163:11;228:14; 249:7;255:2,8; 294:13;322:6;328:20</p> <p>opening (3) 11:16,19;23:11</p> <p>opens (1) 10:11</p> <p>operate (1) 278:17</p> <p>Operating (1) 179:9</p> <p>operations (1) 227:18</p> <p>opinions (1) 8:9</p> <p>opportunities (7) 68:15,22;166:14; 167:4;290:19;313:3; 326:1</p> <p>opportunity (28) 10:11;68:2,5; 78:14;154:1;209:2; 253:18;257:11; 260:3;263:13; 267:12;270:6; 272:10;278:12; 281:21;286:22; 290:14;293:22; 298:6,14;300:4; 304:5;307:16;312:2; 320:17;323:20; 324:5;328:1</p> <p>opposed (2) 155:2;326:7</p> <p>opposite (1) 186:10</p> <p>opposition (1) 268:13</p> <p>optimal (1) 159:1</p> <p>optimism (2) 41:10;44:1</p>	<p>optimist (2) 40:13,14</p> <p>optimistic (2) 40:12;41:4</p> <p>optimize (1) 326:1</p> <p>option (2) 29:3;311:9</p> <p>options (11) 28:1;75:14;240:22; 250:22;274:12,13; 284:15;302:7; 304:21;305:6;324:12</p> <p>oral (2) 10:8,12</p> <p>Orange (1) 314:15</p> <p>order (8) 42:14;113:11; 128:8;227:15,17; 271:2;294:15;295:9</p> <p>ordered (2) 9:18;227:10</p> <p>ordering (1) 188:9</p> <p>ordinary (1) 225:5</p> <p>Orekonty (3) 298:11,13,15</p> <p>organ (1) 294:8</p> <p>organic (1) 222:5</p> <p>organization (20) 15:4;22:2;147:21; 178:3,14;179:4; 180:5,12;191:7; 215:11;264:1; 272:17,18;273:6; 274:7,18;300:13; 316:5,14;320:20</p> <p>organizations (19) 99:4;147:17; 148:22;149:19; 150:1,6;175:3;183:2; 193:4,20;194:3; 196:12,21;203:13; 204:6;205:14; 263:21;274:3;300:8</p> <p>organize (2) 214:14;240:8</p> <p>organized (1) 124:6</p> <p>organizing (1) 177:7</p> <p>oriented (2) 127:20;130:21</p> <p>original (4) 50:11;63:17; 206:16;216:2</p> <p>Originally (2) 150:11;310:22</p> <p>origination (1)</p>
---	---	--	--	--

<p>291:19 originator (16) 51:2,8;141:11,21; 144:12;146:9; 181:16;182:10; 183:20;187:19; 188:22;189:4;263:1; 271:3;273:18;292:6 originators (7) 181:16;182:14; 210:20;249:2; 264:15;265:19;270:6 Orleans (1) 263:19 OTC (1) 92:5 others (19) 25:1;49:20;50:14; 53:13;61:18;63:12; 75:10;76:5;100:1; 136:20;147:4; 148:18;196:22; 198:7;217:13;253:5; 258:5;259:11;287:21 otherwise (6) 9:15;54:18;55:4; 106:15;119:11; 208:12 ourselves (3) 164:10;183:9; 222:18 out (57) 8:18;33:21;36:3; 42:10;45:1;54:4; 55:20;58:16;66:14, 21;67:14;70:14,20; 90:17;92:19;96:19; 125:17,21;127:10,12; 128:12;132:9,14; 135:6;143:6;151:15; 160:3;185:11;186:7; 190:6,7;193:5,10; 200:5;201:3,7; 203:17,18,20;207:5; 209:15;210:18; 212:8;215:15; 223:19;224:22; 243:2,18;248:6; 249:19;250:2,9; 259:9;266:15;282:9; 297:6;328:14 outbreak (3) 12:11,19;291:21 outcome (2) 149:13;198:15 outcomes (4) 116:18;295:18; 301:19;318:18 outlined (4) 13:16;109:19; 119:9;326:8 outlook (1) 60:3</p>	<p>out-of-patient (1) 162:6 out-of-pocket (1) 152:14 output (2) 229:19;239:1 outreach (4) 73:15;172:14; 174:10;306:19 outside (9) 7:21;10:14;45:16; 53:15;69:1;92:11; 169:17;179:17;329:2 outweigh (1) 301:16 over (46) 18:7;37:11;50:9, 17;61:22;62:1;66:18; 73:2;81:14;91:15; 93:21;94:10;101:8; 114:7;120:9;129:8; 144:19;148:17; 149:10;158:17; 162:22;163:18; 165:15;166:2,12; 167:1;171:4;172:15; 173:12;176:20; 197:21;198:2;206:5; 222:4;249:2;259:1,2; 264:12;276:20; 286:9;304:2;305:17; 306:6;312:21;318:1; 328:5 overabundance (1) 296:9 overall (19) 18:14;60:3;65:8; 75:13;77:5;117:14, 22;122:10;125:17, 19;126:12;127:8; 131:7;133:19;136:1; 231:15;239:13; 284:4;322:21 overarching (2) 80:16;102:11 overcome (2) 72:10;310:13 overconsolidation (1) 302:16 overflow (1) 8:3 overly (1) 302:2 oversees (1) 173:18 overstate (1) 88:20 overstated (2) 63:10;130:11 overstatement (1) 88:17 overtly (2) 76:22;77:1</p>	<p>overview (4) 79:12;124:11; 174:9;218:14 overwhelming (1) 77:22 own (12) 78:7;88:6;180:1,5; 196:21;224:21; 236:5;247:19; 252:20;273:15; 276:5;302:13</p> <p style="text-align: center;">P</p> <p>PA (1) 64:9 pace (2) 147:12;320:4 package (4) 89:8;90:5,6;226:16 packer (2) 81:2,16 packers (2) 91:11;104:1 page (3) 88:9;176:18; 214:10 pages (2) 87:8;206:13 paid (5) 93:10;137:6;149:1, 14;265:12 painful (1) 284:13 palatable (1) 69:12 Palm (1) 227:3 panel (37) 9:9,21;31:19;32:3; 37:11;44:5;70:8; 74:17,17,22;90:3; 98:8;120:10;122:19; 124:4,6;136:8,22; 167:10,12;172:6,11, 16;181:7;189:15; 206:2;208:4;214:8; 218:1,9;225:9; 254:22;255:12,14; 275:8,11,14 panelist (1) 246:13 panelists (13) 32:1;60:8;79:11; 124:8,14;172:15,17; 177:9;206:6;209:7; 212:9;256:12;328:9 panels (2) 9:7;174:12 paper (5) 50:6;144:2,4; 147:13;149:21 parachuted (1)</p>	<p>177:14 paradigm (2) 211:9;218:10 parallel (7) 33:15;34:9;74:5; 144:11;145:2,6; 286:16 parallels (3) 33:12;71:4,5 paramount (1) 180:6 paraphrase (1) 65:18 parity (2) 195:19;196:6 part (41) 8:12;23:22;43:12; 47:9;48:11,12;51:11; 59:8;67:16;75:17; 78:2;82:15;83:10; 112:16;115:9,19; 116:10;126:9; 128:12,14,19;129:10; 131:16;132:1; 154:21,21;158:14; 159:3;170:7;179:5; 192:6,12;211:17; 227:8;239:13; 250:18;270:12; 271:2;275:5,19; 278:11 partes (2) 55:8,12 participant (1) 8:11 participants (6) 9:22;164:9,12,15; 166:4,19 participating (2) 328:10;329:9 participation (1) 15:7 particular (22) 50:13;51:14;57:4; 83:8;86:19;94:19; 97:20;106:3;111:19; 112:14;133:10; 170:19;179:12; 188:1,16;189:2; 199:7;228:9;287:22; 296:19;313:22; 326:21 particularly (17) 16:6;19:3;41:21; 42:9;61:8;81:12; 85:8;96:3;127:15; 130:21;133:16; 167:2,16;265:4; 267:9;276:9;315:2 parties (2) 108:14;202:2 partner (4) 12:5;173:14;</p>	<p>178:16;195:5 partners (3) 14:14;19:4;195:11 partnership (5) 14:17;15:8;20:6; 21:18;22:15 Parts (4) 82:6;128:7;132:10; 170:18 party (1) 247:4 pass (2) 91:15;125:13 passage (1) 147:14 passed (2) 17:8;77:9 passionate (2) 23:4,18 past (12) 8:13;30:15;44:9; 58:20;130:20; 133:14;178:5,5; 197:21;236:5; 264:13;286:10 patent (23) 26:6,13,17;30:19; 42:13,13;50:5,16; 53:20;54:14,15,21; 55:13;71:17;165:4; 236:17;250:11; 271:5,6;280:6,17,17; 308:19 patenting (1) 161:3 patents (12) 50:10;53:16;54:2, 4;55:10;78:12; 129:16;158:13,13; 160:21;250:10; 314:14 path (1) 78:1 pathway (20) 27:21;28:2,5,9; 34:6,7;72:13,15; 141:17;142:3; 201:14,16,17,19,20; 211:6;279:18; 283:17;303:22; 325:14 pathways (2) 33:22;34:9 patient (119) 6:20;15:21;16:8; 38:6,16;68:10;75:8; 90:14;97:13;142:17, 18;147:19;148:1; 159:18,22;162:3; 173:11,13,14,19; 174:5;175:3;176:12; 178:3,14;179:3; 180:20;183:2,7,7;</p>
---	--	---	--	--

<p>184:19;191:7,10; 192:6,13;193:3,4,15, 17,19;194:4,7,19; 195:8;196:5,12; 198:14;202:7,9,10; 204:4,5,11,16; 206:22;208:10,17; 211:15;212:6,10; 216:9;220:11; 228:15;246:20; 248:1;262:5,6;264:2; 265:5,8,11;266:9; 273:13;274:2,3,10, 18,21;277:9;289:1, 12;293:22;294:21; 295:10;296:22; 297:4,14,20;298:1,8; 299:4;301:4,8,17; 304:15;306:20; 307:8,12,13;309:12, 13;311:4;313:4,16; 317:3,18,18;318:3,5, 6,12,15,19;319:5,6, 12;320:7,9;326:17</p> <p>patient-centered (1) 272:20</p> <p>patient-centric (1) 286:17</p> <p>patient-days (1) 210:15</p> <p>patient-doctor (1) 284:11</p> <p>patient-focused (1) 268:12</p> <p>patient-friendly (1) 175:15</p> <p>patient-reported (1) 295:18</p> <p>patients (165) 7:6,13;15:10,16; 16:9,20;20:22;21:21; 22:8;29:9,22;35:18; 40:2;48:16;55:3; 62:8;63:3,5;68:12; 69:10;72:22;75:10; 76:5,9,12;77:10,12, 20;90:8,95;11:99;12; 110:6;115:13,15,22; 116:1,12;117:13,15; 151:16,18;152:2,8, 10;155:15;174:17; 175:14,17;176:4,7, 10,14;181:9;182:9; 185:19,21;187:17,18; 188:11,13,19;189:11, 21;190:10;191:15; 192:10;193:8; 194:14,21;195:13; 197:10;199:16; 202:9;203:1,3,12; 204:18;206:14; 207:1;208:22; 209:10;211:7,21;</p>	<p>228:17;233:18; 237:5,7,7,8,14; 247:11,19;248:8,9; 257:20;258:4,9,20; 259:11,15,18;264:4; 265:14,16,20;267:3, 8,11;268:2,4,21; 269:21;273:14; 274:4;275:3;281:7, 10,18;283:18,22; 284:12,18,22;285:5; 286:19;287:10; 292:20;294:11,19; 295:19;296:17; 297:3,19;299:8; 302:4;304:7,21; 305:7;306:3,13; 307:20;309:9,16; 310:16,18,20;311:16, 17;312:8;314:5; 315:13,16;316:15,17; 317:6,14,21;318:11; 319:3,12;320:2; 324:13;327:5,13,21</p> <p>patient's (4) 209:21;266:11; 269:14;309:14</p> <p>patients' (3) 172:2;302:6; 309:14</p> <p>patient-specific (1) 66:6</p> <p>pattern (3) 129:21;258:3; 277:2</p> <p>pause (3) 40:7;114:12;136:3</p> <p>pave (1) 26:2</p> <p>pay (10) 74:2;128:1;140:20, 21;155:20;190:2; 192:4;236:21;247:7; 317:19</p> <p>payer (14) 131:6,14;137:9,18; 138:20;139:4,6; 154:16;166:20; 262:19;289:18; 292:18;296:9;310:21</p> <p>payers (21) 137:6;143:19; 144:1,15;146:12; 152:1;155:13; 160:16;174:17; 179:21;233:18; 259:11;265:9; 285:11,14;294:20; 297:5;306:3,14; 309:10;314:6</p> <p>payer's (1) 267:10</p> <p>pay-for-delay (3)</p>	<p>55:2;236:20; 308:20</p> <p>paying (10) 140:13,19,22; 142:13;148:2,6; 152:8;155:20;237:1; 319:17</p> <p>payment (9) 27:3,12,15;30:21; 128:6;154:19;293:1; 304:6;315:2</p> <p>payments (1) 152:14</p> <p>payors (1) 247:7</p> <p>PBM (5) 49:11;301:22; 302:14,22;319:6</p> <p>PBMs (4) 247:12;309:9; 310:1;311:11</p> <p>PCMA (3) 278:14,15;279:2</p> <p>PDLs (1) 150:11</p> <p>pediatric (1) 289:7</p> <p>peer-reviewed (1) 93:16</p> <p>peers (3) 208:17,17,18</p> <p>peer-to-peer (1) 195:7</p> <p>pegfilgrastim (3) 61:16;66:15; 144:21</p> <p>pending (1) 249:13</p> <p>penetration (4) 149:22;244:21; 245:5,13</p> <p>people (45) 7:9;12:16;18:6; 23:2;45:15;73:12; 92:2;136:22;168:2, 11,20;169:7;175:4,5; 184:7;187:19,20; 198:5;199:1,11,22; 200:19;201:18; 203:19;204:9; 207:10,13,18,21; 208:12;209:1,2,3,18, 18;210:13;215:1; 219:22;220:14; 225:21;256:4;274:5; 275:10;294:2;298:2</p> <p>people's (1) 277:12</p> <p>Pepinsky (4) 100:17;101:9,10; 121:20</p> <p>per (3) 129:18;130:1;</p>	<p>143:17</p> <p>percent (71) 17:15,21;18:2,15, 17;50:10;61:10,17; 67:17,19;71:11,12; 129:6,8,8;130:5,6,7, 12,13;131:9,10,15, 17,18,19,20,21; 132:2,3,4,5,6;134:5, 6,10,18;135:4,20; 149:11;184:4,5; 186:22;187:7;189:5, 10;190:14;221:3; 229:14,16;230:6,6,7; 243:13;245:8,9,11; 262:1,3,14;270:22; 276:20;277:1;286:4; 289:4,5,8;306:5; 308:2,4,15</p> <p>percentage (3) 64:1;133:22; 134:14</p> <p>perception (5) 198:13;222:13; 260:21;266:14;270:7</p> <p>perceptions (4) 172:3;224:17; 263:5;325:12</p> <p>performance (1) 288:18</p> <p>performing (3) 220:7,8,8</p> <p>Perhaps (15) 27:13;77:4;139:18; 166:3;189:3,5,10; 207:6;217:8;229:15; 239:20;242:20; 247:21;261:19; 264:10</p> <p>period (19) 9:9;10:3;16:14; 45:19;57:13;78:14; 129:9;158:16,18,22; 159:1;161:5,21; 165:3;190:14;215:2; 255:15;275:22; 282:17</p> <p>periods (2) 232:9;234:3</p> <p>Permanente (5) 173:21;185:20; 187:14;189:16; 204:10</p> <p>permission (1) 187:8</p> <p>permitted (1) 9:14</p> <p>perniciousness (1) 58:9</p> <p>persistence (1) 328:17</p> <p>person (10) 12:1;95:6,9;130:1;</p>	<p>177:4;178:4;297:16; 300:5;319:17;328:11</p> <p>personal (2) 296:14;297:12</p> <p>personalized (1) 323:15</p> <p>personally (3) 192:13,22;261:1</p> <p>perspective (28) 6:20;10:19;25:4; 29:21;33:11;45:14; 126:13;127:3;135:9; 137:19;157:3; 177:15;193:15; 195:8,9;212:6;225:7; 240:4;248:2,4,20; 257:11;284:7;290:1; 298:7;303:10;320:7; 323:21</p> <p>perspectives (3) 8:8;264:3;284:17</p> <p>persuaded (1) 247:22</p> <p>perverse (1) 309:10</p> <p>pessimism (1) 136:12</p> <p>petition (2) 216:4;324:17</p> <p>petitioning (1) 302:19</p> <p>petitions (1) 239:9</p> <p>Pfizer (16) 216:3;230:4,5; 253:11,12;257:9; 258:18;324:2,5,16, 21;325:10,20; 326:21;327:7,22</p> <p>Pharma (4) 143:12,17;249:22; 250:9</p> <p>pharmaceutical (19) 25:14;26:20;55:11; 140:17;142:13,15,20, 21;143:1;155:12; 249:22;254:14; 278:4,13;283:8; 289:11;291:18; 316:3,6</p> <p>pharmaceuticals (2) 24:2;27:16</p> <p>pharmacies (3) 126:8;140:5; 278:18</p> <p>pharmacist (4) 47:2,17;66:22; 278:6</p> <p>pharmacists (10) 25:18;48:13; 186:10;188:12; 189:9;264:4;291:11; 292:10;294:20;302:5</p>
---	---	---	---	---

<p>Pharmacopeia (1) 320:16</p> <p>pharmacovigilance (1) 273:9</p> <p>pharmacovigilant (2) 267:9;295:8</p> <p>Pharmacy (45) 32:12;46:16,20,21; 48:11;49:4;51:5,17; 52:2;60:21;61:13,21, 22;62:14,17;63:4; 64:12,12;65:6,14; 66:18,20,20;67:1,6,9; 137:13;142:17,19; 156:6;173:22; 185:22;186:16; 205:9;260:1,4;266:3; 270:2;273:3;278:8, 10,16;288:16; 301:22;302:22</p> <p>pharmacy-level (1) 200:13</p> <p>pharmacy's (1) 62:18</p> <p>phase (2) 41:22;127:17</p> <p>phenomenal (1) 275:20</p> <p>Philip (2) 259:22;260:3</p> <p>phones (1) 7:17</p> <p>phrase (1) 96:17</p> <p>PhRMA (7) 311:20;312:1,2,5, 10;313:14;314:7</p> <p>physician (15) 46:15;65:10;95:10; 185:18;186:8; 192:19;193:1; 195:13;247:21; 261:6,7;262:17; 264:2;266:10;314:1</p> <p>physician-administered (1) 47:5</p> <p>physician-led (1) 70:9</p> <p>physicians (42) 29:9;30:1;59:8; 65:16;69:10;72:21; 186:11;187:6; 188:13;189:2,13; 190:9,15;199:15; 200:9,14;202:7,8; 204:19;209:10; 212:3;228:10; 246:16;258:9; 261:10,12,15,17,20; 264:4,9;265:22; 266:21;274:22; 275:4;291:12; 292:10;297:18;</p>	<p>317:21;318:21; 319:3;327:20</p> <p>physicians' (1) 302:7</p> <p>picture (7) 36:8;61:5,12; 129:2;142:14;229:5; 249:21</p> <p>piece (13) 47:6;60:13;86:16, 19;88:5;102:1;122:8; 165:17;171:5; 175:20;178:22; 229:11;239:10</p> <p>pieces (3) 36:22;128:5; 176:13</p> <p>pioneered (1) 283:12</p> <p>pipeline (5) 127:13,15,16; 130:9,22</p> <p>Pittsburgh (1) 124:20</p> <p>PK/PD (1) 272:3</p> <p>place (8) 14:22;33:21;58:14; 136:2;167:7;205:22; 244:15;255:18</p> <p>placed (1) 328:22</p> <p>placement (2) 142:22;266:3</p> <p>places (1) 276:7</p> <p>plaintiff (10) 219:1,3,13;220:9; 221:5;228:14;232:3; 234:7;244:3;253:12</p> <p>plaintiffs (1) 218:16</p> <p>plan (11) 45:1,7;49:11;61:1; 74:4;82:16;186:7; 279:9;311:5;313:22; 323:11</p> <p>planned (1) 9:7</p> <p>Planning (4) 23:6;24:12;172:9; 205:6</p> <p>plans (7) 142:18;151:18; 278:17;309:9;310:1; 311:2,11</p> <p>platforms (1) 299:15</p> <p>play (19) 38:17;46:9;58:8; 60:19;70:9;77:18; 128:12;132:14; 140:8;146:4,18;</p>	<p>169:6;193:6;236:7, 10;240:12,17;246:7; 254:15</p> <p>playbook (4) 71:19;77:18;168:9, 12</p> <p>played (2) 117:3;195:15</p> <p>player (1) 301:7</p> <p>players (2) 170:14;253:4</p> <p>playing (7) 16:17;22:7;99:14; 125:21;127:10; 285:19;304:22</p> <p>plays (5) 25:12;193:1;194:1; 197:2,8</p> <p>please (11) 7:16;8:8,20,22; 10:13,22;91:12; 256:2,5,7,8</p> <p>pleased (5) 11:21;23:19; 171:13;263:9;295:1</p> <p>pleasure (2) 11:4;22:16</p> <p>plenty (2) 24:13;228:16</p> <p>plus (7) 67:16,17,19,19,22; 166:17;270:22</p> <p>pm (3) 124:2;212:22; 329:12</p> <p>podium (1) 255:20</p> <p>point (32) 10:7;13:14,14; 20:5;37:18;41:10; 44:22;45:3;48:9; 58:13;61:9,19;62:4; 96:2;122:19;139:16; 144:22;147:5; 151:15;155:18; 169:2;170:21; 184:13;190:7; 193:11;211:5;223:2; 226:9;252:13,21; 269:22;287:18</p> <p>pointed (2) 55:20;243:17</p> <p>points (5) 53:4;59:14;127:6; 249:19;284:8</p> <p>poisons (1) 241:5</p> <p>policies (20) 43:10;164:3;167:8; 174:5;183:12;259:6; 260:17;262:20; 272:20;285:16;</p>	<p>293:2;296:10;297:7; 305:8;306:9;310:20; 311:3;312:11; 315:11,14</p> <p>policy (31) 6:9;9:11;23:6; 32:16;33:1;44:19; 75:4;79:16;83:18; 100:11;101:3,4; 157:16;159:4,5; 160:7;172:8,9; 183:14,19;211:7; 238:4;256:15,18; 286:17;311:9;312:1; 315:19;316:10; 324:2,5</p> <p>policymakers (9) 165:9,20;167:5; 179:20;264:5; 314:11,22;315:5,10</p> <p>polishing (1) 129:5</p> <p>polled (1) 264:13</p> <p>pops (1) 188:10</p> <p>population (5) 129:21;177:18; 207:20,20;290:2</p> <p>populations (1) 90:15</p> <p>portfolio (1) 304:17</p> <p>portion (1) 255:4</p> <p>portrayed (1) 222:7</p> <p>portraying (1) 222:5</p> <p>pose (2) 85:9;159:20</p> <p>poses (1) 81:12</p> <p>position (6) 23:5;94:21;136:10; 183:10;242:1;253:7</p> <p>positioned (1) 179:22</p> <p>positions (2) 205:18,20</p> <p>positive (14) 13:12;73:6;151:5; 183:4;202:14,18; 209:2;210:7,9; 270:13,21;275:2,17; 318:8</p> <p>positives (1) 317:11</p> <p>possibilities (1) 226:1</p> <p>possibility (2) 238:18;287:11</p> <p>possible (19)</p>	<p>14:6,21;20:1; 54:18;63:2;77:5; 96:8;111:22;138:9; 157:9;165:9;168:22; 205:2;210:10; 231:10;236:3; 250:21;253:9;279:11</p> <p>possibly (1) 277:20</p> <p>Post (2) 214:22;260:12</p> <p>post-approval (2) 31:22;326:19</p> <p>posted (1) 329:4</p> <p>postmarketing (5) 84:10;118:22; 283:11;295:8,11</p> <p>post-starting (1) 188:14</p> <p>potency (4) 110:21;111:6; 113:18;117:19</p> <p>potent (1) 34:5</p> <p>potential (16) 13:12;16:3;21:1,5; 38:15;43:20;53:22; 156:7;170:9;194:22; 199:22;206:18; 294:16;295:22; 304:20;310:13</p> <p>potentially (14) 15:22;26:13;27:14; 43:19;47:15;77:6; 84:18;97:17;220:19, 19;223:15;224:1; 227:2,8</p> <p>power (17) 22:22;178:22; 229:10,11,17,20; 230:9,10;231:11; 232:22;236:9; 240:12;246:2;302:3; 309:21;319:14,15</p> <p>practical (2) 225:1;269:22</p> <p>Practically (1) 270:4</p> <p>practice (17) 29:20;62:8,19; 63:21,21;65:21; 66:13;68:7;261:13, 16;263:19;270:4; 278:7;288:16; 300:12;310:18; 327:11</p> <p>practices (23) 7:12;25:10;42:17; 52:5;58:22;59:1,2; 63:11;79:20,22; 91:17;94:3;160:15; 197:6;240:14;261:8;</p>
---	---	--	--	---

<p>270:3;273:3;300:21; 309:3;318:20; 319:21;327:8 preauthorization (1) 187:5 precedence (1) 268:19 precipitously (1) 27:15 precisely (1) 216:14 predecessor (1) 13:6 predictability (1) 165:6 predictable (1) 165:2 preeminent (1) 302:1 preferred (18) 43:20;64:15;66:21; 148:16;149:3,5,7,9, 10,20;150:7,8,10,13; 266:5;305:17; 309:21;310:21 premised (1) 22:3 premium (2) 74:3;219:12 premiums (2) 151:13;162:5 prepared (2) 32:6;124:9 preparedness (1) 73:4 preparing (1) 328:16 preregister (1) 8:1 preregistered (2) 10:9,10 prescribe (6) 66:8,16;166:6; 200:10;247:6;261:15 prescribed (2) 96:22;311:1 prescriber (3) 67:4;96:15;166:21 prescribers (4) 58:18;166:5; 257:20;262:1 prescribing (5) 246:15;247:19; 262:4;264:18;290:3 Prescription (56) 14:9;17:11;18:14, 16,17,20;79:9,14; 80:11,14,17,21,22; 81:11,15;82:2,6,12; 83:15;84:18;85:8; 86:1,4,22;87:17,21; 89:4,16,18;90:2,4; 91:11;92:7,96:15;</p>	<p>98:20;99:3,6;100:12, 20;101:5,15;102:7, 13;104:2,15;119:2,6, 14;122:17;278:17; 280:10;298:16; 299:1,7,22;309:6 prescriptions (2) 308:3;310:12 presence (3) 49:4,12;88:11 present (14) 10:6;80:12;90:21; 105:3;116:16;141:7; 144:2;153:18; 156:11;255:11; 272:10;320:17; 323:20;324:6 presentation (49) 10:8;33:5,6,9;39:2; 80:6;86:6,20;88:2; 90:17;91:7,18;101:9; 104:17,22;106:4; 111:8,15;112:2; 114:2,9;115:7;116:6, 9,19;117:9,10;118:8; 122:3,9,16;124:7; 125:12,15;141:4,5; 150:15;152:21; 156:12;162:2,10; 172:13;176:22; 177:2;185:16;191:2; 197:14;214:17; 218:12 presentations (22) 8:15;9:6,10;10:12; 32:3;89:18;100:6; 103:4;104:16; 105:22;106:10; 108:22;111:1,2,9; 112:6,12,18;121:17, 21;328:13;329:5 presented (10) 56:11;87:10,22; 88:13;104:20; 105:15;108:16; 118:12;198:9;317:9 presenting (3) 172:18;206:5; 224:3 presents (4) 79:4;88:7;89:5; 217:22 preserving (1) 306:20 presided (1) 264:12 president (11) 257:8,9;263:20; 267:19;283:4,6; 288:4,16;311:20,22; 320:15 press (2) 8:19;93:16</p>	<p>pressure (1) 146:3 prestigious (1) 214:9 presumably (1) 162:5 presume (1) 243:3 presumed (1) 221:9 presumes (2) 241:4,10 presumption (5) 232:1,2;234:18; 243:6;244:8 pretend (1) 254:4 pretty (12) 38:22;51:19;94:12; 133:5;139:2;144:6; 150:2;239:11; 248:20;252:3,6; 253:21 prevail (1) 221:6 prevent (8) 16:12;27:10;72:1; 105:21;151:8;205:3; 310:8;327:20 prevented (1) 25:18 preventing (2) 25:8;258:15 previous (3) 82:13;182:12; 251:5 previously (1) 314:19 price (63) 17:20;18:1;25:22; 28:21;31:7;66:3; 67:17;93:7;126:16, 17,21;129:3;131:4,8; 132:19;140:13; 142:9,11;143:21; 144:17,19;146:9; 147:8;148:6,9,11; 150:20;151:17,20,22; 152:5,11;153:9; 154:9;162:13,14,16; 229:17,18;230:5; 239:1;245:5,12; 246:7,11;247:2,4; 267:2,4;277:6;286:4, 8;296:1;306:1,10; 308:9;309:15;313:8; 316:22;317:19; 318:7;319:18,22 price-based (1) 170:6 priced (3) 265:14;286:5; 318:17</p>	<p>prices (42) 20:10;25:12;29:4; 72:1;74:9,12;127:2; 131:5,7;140:10; 141:10;142:6,6,12; 144:11,12;145:2,3,4, 6,7,18,20;146:3,11, 14;147:3;150:22; 151:10,12,16;152:22; 162:15;163:15; 170:4;266:4;276:13; 286:1;305:22;307:2; 309:11;313:12 pricing (7) 60:5;135:10; 153:22;156:2; 163:17;289:14; 318:21 prides (1) 254:2 primarily (4) 101:4;192:16; 197:20;291:22 primary (5) 26:12;46:18;79:22; 81:19;89:8 principal (1) 75:4 principles (4) 94:10;109:19; 174:4;313:10 print (2) 196:6;203:18 printed (1) 207:14 Prior (4) 23:4;41:6;64:5; 83:1 priorities (3) 30:10;45:16; 196:16 prioritize (1) 311:13 prioritizing (1) 294:21 priority (1) 44:21 private (18) 213:6,9;218:10,15; 224:9,9;238:6; 239:20;240:3; 251:18,21;252:11,19; 253:1,6;263:19; 300:12;316:4 privilege (1) 273:22 proactive (2) 259:9;295:20 proactively (2) 259:6,12 probably (13) 44:17;64:11;72:12; 151:22;152:2;177:5;</p>	<p>184:3;200:19; 210:11;218:17; 219:3;221:17;226:2 problem (5) 201:15;236:4; 241:2;247:10;251:8 problematic (1) 167:17 problems (2) 197:20;234:9 procedural (1) 9:4 procedures (1) 9:12 proceed (1) 215:4 proceedings (2) 9:16;261:4 process (25) 19:12,18;27:2; 31:22;42:16;55:9; 82:19,21;118:19; 138:4;159:15;163:6; 165:14,16;267:7; 268:18;277:14,18; 289:18,21;298:9; 302:21;322:7;326:2, 19 processes (1) 236:15 pro-competitive (2) 54:16,22 procure (3) 66:2,3;74:11 procurement (2) 51:19;57:15 procurers (1) 51:4 produce (1) 207:17 produced (1) 16:10 producer (1) 222:5 producers (1) 230:7 produces (1) 228:3 product (176) 6:19;14:1;17:20, 21,22;19:11;21:3,12; 34:4;35:3,3,4,6,7,8, 14,17,19,21,21;37:6, 8,9;38:4,6,9;46:5,13, 14,15,16;48:3;60:18; 64:15;66:22;69:16; 70:7;76:3,4,7,17,20; 80:18;83:7;89:5; 90:3;93:2,4,7,9; 96:10,11,14,16,22; 97:9,14,15,15;103:5, 16;105:9,12,16,18, 20;106:1,3,7,9;107:9,</p>
--	--	--	---	---

<p>12,14,19,21;108:9; 21;109:4,8;110:18; 111:4,10,13,16; 112:6,9,10,14,20,21; 113:3,5,7,9,11,14,17, 21;114:2,4,6,19; 115:5,14;116:2,13; 117:8;119:6;122:11; 143:17;145:15; 152:22;153:21,22; 158:3;159:18; 160:17;162:12,14,16; 163:12,15;165:7; 182:1,10;183:21; 187:1,19;189:1,1,4; 199:14;200:2,7,11, 19;206:17;216:2; 217:17;220:3; 229:22;230:8;239:9; 246:18;250:7;262:6, 22;263:1,2;270:13; 271:9;273:19; 276:13,21,22;277:4; 281:4,15;286:13; 290:17;295:6;304:3; 305:15;310:14; 311:5,6,319:19,19; 322:17;323:1,9; 325:3,5,6,18;327:2</p> <p>production (4) 167:19;169:22; 222:7;291:16</p> <p>productive (2) 31:13;312:9</p> <p>products (169) 7:5;13:19;14:10, 22;15:2,6,11,18;16:1, 10,16,20;17:5;18:1; 20:19;29:1;33:22; 34:8,12,19,20,22; 38:15,21;40:1;47:4,4, 5,9,16,49:1;53:17; 55:12;58:3;59:18,22; 60:1,9,10,15;65:13; 70:10;73:19;75:20; 76:15;79:8,10,10; 80:2,15;81:12;82:12; 86:1;90:22;91:5,12; 93:5;97:10,12;98:20; 99:4,6,6,13;100:21; 101:16,20,20;102:3, 22;103:2,7,11,14,21, 21;104:4,11,12; 105:5,7,8,14,20; 106:3,7,16;107:1,3; 110:9,11,14;111:1,6, 21;114:20;118:11,17, 18;119:15,18;120:7, 16,18;121:14,19; 122:14;126:7; 127:17;131:2; 137:11;148:15; 153:5,8,9,12;163:5;</p>	<p>165:13;167:18; 169:9;172:4;201:20; 211:2;223:1;229:21; 241:7;266:17; 268:21;269:21; 270:19;279:4,7,19; 280:9;281:2;285:2, 20;287:13;290:7; 294:19;299:2,2; 301:5;303:14,17,21; 304:9,18;305:2,11, 12,22;306:2,15; 310:5;313:1;314:14, 16;315:5;321:8,19; 322:5,20;323:4,8; 325:13,22;327:11,20</p> <p>product's (4) 107:6;109:9,11; 117:22</p> <p>product-specific (1) 47:22</p> <p>professional (7) 83:15;202:5; 206:22;210:3; 211:14;299:5;319:7</p> <p>professionals (9) 15:9;84:12;99:11; 203:11;258:5;263:3; 267:8;317:10;324:14</p> <p>professor (17) 158:19;213:12,15, 20;218:6,8;225:11, 22;229:2;231:7; 237:21;239:19; 243:1,17;247:16; 249:19;260:4</p> <p>Professors (2) 214:6;253:17</p> <p>profile (1) 210:10</p> <p>profit (1) 265:15</p> <p>profitability (1) 301:21</p> <p>profiteering (1) 302:20</p> <p>profits (3) 301:12;319:12,16</p> <p>program (22) 21:12;68:6,11; 75:16;81:4;82:15; 83:11,12,22;84:4,17; 99:19;102:16;125:7; 166:17,17;192:6; 194:19;278:11,22; 286:14;304:3</p> <p>programs (9) 38:20;72:20; 154:11;180:19; 267:8,9;278:21; 280:11;304:2</p> <p>progress (7) 16:13;48:18;72:3,</p>	<p>4;84:2;161:8;279:22</p> <p>progressive (1) 283:19</p> <p>prohibit (1) 309:2</p> <p>prohibits (2) 94:2,4</p> <p>projects (3) 44:19,20;45:11</p> <p>prolonged (2) 232:9;234:3</p> <p>prominence (3) 87:22;88:3,14</p> <p>prominently (1) 117:1</p> <p>promise (14) 7:6;17:8;19:5; 21:20;28:20;33:13; 38:22;40:16;41:2; 78:21;186:22;195:3; 285:16;294:1</p> <p>promising (1) 254:9</p> <p>promote (11) 22:5;24:2;25:8; 110:5;148:14; 280:22;295:22; 305:9;307:18; 312:11;315:7</p> <p>promotes (1) 26:19</p> <p>promoting (7) 25:13;89:4;93:2; 133:11;197:18; 303:15;306:17</p> <p>Promotion (14) 79:14;80:11;81:11; 84:7,19;86:1;100:11, 12;101:5;102:7; 103:16;119:14; 256:18;283:11</p> <p>Promotional (92) 14:8;75:2;80:14, 21;81:1,9,14;82:1,11, 18,20;83:4,15;84:8, 14;85:7;86:5,22; 87:2,21;88:16,18; 89:16,18;90:2;91:10; 92:10,12,15;100:19; 101:13,19;102:22; 103:1,3,10,13,17,20, 22;104:6,10,14,16, 17;105:4,8,11,13,21; 106:4,11,13,20; 107:1,12;108:2,16, 22;109:14,21;110:3, 10,15;111:7;112:18, 21;113:4;114:1; 115:2;117:12; 118:12,15,16,19; 119:1,4,7,11;120:6, 15,20;121:1,4,6,18; 122:8,16;298:22;</p>	<p>325:3,10,16</p> <p>promotions (1) 100:2</p> <p>promulgated (1) 82:4</p> <p>prong (1) 227:20</p> <p>proof (2) 225:5;248:5</p> <p>proper (1) 105:10</p> <p>property (1) 213:14</p> <p>proportion (1) 149:14</p> <p>proposal (1) 68:18</p> <p>proposals (1) 67:14</p> <p>proposed (7) 34:4;35:3;38:4,10; 122:14;164:4;216:12</p> <p>proposition (1) 182:13</p> <p>proprietary (2) 105:10;143:2</p> <p>protect (12) 25:7;71:22;80:16; 83:19;99:2;102:12; 110:5;158:7,8;307:8, 12;319:16</p> <p>protection (13) 25:5;29:12,13; 52:20;79:21;91:17; 98:18;99:20;219:6; 226:7;238:7,10; 239:21</p> <p>protocols (2) 66:17;296:11</p> <p>proud (1) 272:16</p> <p>prove (5) 241:17,17;245:21; 249:1,5</p> <p>proved (1) 208:1</p> <p>proven (3) 199:9,12,19</p> <p>provide (30) 14:5;19:15,22; 25:4;44:13;45:3; 82:19;83:3;85:11; 86:2,10;92:8;107:10; 157:14,14;163:4; 176:13,22;206:17; 257:11;270:13; 281:3,21;292:11; 293:22;307:17; 313:3;321:16;322:3; 329:5</p> <p>provided (8) 27:20;28:4,10; 90:18;94:9;112:2;</p>	<p>271:2;291:3</p> <p>provider (30) 7:7;15:14;21:8; 37:10;57:15;61:3; 62:4,21,21;63:7;67:3, 14;68:3,9;175:3,9; 193:14,19;194:3,8, 10,20;195:9;196:12; 208:17;212:6; 296:12;297:4;317:3, 17</p> <p>providers (40) 15:16,19;16:9; 20:4,22;22:8;44:15; 60:16;63:15;67:16; 68:12;75:10;76:5,9, 13;77:21;108:13; 110:6;174:17; 176:11,16;197:10; 202:11;206:14,21; 275:4;286:19; 287:11;289:4,8; 290:2;292:19; 294:14,20;297:11; 305:6;306:13;327:5, 16,18</p> <p>providers' (1) 172:2</p> <p>provides (8) 68:11;79:15;83:7; 109:12;114:14,22; 117:1;289:3</p> <p>providing (3) 11:16;79:11; 324:10</p> <p>province (3) 183:15,16,17</p> <p>provinces (3) 183:13,16;188:17</p> <p>provincial (2) 178:12;207:12</p> <p>proving (1) 60:12</p> <p>provisions (4) 26:7;81:20;119:17; 281:6</p> <p>proxy (1) 152:11</p> <p>Psoriasis (1) 204:15</p> <p>public (62) 9:8;10:3;13:13; 14:6;15:19;19:1; 20:3;21:2,12;22:8; 32:16;34:1;37:7; 39:12;75:22,22;77:7; 80:17;81:6,13;82:15, 16;83:2,7,19,20; 84:14,16;85:9;98:18; 99:2,7;102:4,12,18; 104:12;110:5,11,12; 181:9;208:10,10; 215:2;224:9;238:6;</p>
---	--	--	---	--

<p>240:3;251:18;255:2, 4,8;268:5;274:21; 280:11;300:3; 307:10;320:7,22; 321:4,9,12,22;322:10 publication (3) 20:20;289:21; 325:1 publicly (6) 50:7;61:18;86:14; 143:11;149:13;313:5 publicly-funded (1) 184:17 publish (2) 93:10;189:16 published (9) 25:17;69:6;101:12; 146:5;173:14;189:8, 14,17;190:1 Puerto (1) 300:15 pull (2) 165:11;192:14 purchase (1) 218:22 purchasing (2) 204:6;327:19 Purdue (1) 143:12 pure (1) 34:5 purely (3) 50:4;57:14;61:10 purity (4) 110:21;111:5; 113:18;117:19 Purple (4) 53:11,17;54:2; 176:18 purpose (4) 6:14;143:5;199:10, 20 purposely (1) 203:9 purposes (1) 114:17 pursue (4) 55:12;85:17;165:8; 321:7 pursuing (1) 167:7 purview (3) 43:17;53:15;69:1 push (2) 165:11;192:12 pushing (1) 137:16 push-pull (1) 192:9 put (21) 21:1;31:19;34:14; 41:3;45:1;55:1; 57:22;58:15;62:22;</p>	<p>70:14;136:13; 156:19;180:16; 196:13;203:19; 237:10;242:1; 244:11;252:13; 269:13;277:15 puts (2) 219:12;266:5 putting (3) 24:15;239:17; 255:18</p>	<p>57:6 raise (1) 309:5 raised (2) 58:13;59:15 raises (2) 223:8;311:17 raising (2) 249:14;252:4 Ramanam (3) 267:17,18,19 Randall (1) 225:10 Randy (1) 213:3 range (1) 221:20 ranges (2) 262:14,15 rapid (1) 58:5 rapidly (1) 25:2 rare (1) 95:15 rarely (1) 301:18 rate (6) 63:2;77:22;117:15; 187:7;189:5,10 rates (9) 56:1;90:10;111:18; 118:1,3,7;139:2,10; 156:9 rather (8) 60:22;63:6;113:12; 186:19;196:19; 228:21;301:21; 309:10 rationale (1) 271:17 raw (1) 322:21 RBST (2) 222:5,16 RBST-derived (1) 222:22 reach (10) 21:21;39:19;41:10; 127:22;131:3;221:9; 248:8,9;294:15; 297:6 reached (2) 25:3;144:14 react (2) 97:13;216:9 reaction (4) 111:19;221:8,15; 275:2 read (6) 9:4;71:10;95:13, 14,14;204:8 readability (2)</p>	<p>88:1,3 reader (1) 88:11 readily (2) 203:3;228:19 real (11) 59:9;71:3;78:14; 129:18;153:2; 176:13;181:18; 217:22;226:1;234:9; 306:14 realistic (1) 254:7 realities (1) 253:22 reality (2) 162:21;171:16 realization (1) 139:10 realize (6) 17:14;19:5,9; 152:11;200:8;203:16 realized (2) 75:9;324:13 really (91) 10:21;11:21;12:1; 13:4,7;14:12,22;14, 22;34:16;36:11; 38:15;41:3;42:6; 43:4,16;47:8;48:4; 50:18;55:2;56:18; 59:3,15;64:14;65:3, 19;66:19;67:7;69:15; 72:16;73:6;92:19; 137:3;139:1;146:2; 147:7;150:22;154:5; 160:6;167:16; 168:13;169:17; 170:17;175:16; 178:2,22;179:1,3,5; 180:14;181:17; 182:2,6;183:3;187:2, 4;188:6;193:11,13; 195:6;196:22; 202:11;203:1; 205:11;207:17; 208:5,9;211:11; 215:19;216:16; 217:3;218:3;221:20; 223:4;225:4,18; 226:19;232:16; 234:12;235:13; 237:11;240:9;242:2; 250:18;251:9; 252:13;253:7,10; 254:13;257:10; 281:9;282:19 realm (2) 196:22;226:2 real-world (4) 171:22;267:12; 269:2;295:18 reason (11)</p>	<p>40:12;46:17; 119:20;139:13; 140:8;168:18; 178:13;252:16; 277:2;287:17;317:4 reasonable (14) 69:18;95:6,12,18; 139:8;158:12;180:4; 218:21;221:1,10; 228:2,7;232:7; 233:17 reasonably (3) 88:1;95:2;161:4 reasons (4) 35:9;70:12;253:1; 296:19 rebate (22) 42:22;49:8;51:12; 52:15;53:5;55:19; 148:12;155:13; 160:19;308:20,21; 309:2,19,19;310:4,7, 10,12,13;311:14; 315:6;318:20 rebates (26) 51:13;52:3,16,20; 126:18,20;140:11; 143:2,18;147:15; 148:1,4,6;154:10; 237:4;247:13; 301:13;309:5,8,9,12, 13;310:1;311:12; 318:20;327:12 Rebecca (2) 213:14;218:12 rebut (1) 234:12 rebutted (2) 232:3;234:19 receive (10) 15:10;55:4;85:3; 96:13;99:12;221:1,4; 224:18,20;324:14 received (3) 127:4;300:22; 316:6 receives (1) 263:1 receiving (1) 120:1 recent (11) 39:19;43:18;46:2; 53:10;61:17;83:6; 183:15;196:14; 279:13;314:18;323:5 recently (6) 27:20;98:16; 175:13;206:13; 306:6;313:1 receptive (1) 240:6 recess (3) 74:19;123:3;</p>
	Q			
	<p>Q&A (3) 83:6;190:17;206:6 Q&A's (1) 120:17 q1 (1) 134:13 quality (26) 93:7;104:21; 167:19;176:13; 184:12,18;199:2; 200:16,17;201:8; 202:16;211:12; 247:4;292:3;302:7; 316:16;321:5,13,14, 15,19;322:3,21; 323:7,12,13 quantifiable (1) 319:11 quarter (2) 134:4;143:15 quarterly (1) 134:3 quick (8) 48:22;73:20;92:9; 137:22;164:16; 172:12;185:20; 218:14 quicker (1) 164:11 quickly (5) 9:4;71:3;128:2; 266:19;306:4 quite (10) 60:13;65:5;121:16; 133:7;174:13; 189:11;210:16; 223:1;264:21;282:10 quote (7) 50:7;215:5,8,10, 12;260:11,12 quote/unquote (3) 62:16;63:20; 299:18</p>			
	R			
	<p>R&D (1) 129:15 RA (1)</p>			

212:22 recipe (2) 168:2;252:7 recognize (12) 75:18;157:13; 159:19;160:13; 161:1,12;165:20; 169:18;194:6;195:5; 197:1;275:6 recognized (4) 17:7;93:11,12; 191:17 recognizing (4) 159:9;162:19; 298:8;319:20 recommend (2) 205:13;281:3 recommendation (2) 26:10;122:13 recommendations (7) 109:13;116:20,21; 197:22;201:22; 207:1;289:16 recommended (2) 26:5;108:5 recommends (2) 107:3;110:22 reconsider (2) 269:5,8 record (4) 9:15;26:22;210:18; 295:15 records (1) 188:9 red (3) 56:22;255:22; 287:2 reduce (9) 11:12;15:21;17:17, 22;160:10;165:16; 271:4;279:14;326:12 reduced (4) 38:8;156:7;239:1; 274:13 reduces (2) 17:20;170:6 reducing (5) 25:12;28:21;159:7; 284:4;324:12 reduction (1) 267:2 reductions (1) 229:19 Reed (3) 257:5,7,7 re-establishment (1) 35:1 refer (4) 92:13;107:15; 144:7;168:2 Reference (137) 14:10;17:5,19; 28:16,20;29:7,11,18;	34:2,20,22;35:3,6,8, 14,17,19,21;37:8; 38:6,9,21;53:17; 60:18;67:18;76:4,7, 14,17,20;79:9;83:6; 94:15;96:11,14,22; 97:9,12,15,15; 100:21;101:15,20; 102:3;103:2,5,11,14, 21;104:3,11;105:5,7; 106:6,9;107:5,9,12, 14,19,21;108:9,21; 110:9,14,18;111:1,4, 10,13,16;112:6,8,10, 14,19;113:3,5,7,9,11, 14,17,21;114:2,4,5, 19;115:5;117:22; 118:17;121:14,18; 122:14;128:3; 152:22;153:8,12,21, 22;162:11,14;163:12, 15;165:7;176:2; 182:9;183:20;189:1; 199:14;200:1,6,18; 201:20;206:16,19; 211:2;216:2;246:18; 262:6;270:12;271:9; 275:12;276:21; 277:4;281:2;285:19; 286:1;294:19;295:6; 299:2;306:2;325:2,6, 327:2,11,20 referenced (1) 69:8 references (1) 224:13 referencing (1) 38:21 referred (2) 109:5;314:19 referring (3) 207:13;292:8; 296:3 refers (1) 93:4 reflect (1) 180:15 reflection (1) 129:13 reflective (1) 242:3 reflects (1) 304:4 reform (1) 315:6 refrain (1) 74:6 refused (1) 230:7 regard (13) 81:8;92:10;93:15; 94:20;96:9;138:13; 163:8;192:10;197:9;	265:1;271:20; 309:12;324:21 regarding (22) 84:13;85:7;87:2,4, 8,13,16;88:22;101:5; 106:21;121:3;172:3; 183:6;264:7;265:3; 272:21;290:5;292:4; 293:6,18;316:1; 326:19 regardless (1) 296:14 regards (1) 271:11 region (2) 64:2,2 regional (1) 300:14 regions (1) 304:1 Register (4) 10:17;120:2;325:9; 329:1 registered (5) 10:5;255:9;256:5; 278:6;328:4 registration (5) 7:21;8:18;10:13; 329:2,7 regrets (1) 23:15 regs (1) 85:22 regularly (3) 79:15;84:6;224:10 regulates (1) 103:22 regulating (1) 313:15 regulation (6) 87:15;110:4;119:5; 223:5,13;319:21 regulations (10) 45:10;81:10;82:5, 7,9;84:5;85:7;104:6; 119:14;289:22 regulators (5) 160:9;183:1; 260:16;264:5;277:19 regulatory (27) 20:1;33:19;38:11; 78:18;79:13,15; 80:10;101:1;124:16; 164:1,16;169:22; 199:3;201:14,18; 211:6;235:17;238:4, 11;246:5;267:20; 269:11;270:5;298:9; 305:8;324:1,4 reimburse (2) 140:4;142:19 reimbursed (1) 147:16	reimbursement (6) 43:14;67:16; 132:14;270:22; 292:18;305:8 reinforce (2) 195:21;281:18 reinforcing (1) 11:11 reinterpretation (1) 248:17 reiterate (2) 31:1;297:9 related (17) 15:13;17:5;82:5; 83:4;87:19;103:2; 119:14;160:7; 165:10;171:14; 174:4;224:7;260:11; 271:11;289:17; 292:12;310:18 relatedly (1) 233:18 relates (4) 81:22;82:2;169:20; 260:12 relating (1) 280:2 relationship (6) 17:13;35:2;51:6; 224:8;284:11;297:11 relative (9) 127:9;128:7,20,21; 137:5;153:4,21,22; 263:1 relatively (6) 16:14;221:5; 225:18;275:21; 276:20;277:6 release (1) 93:16 released (2) 14:7;175:13 relevance (7) 20:5;83:14;169:19; 219:18;223:3,5; 271:12 relevant (22) 35:5;36:20;47:10; 80:3;94:1;105:20; 107:5,22;117:4; 132:11;153:1;156:5; 170:19;180:19; 200:22;220:18; 221:2;222:17;225:6; 228:20;241:20;285:1 reliability (1) 304:17 reliable (2) 29:6;70:18 reliance (2) 232:7;233:17 relied (1) 104:21	relief (4) 89:10;227:9; 283:21;320:2 relies (1) 81:20 reluctance (2) 59:2,8 reluctant (1) 327:16 rely (1) 82:8 relying (1) 96:19 remain (2) 163:9;284:1 remained (1) 191:17 remaining (1) 36:15 remains (4) 36:19;72:7;181:4; 307:3 Remarkably (1) 311:2 remarks (10) 11:16,19;23:11; 54:19;253:18;256:1, 11;258:2;328:5,6 remedies (2) 97:20;301:11 remember (3) 152:2;207:19; 256:7 Remicade (7) 191:12;217:2,12; 283:13;285:21; 286:4;288:1 Remicade's (2) 286:3,8 remind (4) 84:16;86:12; 118:21;119:8 reminder (1) 328:18 remiss (1) 67:13 remission' (1) 215:15 remotely (1) 172:18 remove (2) 259:6;315:6 removing (1) 52:20 render (1) 86:6 rent (1) 161:21 repeating (1) 266:13 replacement (2) 43:15;270:1 replicamab (3)
--	---	--	--	---

<p>114:20;115:14; 116:2 report (3) 25:17;84:17;306:7 reported (3) 143:8,10;306:6 reporters (1) 85:1 reporting (1) 84:10 reports (2) 61:18;84:22 reprehensible (1) 302:14 represent (6) 111:2;142:12,14; 257:16;272:16;312:2 representation (1) 90:18 representations (1) 113:19 representative (6) 89:4,5;140:13; 264:21;275:13;277:8 Representatives (1) 9:13 represented (1) 131:1 representing (6) 23:19;278:15; 293:16;316:14; 325:4,17 represents (5) 32:20;101:22; 131:9;143:16;312:5 request (12) 8:16;82:17,21; 118:14;268:16; 269:4;271:7,22; 272:2,5;299:12; 329:6 requested (1) 28:3 requesting (2) 302:18;324:17 requests (1) 184:5 require (7) 38:2;53:16;98:2; 121:22;284:21; 290:8;293:4 required (12) 26:8;63:4;109:5; 113:10;202:2; 216:15;221:11; 271:11;279:17; 289:13;290:11; 317:14 requirement (3) 269:11,15,17 requirements (11) 11:13;36:1;37:15; 84:10;103:19;</p>	<p>104:10;118:22; 119:12;210:12; 269:10;290:20 requires (6) 7:11;38:3;174:21; 192:7;216:11;294:12 requiring (3) 201:11;295:4; 296:13 rescaled (1) 135:13 research (15) 83:11,12,17,22; 84:2;102:10;141:8; 143:4;144:6;173:14; 178:15;186:11; 207:4;247:17;312:6 research-based (1) 180:18 researchers (2) 137:15;179:14 researching (1) 196:19 resets (1) 135:3 resident (1) 124:22 residual (3) 36:15,18;272:1 resolve (2) 163:18;166:8 resonate (1) 213:7 resources (5) 14:18;70:14; 252:10;253:15; 269:20 respect (6) 53:9;94:8;98:19; 162:12;177:21; 274:16 respective (4) 99:10;139:20; 214:7;306:1 responding (1) 195:17 response (6) 82:17;90:10; 117:14;118:1,2,7 responsibilities (1) 179:4 responsible (3) 94:13;222:21; 301:3 rest (3) 55:1;186:20; 247:15 restraint (1) 235:5 restricting (1) 25:22 restrictive (1) 30:16</p>	<p>restrooms (1) 8:13 result (9) 7:13;27:13;38:5; 65:20;85:4;273:13; 301:6;304:9;307:19 results (7) 90:4,5;144:9; 145:19;146:5; 149:16;269:19 retail (12) 46:22;48:10;126:8; 131:8,14,15,17,18,19, 21;270:2;317:19 rethinking (1) 242:15 return (1) 49:14 reveal (1) 104:9 reverse (4) 27:3,12,14;30:21 review (16) 10:20;19:17;30:19; 55:9,13;84:1;118:14; 203:19,20;224:15; 250:11;268:17; 326:5,7,7,12 reviewers (2) 19:17;79:17 reviewing (3) 45:9;84:8;120:1 reviews (2) 26:17;84:11 revise (1) 203:20 revolutionized (1) 294:3 rewarding (1) 235:18 reworked (2) 175:18,19 rheumatic (1) 191:9 rheumatoid (3) 173:12;178:4; 265:7 rheumatologic (1) 57:7 rheumatologist (2) 263:18;300:11 Rheumatologists (6) 204:20;264:11,21; 265:8;300:16,19 rheumatology (8) 59:1;209:14; 261:13;263:20,21; 264:12;300:8,14 Rich (2) 91:15;214:3 Richard (3) 79:18;91:18; 225:10</p>	<p>richness (1) 225:8 Rich's (1) 100:13 Rico (1) 300:15 right (39) 7:12;8:14;18:19; 49:11;53:4,20;57:21; 67:1,2;68:17;130:11; 136:19;147:11; 156:1;168:3;180:5; 186:12;188:8,10; 189:12,13;190:1,3, 11;192:16;209:11,17, 17;210:16;213:10; 225:13;227:11,16; 237:2;241:13,22; 242:14;255:20; 291:16 right-hand (1) 131:11 rightly (1) 315:10 rights (5) 213:6;218:10; 226:13;253:6,8 rigorous (4) 201:20,21;211:1; 325:20 rigs (1) 213:19 rising (1) 302:9 risk (21) 21:2;38:7;78:21; 80:20;81:13;85:9; 87:1,11,14,16,20,21; 88:8,13;91:1;102:15; 106:8,10;271:18; 327:1,4 risks (4) 87:4;88:15;90:22; 104:8 rituximab (2) 56:16;57:18 rival (4) 231:13;236:21; 310:3,7 rivals (4) 229:9;231:12; 236:16;244:12 robust (22) 14:21;72:17,21; 73:18;82:14;84:3; 138:9,11;144:6; 145:1;276:10;295:7; 296:22;303:1;304:4; 305:3;307:1;308:8; 313:17;314:8;317:2; 318:10 robust-to-competitive (1) 303:16</p>	<p>role (39) 16:17;25:11;38:18; 46:9;60:18;63:13; 70:10;72:16;85:20; 117:3;140:9;169:7,8; 193:2,7;194:2;195:7, 15;197:1,9;236:10, 11;238:16,17;240:11, 16;243:20;246:7,19; 247:19;252:11; 253:2;258:6;260:13; 284:10;315:12; 321:10;323:10,14 roles (1) 274:1 roll (1) 249:2 rolls (1) 53:20 room (17) 7:18,21;8:1,2,3,4; 10:14;25:6;39:11; 173:5;185:12; 215:13;224:2;247:8, 13;273:13;329:2 root (1) 160:3 round (2) 90:17;191:16 roundtables (2) 323:5,12 route (3) 114:22;115:3,10 routine (1) 277:3 rule (1) 221:3 rulemaking (5) 250:22;251:3,4,6,7 rules (8) 9:2,4;169:13; 179:4;251:14; 278:11;280:14; 311:15 run (3) 49:9;94:16;97:2 rust (1) 277:17 Rutgers (1) 213:13</p>
S				
			<p>safe (33) 28:19;29:10;31:6; 34:4,5;35:17;76:14; 77:14;97:14;112:8, 13;113:6;114:3; 165:13;191:22; 200:7;206:15;215:3; 217:7,18;218:4; 246:17;260:7; 263:15;270:8;</p>	

272:17;284:1;289:1; 294:18;324:11; 325:5,18;329:9 safeguard (1) 286:20 safeguards (1) 297:1 safer (5) 89:19;90:12;97:16; 111:10,12 safety (49) 19:21;35:1;38:7; 103:6;107:8;110:21; 111:5;113:18; 117:19;122:10; 159:17;176:6; 181:11;182:21; 198:15;199:2,18,19; 210:9,20;211:11; 215:9;216:22;225:3; 233:15;234:9; 237:15;252:4; 260:13,17;266:20; 269:4,14;276:2; 281:14;283:11; 292:3;294:22;295:3, 9,10;297:1,14; 301:20;313:16; 324:19;325:12; 326:20,22 sailed (1) 58:19 sales (19) 67:17;87:6,7,10, 12;89:3,4,5;132:19, 20;133:3;143:9,10; 168:8,12;242:9; 286:3;306:1;313:8 same (43) 14:4;18:2;33:20; 38:5;50:21;59:16; 62:7,8;65:11;66:14; 71:17,19;77:18,18; 104:13;115:3,10,12, 16;122:12;134:12; 135:12;137:6,6; 140:7;147:18; 150:21;153:17; 167:4;182:15; 193:21;198:14,15; 206:17,18;209:8; 210:9;212:2;217:14; 224:4;233:12;238:5; 311:6 Sameer (6) 173:20;185:15,16, 17;190:20;195:9 sample (4) 239:9,10;271:20; 308:19 samples (3) 30:13;314:18,20 San (1)	275:9 sanctity (1) 297:10 Sandoz (2) 174:3;197:15 Sandoz's (1) 39:18 Sarah (6) 69:20;171:10; 177:10;180:21; 206:3;255:5 Sarah's (1) 177:13 sat (2) 39:11;212:15 satisfied (3) 167:6;234:6,17 satisfies (1) 269:16 satisfy (1) 119:12 save (2) 308:10;319:6 saved (1) 18:9 savings (25) 40:2;60:5;68:6,10, 13,16;72:20;73:7; 91:20;100:14;153:1, 17;166:17;258:10; 259:14,15;267:2; 279:11;286:10; 304:8,11,13,20; 305:5;306:3 saw (11) 49:16;54:4;71:8; 92:2;139:13;149:8; 162:10;189:4;234:4; 236:12;250:4 saying (17) 56:21;57:2;62:22; 71:11;164:13;188:4; 198:7;201:5;208:4; 210:19;217:16; 225:20;233:2,10; 234:2;240:9;282:11 scale (4) 18:3;147:18; 167:19;277:12 scare (1) 77:12 scary (1) 222:16 scary-toothed (1) 222:8 scenario (5) 114:21;116:8; 117:12;221:18; 222:17 scenarios (2) 138:17;300:1 scheme (2) 30:17;246:5	schemes (1) 301:13 Schick (3) 125:5,5;167:15 SCHILLER (5) 74:21;75:3;98:8,9; 100:5 Schimizzi (3) 300:7,9,10 SCHMIDT (6) 125:2,3;136:9; 152:6;154:5;169:1 Schneider (3) 259:22;260:2,3 School (2) 213:13,16 schools (4) 205:9,9,10 science (9) 16:5,8;22:4;83:10, 21;101:3;129:14; 269:12;322:14 science-based (4) 22:1;83:18;268:11; 313:15 scientific (17) 14:20;15:3,4,5; 93:16;116:22;174:3; 178:16;210:21; 211:7;271:17;297:1; 316:6;320:19;322:8; 326:3,14 scientifically (3) 290:9,22;306:18 scientists (1) 169:12 scope (1) 36:17 Scott (1) 24:7 screen (2) 172:19;173:8 script (1) 64:18 search (2) 298:20;299:12 searchable (1) 53:11 second (18) 7:4,20;39:5;44:16; 50:18;62:12;87:19; 99:20;116:7;141:13; 147:12;215:22; 230:16;231:20,21; 233:14;284:17; 314:17 seconds (2) 281:22;282:3 secrecy (1) 236:14 Section (13) 37:7;81:21;82:1; 94:1,1,2,4,7;98:5;	104:12;124:8;229:7; 240:13 sections (3) 93:22;124:7,10 sector (1) 251:21 secure (3) 309:12,21;311:11 secured (1) 306:5 seeds (1) 76:12 seeing (9) 16:5;59:21;77:17; 145:15;153:6,11; 168:19;214:13; 276:17 seek (8) 7:4;30:12;35:12; 43:19;55:11;85:12; 86:11;118:16 seeking (3) 27:2;120:5;326:13 seeks (1) 325:9 seem (4) 20:20;145:4; 150:17;242:13 seemed (1) 275:5 seems (1) 242:5 sees (1) 86:21 segment (1) 308:6 segmentation (2) 211:20;212:5 segments (3) 131:12;132:12,15 segue (1) 141:4 seizures (1) 85:19 selectively (1) 77:2 self-administered (1) 47:11 self-help (1) 165:6 sell (3) 142:16;305:15; 317:20 Senator (1) 53:19 send (4) 84:20;85:10;86:9; 328:14 senior (2) 171:11;255:6 sense (10) 148:8;155:17; 162:8;201:15;	202:18;210:8; 217:21;224:21; 244:17;251:15 senses (1) 160:22 sensitivity (1) 144:5 sensitized (1) 265:9 sent (1) 66:5 separate (3) 135:9;196:3;306:9 separately (1) 143:22 September (2) 132:18,22 sequestration (1) 67:21 series (7) 32:5;77:3;196:13; 207:11,15;323:5,11 serious (4) 16:18;24:18;99:4; 307:22 seriously (2) 91:4;174:15 serve (5) 258:21;259:19,20; 273:22;321:9 served (1) 22:18 service (9) 23:1;34:1;37:7; 93:2,7;94:5;104:13; 143:20;157:14 Services (5) 43:18;63:6;80:2; 93:5;241:7 servicing (1) 11:6 session (5) 122:20;156:4; 160:6;171:22;255:8 sessions (1) 328:13 set (6) 159:13;163:20; 231:2;296:13;314:8; 323:8 sets (1) 152:9 setting (5) 48:11;60:22;72:22; 137:10;268:5 settings (2) 137:7;271:13 settle (1) 55:13 settlement (7) 26:17;30:19;54:14, 15,21;55:5;280:7 settlements (8)
---	---	---	--	---

26:8,13;27:10; 55:8;236:19,22; 250:7;280:17 settling (1) 26:6 seven (2) 158:21;317:1 Seventh (3) 222:3,10;230:20 several (8) 8:6,47:11;78:6; 197:21;198:1;236:5; 305:17;312:21 share (32) 29:22;60:19;68:10; 91:2;100:13;127:8; 128:16;129:7; 130:22;134:22; 137:11;149:17; 170:8;186:22; 190:12;196:21; 202:2;229:13;230:6; 236:16;244:11; 246:11;262:10,13; 266:4;276:15;277:1; 298:6;303:10;306:5, 16;307:2 shared (8) 13:17;68:5,13,15; 72:20;99:9;166:17; 195:3 shares (2) 153:11;303:14 sharing (1) 264:3 sharp (1) 219:7 shed (1) 251:8 sheets (1) 175:10 shenanigans (6) 13:7;78:9;235:21; 250:20;283:1;308:18 Sherman (1) 229:7 shift (3) 61:20;129:13; 155:15 shifting (1) 44:21 ship (1) 66:21 shipped (1) 66:14 shipping (1) 126:7 shock (1) 222:9 shoes (1) 62:22 short (9) 11:9;16:14;33:4,9;	231:4;263:10; 275:21;281:17; 311:13 shortages (1) 291:20 shorter (2) 89:11;268:17 Shortly (2) 139:3;190:2 shot (1) 99:17 show (22) 40:8;130:19,21; 134:13;144:9; 149:21;186:4;211:1; 215:2;228:14,19; 229:9,12;232:3,5; 241:20;242:9;244:2, 3,9;245:21;318:5 showcase (1) 99:1 showed (3) 50:2;90:7;144:4 showing (2) 115:9;150:16 shown (2) 230:19;313:6 shows (10) 28:13;146:8; 152:21;182:20; 190:18;216:3;218:3; 285:22;319:13,14 shrouded (1) 180:7 sick (1) 33:8 side (27) 17:11,12,16;18:20, 22;20:11;49:13;51:5, 16,17,20;52:2,7; 65:12;66:18;67:11; 74:8;76:6;77:20; 99:21;131:11; 155:12;166:20,21; 206:18;249:6;266:3 sides (3) 163:8;168:14; 205:20 sign (7) 7:20;8:21;10:13; 136:1;151:13,22; 226:10 signals (1) 88:10 signed (1) 13:15 significance (1) 47:1 significant (20) 19:7;46:3;55:22; 59:21;65:7;69:2; 71:5;75:7;95:20; 118:3,8;126:19;	150:3;170:3;231:14; 272:6;301:5;306:2; 311:12;327:12 significantly (5) 17:17;90:8;245:6; 303:20;312:14 silence (1) 7:17 similar (32) 29:1;34:20;60:7; 97:11,11;106:10; 110:17;111:3; 113:13;129:22; 138:16;140:22; 141:11,18;145:1,5; 147:13;154:7; 165:14;190:5; 200:20,20;215:17; 216:9,11;217:2,12; 251:10;252:5; 262:15;285:14; 290:14 similarities (1) 176:1 similarity (2) 36:8,9 Similarly (5) 26:4;29:21;42:22; 73:18;217:10 Simmon (14) 32:17,17;39:2,3; 40:8,19;41:3,19; 47:20;53:3;57:21; 67:12;71:3;160:5 Simon (2) 23:15;31:8 Simons (1) 21:17 Simon's (1) 22:18 simplicity (1) 156:7 simply (2) 112:9;277:15 Simponi (1) 145:12 SINGH (9) 32:9,10;48:22; 49:20;56:5;58:12; 61:2;65:18;73:20 single (2) 44:8;115:22 singularity (1) 195:21 sit (2) 60:10;69:16 site (2) 132:2;176:8 sites (1) 66:13 situation (4) 14:3;201:10; 235:18;241:22	situations (2) 16:19,21 six (7) 232:3,5,5;261:10; 262:10;265:17;306:6 Sixth (1) 231:21 size (5) 88:4;126:14;128:7; 171:7;271:20 sketch (1) 172:10 skills (1) 254:12 skin (2) 65:11;204:13 sky (1) 180:1 slap (1) 236:8 slapping (1) 187:7 slide (23) 33:10,21;34:16; 36:5;39:5,15;40:16, 17;41:4,5,6;82:13; 91:12;165:19;178:2; 185:20;187:9; 191:13,18;193:17; 197:13;222:1;234:5 slides (13) 47:3;50:1;125:12; 127:7;140:2;141:20; 142:4;171:20; 184:13;185:5,8,13,14 slightly (1) 73:9 slow (2) 71:7;320:4 slowed (1) 59:12 slower (1) 277:16 small (34) 28:18;30:18;34:10; 127:9;128:12;129:7; 130:4,13,15,17; 133:21,22;134:7,11; 136:16;137:12; 138:17,22;139:11,19; 140:9,18;153:4,7; 154:8,14;155:3; 161:15;167:21,21; 169:4;205:10;249:9; 275:19 smaller (3) 58:1;131:12;171:6 smattering (1) 205:10 snapshot (1) 175:8 snapshots (2) 138:10,10	' 'so (1) 215:5 S social (3) 83:10,21;146:3 societies (8) 202:6,6;206:22; 209:12,15;211:14; 264:2;300:14 society (2) 210:3;315:16 sold (2) 143:15;187:21 sold-out (1) 7:22 solid (3) 179:21;182:6; 183:4 solidify (1) 265:14 solutions (4) 289:3;302:19; 322:15;323:8 solve (1) 236:4 solved (1) 247:11 somebody (1) 248:3 somehow (1) 244:11 someone (8) 24:13;139:21; 146:6;187:8;205:18; 212:1;215:10;221:19 sometimes (14) 50:21;75:18; 130:11,16;145:14; 159:7;205:14; 219:18;221:16; 227:16;252:2; 254:15;297:20,22 somewhat (2) 41:7;42:8 somewhere (1) 44:1 soon (5) 38:20;56:17;173:8; 176:12,15 sorry (3) 185:8;288:10; 293:12 sort (13) 18:2;49:21;57:22; 59:19;60:7;71:19; 165:6;209:8;229:20; 245:13;246:3; 250:22;252:4
--	---	---	---	--

<p>sorts (1) 154:10</p> <p>sought (1) 315:10</p> <p>sound (4) 22:4;211:7,10; 297:7</p> <p>sounds (2) 139:17;252:6</p> <p>source (3) 70:18;203:5; 291:19</p> <p>sources (3) 126:3;179:10; 181:5</p> <p>sow (1) 76:12</p> <p>space (24) 17:11,22;18:4,8,11, 12;86:17;88:5;92:7; 139:1,11;150:18; 153:4,8,13;156:6; 161:15;167:17; 168:11;171:7; 226:18;245:10; 268:19;299:15</p> <p>Spain (1) 261:11</p> <p>span (1) 208:7</p> <p>spark (1) 24:4</p> <p>speak (15) 9:22;10:5;58:7; 59:3;101:7;156:15; 157:19;179:6; 181:20;197:13; 256:5;264:7;286:22; 316:13;328:2</p> <p>speaker (17) 10:10;79:18; 182:12;255:11,13,13, 16;257:5;259:22; 267:17;278:3; 287:18;288:3; 298:11;300:7;307:7; 311:19</p> <p>speakers (10) 8:6;9:21;10:4,9; 178:19;255:9,17; 256:6;258:13;328:9</p> <p>speaker's (1) 93:13</p> <p>speaking (16) 8:22;60:18;79:12; 169:10;179:8; 193:20;197:7,16; 205:18;256:9;266:2; 270:5;274:17;277:8; 300:12;307:14</p> <p>speaks (3) 58:8;133:5;178:2</p> <p>special (3)</p>	<p>20:5;48:6;184:4</p> <p>specialist (2) 186:12;209:11</p> <p>specialists (6) 184:9;186:14; 187:22;188:2; 190:10,11</p> <p>specializing (1) 172:7</p> <p>specialties (2) 204:22;310:6</p> <p>Specialty (13) 32:12;43:21;46:22; 51:4;62:17,18;63:4; 64:12;66:20,20;67:1; 271:1;278:18</p> <p>specific (23) 56:8;61:6;66:8; 82:18;83:1;86:18; 93:5;97:7;120:5; 121:4;122:1,5;165:4; 184:7;199:4;228:18; 287:5,20;298:21; 299:8,11;300:1,2</p> <p>specifically (15) 56:15;70:4;80:12; 81:19;86:4;93:20; 96:16;105:17;119:9; 128:10;192:12; 271:22;290:7; 299:13;325:2</p> <p>specifics (2) 60:9;70:7</p> <p>speech (12) 92:18,22;93:1,4,5, 10,14,17,21;223:10, 13,16</p> <p>spell (1) 282:9</p> <p>spend (5) 12:8,10;125:16; 185:21;230:10</p> <p>spending (5) 18:14;25:2;130:4; 308:4,7</p> <p>spent (3) 130:2;178:5; 258:16</p> <p>sphere (1) 17:1</p> <p>Spiegel (8) 272:12,14,15; 278:1;282:4,12,15,19</p> <p>spite (1) 262:9</p> <p>spitting (1) 54:4</p> <p>splintered (3) 49:10;51:21;74:10</p> <p>split (1) 159:8</p> <p>spoke (1) 214:5</p>	<p>spoken (2) 198:5;199:3</p> <p>sponsors (1) 324:18</p> <p>spreading (1) 260:22</p> <p>sprinkled (1) 177:19</p> <p>spur (2) 284:9;286:15</p> <p>squeeze (1) 287:1</p> <p>SSR (1) 143:7</p> <p>stability (1) 313:19</p> <p>stabilize (1) 265:7</p> <p>stabilized (1) 265:11</p> <p>stable (8) 183:19;191:22; 209:21;212:1;262:7; 265:5;296:18;297:2</p> <p>staff (8) 11:16;12:5;22:17, 19;23:5;24:11; 100:11;256:19</p> <p>stage (2) 231:2;250:16</p> <p>stages (2) 20:15;205:6</p> <p>stagnate (1) 145:4</p> <p>stagnated (1) 146:10</p> <p>Stake (4) 124:4;179:12; 180:2;277:13</p> <p>stakeholder (9) 62:11;121:2; 171:18;196:9;259:4; 294:16;295:12; 296:5;306:17</p> <p>stakeholders (16) 8:6;69:10;121:11; 143:9;174:6,19,20; 175:3;203:22; 294:21;314:12; 322:11,15;323:3,6,18</p> <p>stand-alone (1) 34:2</p> <p>standard (15) 19:20;34:13,14; 201:4,10;215:20; 216:22;228:21; 234:14;270:7;273:8; 275:5;281:13; 287:16,19</p> <p>standards (20) 38:12;159:20,20; 232:15;266:20; 276:2;297:2;320:22;</p>	<p>321:9,12,14,16,20; 322:1,2,6,9,18; 325:21;326:3</p> <p>standing (4) 226:5,6;238:8; 239:12</p> <p>standpoint (1) 57:11</p> <p>Stanton (1) 213:15</p> <p>star (1) 179:22</p> <p>start (21) 33:3;39:4;40:1; 46:10;49:20;54:5; 56:5;61:2,9;62:3; 69:7;98:11,21; 141:19;146:15,17; 166:6;187:16; 224:14;233:2;259:12</p> <p>started (13) 6:6;33:10;101:8; 102:21;124:13; 141:6;144:12;145:7, 20;150:11;191:10; 195:20;255:4</p> <p>starting (9) 77:10;102:19; 125:11;129:2; 131:12;134:13; 256:13;298:1;318:8</p> <p>starts (1) 234:17</p> <p>state (25) 25:17;26:2;48:17, 18,20;117:12; 147:22;148:5,7,13, 15;169:5,7,13; 218:16;219:6;226:7; 260:1,4;263:20; 264:5;273:2;278:9; 300:8,14</p> <p>stated (1) 251:2</p> <p>statement (14) 11:11;13:16;77:1; 94:15;96:10;110:2; 117:16,21;206:8; 218:20,21;232:6; 260:9;282:6</p> <p>statements (19) 29:7;76:22;77:3; 94:18;97:17;99:5; 112:1;198:13,20; 199:18;201:3,6; 218:5;230:21;231:2, 5;233:6;235:4,7</p> <p>States (32) 16:6;43:13;45:21; 46:8;49:17;72:15; 76:3;120:14;147:15; 148:8,20,20,21; 149:2,4,7,18;150:5,8;</p>	<p>177:21;181:2; 183:10;186:1; 242:21;265:16; 266:17;275:3; 276:18;281:4;308:7, 17;320:16</p> <p>States' (1) 315:12</p> <p>statewide (1) 188:18</p> <p>stating (2) 90:7;297:2</p> <p>statistical (1) 116:22</p> <p>statistically (2) 118:3,7</p> <p>statistics (3) 50:8;136:12;272:1</p> <p>status (7) 271:14;284:20; 285:7,9;286:18; 287:4;305:17</p> <p>statute (3) 38:3;43:12;46:4</p> <p>statutes (3) 82:8;94:11,12</p> <p>statutory (1) 302:19</p> <p>stave (1) 78:17</p> <p>stay (2) 236:21;237:2</p> <p>staying (2) 22:22;189:11</p> <p>steadily (1) 277:21</p> <p>steeper (1) 57:16</p> <p>step (17) 14:16;21:15;22:14; 36:14,16;61:5;73:21; 97:22;157:7;187:5; 235:17;280:20; 296:10,16;310:19; 311:14;319:1</p> <p>Stephen (1) 11:19</p> <p>steps (9) 7:10;11:12;13:22; 270:15,22;279:5,21; 314:13;324:22</p> <p>stepwise (3) 36:6;37:3;38:1</p> <p>stereotypic (1) 137:12</p> <p>Steve (1) 288:8</p> <p>Steven (2) 288:12,15</p> <p>stick (1) 66:4</p> <p>still (33) 37:21;38:1;40:15;</p>
--	---	--	--	---

44:11;46:7;47:14,18; 48:20;60:1;91:3; 97:12;120:21;129:5; 136:21;149:1; 151:15;152:4; 155:18;161:9,13; 167:4;182:15; 185:18;199:11; 200:4;217:13; 222:12;230:6; 246:12,18;289:13; 297:18;303:18	192:15 strongly (4) 205:7;261:5;279:5; 328:18 struck (2) 154:5;159:2 structurally (2) 52:15;53:1 structure (4) 28:5;65:15;73:18; 124:6 structured (1) 315:1 structures (3) 65:2;166:11,16 struggle (1) 283:18 stuck (2) 62:22;185:10 studied (3) 199:17;204:15; 325:6 studies (34) 25:16;31:10;36:18, 21;41:21,22;42:1,7; 84:1;89:2;90:11,13; 107:11,21;108:7,13, 19;109:16,21;141:8; 187:12,12,14;199:20; 269:6,19;271:17; 279:16;290:8,17,22; 295:5;301:19;321:22 study (19) 26:4;90:4,5,15; 106:14,22;111:19; 115:21;116:12,18; 117:2,3,7,13,17; 118:1,4;187:13; 189:18 stuff (8) 92:19;169:10,11; 216:3;220:20; 222:20;239:11; 254:11 style (1) 88:4 stymieing (1) 42:19 subject (21) 9:11,14;23:4;83:8; 100:3;106:3;110:3; 118:21;128:17; 134:7,15;135:21; 149:20;150:6,13; 220:4;225:5;232:8; 233:21;235:14;291:8 submission (2) 119:4;327:2 submissions (1) 169:22 submit (8) 10:16,18,22;26:8; 282:8;300:3;328:19,	21 submitted (3) 84:9;115:19;120:1 submitting (3) 118:19,22;272:9 Suboxone (1) 239:7 subsequently (1) 178:12 substantial (6) 25:21;150:4; 221:10;228:6,21; 293:2 substantially (3) 147:3;276:14; 308:9 substantiated (1) 290:10 substantiation (1) 91:6 substitutability (1) 65:20 substitutable (1) 72:8 substitute (4) 67:2,2;221:15,17 substituted (1) 37:8 substitutes (2) 142:2;230:9 substituting (1) 25:18 substitution (11) 26:3;46:19;65:20; 72:6;169:6,14; 200:15;273:4;281:1, 5,12 substitutions (1) 281:8 subtle (5) 181:22,22;215:21; 217:13;238:14 subtly (1) 217:8 success (5) 68:8;258:15; 275:16;307:4;308:16 successes (2) 27:13;276:9 successful (5) 26:22;85:15;226:8; 297:21;301:14 successfully (2) 7:10;163:5 sued (2) 222:4;230:5 suffering (2) 95:9;253:7 sufficient (3) 158:22;238:7; 245:22 suffix (2) 48:5;272:7	suggest (5) 89:19;111:3; 121:13;263:5;295:16 suggested (2) 273:12,17 suggesting (7) 76:12;111:10,15; 112:12;114:3;325:4, 17 suggestions (1) 113:19 suggests (3) 89:13;127:18; 154:6 suing (1) 253:11 summarize (1) 127:6 summary (4) 146:9;150:4,15; 307:1 summer (1) 45:2 Sundar (2) 267:17,18 super (4) 45:13;182:22; 207:16,16 superior (2) 111:16;118:9 supervisor (2) 100:10;256:18 supplement (3) 92:5;246:10;321:1 supplements (2) 326:10,12 supplement-seeking (1) 326:5 supply (6) 62:17;63:14;73:1; 260:14;266:2;304:17 support (46) 6:16;13:18;14:21; 15:5;17:8;21:19; 22:5;31:9;36:7;45:5; 53:17;58:20;68:3,4; 69:4;89:9,11;90:11; 99:2,14;104:21; 105:3;108:8,20; 116:13,22;118:13; 127:7;208:20;259:3, 6,12;266:18;273:1,3; 279:5;293:9;313:10, 21;314:10;315:11, 14;321:18;322:16, 22;324:7 supported (11) 89:1,22;107:7,11; 109:17;111:20; 115:7,18;116:2; 117:17;326:14 supporting (4) 260:13;289:10;	306:10,21 supports (9) 20:8;29:14;83:17; 248:15;295:7;305:5; 313:14;321:5;325:20 Suppose (1) 220:16 supported (2) 152:1;246:7 Supreme (3) 27:6;223:12; 236:20 sure (34) 6:12;9:22;13:5; 31:12;33:7;37:14; 45:18;49:20;55:6; 58:14,15;63:22; 98:22;132:15;136:9; 138:8;146:1;173:4; 180:9;184:22;188:5; 202:21,22;203:2; 228:15;229:5; 245:12;247:10; 251:5,14;255:9; 256:8;282:2;287:7 surprising (1) 261:19 surrogates (1) 92:16 surrounding (2) 172:1;275:19 surveillance (6) 81:5;82:14;84:3, 15;85:4;102:17 survey (3) 58:20;221:20; 261:9 surveyed (2) 261:12;262:11 surveys (2) 221:2,11 Surya (1) 32:8,10;53:3;55:19 Susan (1) 53:19 susceptible (1) 232:10 sustain (2) 226:17;279:22 sustainable (6) 60:3;72:17;170:13; 263:12;305:3;306:21 sustaining (1) 182:21 sweeping (1) 27:10 switch (19) 183:6;189:5,10,19; 191:21;210:2; 217:11;237:5; 265:16,16,20;267:11; 269:6,19;271:16; 317:14,18;319:4,8
--	--	--	--	---

<p>switched (4) 207:21;287:12; 296:18,20</p> <p>switching (28) 38:8;48:14;70:9; 131:4;183:12; 188:17,20;200:3,6,8; 209:20;215:12; 262:6;265:9,18; 266:1;269:3;273:14; 279:16;281:12; 287:8;295:5;296:11; 297:2,22;318:8; 319:2,10</p> <p>Switzerland (1) 261:11</p> <p>sworn (1) 22:19</p> <p>Symphony (1) 143:14</p> <p>system (27) 16:11;18:9;43:21; 57:15;60:11;75:11; 78:9,11,19;126:5; 150:22;162:17; 166:12;184:17; 258:9;259:15;267:3; 276:4;277:15; 285:17;286:9;294:8; 295:12;303:12; 304:7;318:17,19</p> <p>systemic (1) 327:9</p> <p>systems (11) 52:6;58:1,1,8;73:1, 3;74:11;268:4;289:7, 10;304:6</p>	<p>190:10;202:15,17; 208:22;213:10; 226:1;235:20</p> <p>talked (21) 47:7;70:5,8,12; 114:8;150:21; 169:17;180:9; 198:10;199:10; 200:4,10;201:2; 202:4,14;213:5; 214:11;218:8;223:4; 233:10;236:14</p> <p>talking (25) 12:9;34:18,19; 38:1;41:1;43:3;66:1; 71:10;74:15;151:10; 188:6;194:5;199:1; 208:11;210:7;219:2; 220:20;229:6,7,8; 238:11;243:7; 246:22;249:21; 274:10</p> <p>talks (3) 41:6;201:16,17</p> <p>Tara (6) 11:15;12:4;21:16; 22:17;23:8,11</p> <p>target (1) 95:6</p> <p>targeted (2) 95:9;130:14</p> <p>targets (2) 198:22;223:9</p> <p>taxpayers (1) 68:12</p> <p>teaching (1) 295:19</p> <p>teasing (1) 132:9</p> <p>technical (2) 27:20;40:21</p> <p>technology (1) 171:5</p> <p>teeth (1) 158:17</p> <p>television (1) 179:19</p> <p>telling (3) 187:8;222:15; 317:18</p> <p>Temkin (16) 6:3,4,9;32:22,22; 33:6,7;40:22;44:16; 64:17;73:8;212:20; 256:14,14;287:1; 288:2</p> <p>tempered (1) 277:11</p> <p>temporary (1) 166:1</p> <p>tend (2) 126:10;229:17</p> <p>tenders (1)</p>	<p>170:6</p> <p>tends (2) 229:13;230:8</p> <p>tens (1) 24:22</p> <p>Tenth (1) 231:22</p> <p>teriparatide (1) 135:18</p> <p>term (3) 68:5;220:1,13</p> <p>terminology (4) 8:7;33:19;50:17; 296:3</p> <p>terms (30) 20:10;42:6;47:17; 49:1;70:7;75:7; 103:19;110:20; 111:5;113:18; 117:18;126:15; 131:3;133:18,20; 134:9,11;135:8; 136:1;157:8;164:18; 183:11;194:6;209:6; 227:19;230:1,2; 235:15;236:11;267:1</p> <p>terrific (1) 21:17</p> <p>territories (1) 183:16</p> <p>territory (1) 250:15</p> <p>test (4) 196:4;233:1; 234:13;243:12</p> <p>tested (2) 175:18,18</p> <p>testified (2) 28:6;272:22</p> <p>testimony (3) 28:11;94:22; 221:16</p> <p>testing (5) 94:22;127:17; 176:11;202:22; 322:22</p> <p>Texas (3) 11:7;278:9;282:16</p> <p>thalidomide' (1) 215:6</p> <p>thankfully (1) 276:17</p> <p>thanking (1) 254:22</p> <p>Thanks (8) 31:14;32:14;55:21; 101:10;190:20; 274:11;293:12; 327:22</p> <p>theme (1) 49:22</p> <p>themes (1) 156:20</p>	<p>theoretical (1) 83:13</p> <p>Therapeutic (16) 6:10;33:1;59:11; 75:13;102:8;124:17; 171:12;255:7; 256:16;267:1; 280:22;281:8;294:2; 302:7;305:21;310:5</p> <p>therapeutically (1) 77:15</p> <p>therapeutics (1) 186:16</p> <p>therapies (12) 6:21;7:14;179:12; 274:15;279:12; 281:10;284:2;296:8; 297:15;298:3; 318:18;320:10</p> <p>therapy (16) 115:14;116:2; 127:20;130:19; 185:2;187:5;283:12, 20;286:6;287:9; 296:10,17;297:21; 310:19;311:14;319:1</p> <p>thereafter (1) 139:3</p> <p>thereby (3) 160:17;288:22; 324:12</p> <p>therefore (10) 28:21;29:19;30:5; 65:7;89:12;113:19; 289:15;292:11; 301:2;325:14</p> <p>thicket (2) 50:16;161:2</p> <p>thickets (7) 42:13;50:5;165:4; 236:17;271:6; 280:18;308:19</p> <p>thinking (10) 45:16;50:1;83:8; 109:7;151:3;193:9; 218:1;241:16; 244:14;266:15</p> <p>third (14) 7:7;8:5;39:20; 50:18;51:10;88:16; 216:18;230:17; 233:17;234:20,22; 237:3;285:10;314:22</p> <p>thorniest (1) 72:7</p> <p>though (12) 10:9;33:18;74:6, 10;96:7;159:20; 184:6;217:1;225:4; 259:4;270:5;305:18</p> <p>thought (9) 33:11;86:2;92:8; 97:22;132:19;157:4;</p>	<p>158:21;250:9;264:17</p> <p>thoughts (4) 8:9;45:18;214:14; 247:20</p> <p>thousands (1) 24:22</p> <p>threat (1) 55:10</p> <p>threaten (1) 237:15</p> <p>three (23) 7:10;41:5;89:1; 97:3;114:15;124:6; 147:2,8;155:5; 183:13;191:19; 193:8;196:17; 230:14;237:19; 238:9;240:21; 270:11;273:5;283:9; 286:10;289:16; 305:12</p> <p>threshold (2) 92:17,20</p> <p>thrilled (2) 6:11;295:7</p> <p>throughout (12) 8:9;22:21;82:9; 121:12;174:12; 217:4;278:7;284:1; 297:21;304:12; 322:22;323:9</p> <p>throw (1) 70:20</p> <p>thumb (1) 221:3</p> <p>thus (4) 69:22;275:3,16; 281:19</p> <p>ticket (1) 45:11</p> <p>tie (2) 64:20;140:1</p> <p>tied (1) 65:13</p> <p>tiering (1) 43:21</p> <p>tiers (1) 271:1</p> <p>time-consuming (1) 159:16</p> <p>timeline (1) 19:18</p> <p>timeliness (1) 291:6</p> <p>timely (2) 150:7;327:5</p> <p>timer (2) 255:19,21</p> <p>times (4) 39:12;208:7; 271:22;272:22</p> <p>tiny (1) 88:10</p>
T				
<p>table (9) 8:18;10:13;68:4; 173:15;239:14,17; 319:13;329:2,7</p> <p>tables (1) 7:21</p> <p>tactics (3) 280:5,13,16</p> <p>tailored (1) 203:15</p> <p>takeaway (2) 73:14;195:12</p> <p>takeaways (1) 193:8</p> <p>talk (31) 33:18;35:9;36:4; 37:10;40:11;41:7; 44:17;52:19;67:13; 92:4;99:18;125:19; 132:15;140:14; 141:13;146:14,20; 157:2,11,15;168:6; 176:7;181:7;182:12;</p>	<p>190:10;202:15,17; 208:22;213:10; 226:1;235:20</p> <p>talked (21) 47:7;70:5,8,12; 114:8;150:21; 169:17;180:9; 198:10;199:10; 200:4,10;201:2; 202:4,14;213:5; 214:11;218:8;223:4; 233:10;236:14</p> <p>talking (25) 12:9;34:18,19; 38:1;41:1;43:3;66:1; 71:10;74:15;151:10; 188:6;194:5;199:1; 208:11;210:7;219:2; 220:20;229:6,7,8; 238:11;243:7; 246:22;249:21; 274:10</p> <p>talks (3) 41:6;201:16,17</p> <p>Tara (6) 11:15;12:4;21:16; 22:17;23:8,11</p> <p>target (1) 95:6</p> <p>targeted (2) 95:9;130:14</p> <p>targets (2) 198:22;223:9</p> <p>taxpayers (1) 68:12</p> <p>teaching (1) 295:19</p> <p>teasing (1) 132:9</p> <p>technical (2) 27:20;40:21</p> <p>technology (1) 171:5</p> <p>teeth (1) 158:17</p> <p>television (1) 179:19</p> <p>telling (3) 187:8;222:15; 317:18</p> <p>Temkin (16) 6:3,4,9;32:22,22; 33:6,7;40:22;44:16; 64:17;73:8;212:20; 256:14,14;287:1; 288:2</p> <p>tempered (1) 277:11</p> <p>temporary (1) 166:1</p> <p>tend (2) 126:10;229:17</p> <p>tenders (1)</p>	<p>170:6</p> <p>tends (2) 229:13;230:8</p> <p>tens (1) 24:22</p> <p>Tenth (1) 231:22</p> <p>teriparatide (1) 135:18</p> <p>term (3) 68:5;220:1,13</p> <p>terminology (4) 8:7;33:19;50:17; 296:3</p> <p>terms (30) 20:10;42:6;47:17; 49:1;70:7;75:7; 103:19;110:20; 111:5;113:18; 117:18;126:15; 131:3;133:18,20; 134:9,11;135:8; 136:1;157:8;164:18; 183:11;194:6;209:6; 227:19;230:1,2; 235:15;236:11;267:1</p> <p>terrific (1) 21:17</p> <p>territories (1) 183:16</p> <p>territory (1) 250:15</p> <p>test (4) 196:4;233:1; 234:13;243:12</p> <p>tested (2) 175:18,18</p> <p>testified (2) 28:6;272:22</p> <p>testimony (3) 28:11;94:22; 221:16</p> <p>testing (5) 94:22;127:17; 176:11;202:22; 322:22</p> <p>Texas (3) 11:7;278:9;282:16</p> <p>thalidomide' (1) 215:6</p> <p>thankfully (1) 276:17</p> <p>thanking (1) 254:22</p> <p>Thanks (8) 31:14;32:14;55:21; 101:10;190:20; 274:11;293:12; 327:22</p> <p>theme (1) 49:22</p> <p>themes (1) 156:20</p>	<p>theoretical (1) 83:13</p> <p>Therapeutic (16) 6:10;33:1;59:11; 75:13;102:8;124:17; 171:12;255:7; 256:16;267:1; 280:22;281:8;294:2; 302:7;305:21;310:5</p> <p>therapeutically (1) 77:15</p> <p>therapeutics (1) 186:16</p> <p>therapies (12) 6:21;7:14;179:12; 274:15;279:12; 281:10;284:2;296:8; 297:15;298:3; 318:18;320:10</p> <p>therapy (16) 115:14;116:2; 127:20;130:19; 185:2;187:5;283:12, 20;286:6;287:9; 296:10,17;297:21; 310:19;311:14;319:1</p> <p>thereafter (1) 139:3</p> <p>thereby (3) 160:17;288:22; 324:12</p> <p>therefore (10) 28:21;29:19;30:5; 65:7;89:12;113:19; 289:15;292:11; 301:2;325:14</p> <p>thicket (2) 50:16;161:2</p> <p>thickets (7) 42:13;50:5;165:4; 236:17;271:6; 280:18;308:19</p> <p>thinking (10) 45:16;50:1;83:8; 109:7;151:3;193:9; 218:1;241:16; 244:14;266:15</p> <p>third (14) 7:7;8:5;39:20; 50:18;51:10;88:16; 216:18;230:17; 233:17;234:20,22; 237:3;285:10;314:22</p> <p>thorniest (1) 72:7</p> <p>though (12) 10:9;33:18;74:6, 10;96:7;159:20; 184:6;217:1;225:4; 259:4;270:5;305:18</p> <p>thought (9) 33:11;86:2;92:8; 97:22;132:19;157:4;</p>	<p>158:21;250:9;264:17</p> <p>thoughts (4) 8:9;45:18;214:14; 247:20</p> <p>thousands (1) 24:22</p> <p>threat (1) 55:10</p> <p>threaten (1) 237:15</p> <p>three (23) 7:10;41:5;89:1; 97:3;114:15;124:6; 147:2,8;155:5; 183:13;191:19; 193:8;196:17; 230:14;237:19; 238:9;240:21; 270:11;273:5;283:9; 286:10;289:16; 305:12</p> <p>threshold (2) 92:17,20</p> <p>thrilled (2) 6:11;295:7</p> <p>throughout (12) 8:9;22:21;82:9; 121:12;174:12; 217:4;278:7;284:1; 297:21;304:12; 322:22;323:9</p> <p>throw (1) 70:20</p> <p>thumb (1) 221:3</p> <p>thus (4) 69:22;275:3,16; 281:19</p> <p>ticket (1) 45:11</p> <p>tie (2) 64:20;140:1</p> <p>tied (1) 65:13</p> <p>tiering (1) 43:21</p> <p>tiers (1) 271:1</p> <p>time-consuming (1) 159:16</p> <p>timeline (1) 19:18</p> <p>timeliness (1) 291:6</p> <p>timely (2) 150:7;327:5</p> <p>timer (2) 255:19,21</p> <p>times (4) 39:12;208:7; 271:22;272:22</p> <p>tiny (1) 88:10</p>

tippling (1) 193:11	190:8,11	299:7	243:8	295:21
tirelessly (2) 12:18;328:15	tool (3) 157:14;161:1; 275:7	training (1) 32:11	treatment (19) 16:18;35:18,19,19; 89:12;115:15;133:9; 206:17;274:12,13; 284:1,12,15;294:3; 297:13;304:20; 305:6;307:22;324:11	trusted (1) 70:17
Title (1) 82:7	tools (10) 70:17;79:7;81:7; 82:13;94:12;98:1; 188:8;241:18; 322:17,20	trajectory (1) 289:14		trusting (1) 192:15
titled (1) 100:19		transagency (1) 13:20		Truth (3) 178:22;179:8,8
TNF (1) 283:14	top (8) 129:11;130:1,6; 132:17;133:2;134:8; 237:13;255:20	transcribed (3) 9:17;256:8,10	treatment- (1) 211:21	truthful (28) 15:10;29:6,15; 75:1;78:3;79:7; 80:13,18;82:10;91:9; 98:14;99:12;101:21; 102:13;103:11; 104:7,17;105:5; 109:2,14;110:4; 121:6,15;122:3; 180:15;202:3; 257:21;324:20
TNFs (1) 286:7		transcript (2) 9:18;329:3	treatment-naive (1) 262:4	
today (62) 6:14;7:1,19;8:3,19, 20;9:3;10:4;11:22; 12:9;14:15;16:3; 23:14,16;24:3;33:17; 41:7;43:3,15;68:20, 21;70:12;71:18; 77:17;79:11,12;80:3, 11;99:19;127:8; 156:16;167:7; 178:20;197:16; 198:11;207:2,4; 213:4,11;214:5,12; 218:9;238:12; 244:18;246:13; 258:14;259:10; 261:2,4;272:16; 275:10;276:21; 278:12;284:17; 292:17;293:18; 298:14;300:5; 307:17;312:18; 316:1;324:6	topic (8) 12:2,8;84:15; 101:7;121:11; 171:14;206:9;303:10	transcription (1) 10:2	treatments (14) 21:5;22:6;24:5,18, 21;28:22;31:6;74:3; 130:14;184:21; 265:3;284:21; 294:13;315:12	
	topical (1) 207:18	transcriptionist (1) 10:1		
	topics (6) 70:5;207:5;214:8; 323:12,14,17	transfer (1) 268:3	treats (1) 57:8	try (20) 20:2;40:20;68:2; 69:15;73:17;78:17; 99:22;100:7;129:1; 138:16;140:1; 160:10;165:10; 166:11;175:16; 195:1,10;223:17; 253:13;310:21
	torts (1) 231:1	transferred (2) 195:13;250:10	treble (1) 239:3	
	total (9) 17:4;18:15;25:1; 128:21;129:3,6; 131:9,15;162:17	transform (2) 267:22,22	tremendous (3) 70:13;291:17; 294:1	
	totality (2) 37:1,21	transition (9) 48:5;115:22;138:2; 182:9;183:6,14,19; 184:2;312:22	tremendously (2) 69:9;70:1	
	touch (4) 6:22;36:1;71:3; 222:9	transitioned (1) 207:21	trend (1) 130:9	
	touched (2) 180:21;206:10	transitioning (1) 183:11	trials (4) 89:9;199:10,11; 211:8	
	tough (3) 226:14;234:10,12	transitions (1) 184:4	tribe (1) 250:11	
	tour (1) 225:6	translation (1) 17:15	trick (1) 77:8	
	towards (7) 61:20;129:14; 130:10;138:11; 202:12;203:12;268:6	translators (1) 180:14	tricky (1) 162:20	
	track (1) 126:4	transmitted (1) 226:12	tries (2) 143:8,14	
	tracking (2) 134:21;295:11	Transparency (7) 53:20;140:12; 291:18;292:1; 313:20;314:13;322:3	triggers (1) 197:5	
	Trade (12) 11:14;12:6;24:1; 31:19;125:4;172:9; 197:17;213:4;214:4; 236:14;247:1;257:2	transparent (4) 14:5;294:13;318:4; 322:7	trillion (1) 18:10	
	traded (1) 143:11	trap (5) 42:22;51:12;52:15; 160:19;309:20	triple (1) 274:8	
	trademark (1) 213:17	traps (2) 53:5;155:14	trivial (1) 167:20	
	tradeoff (1) 154:3	trastuzumab (2) 56:16;57:18	troubling (1) 76:6	
	traditional (1) 127:20	travel (1) 316:1	true (11) 12:19;67:22;77:3; 141:16;159:1; 220:19;224:11; 241:12;246:18; 260:10;267:1	
	traditionally (1) 93:10	treat (6) 16:12,20;56:2,3; 294:10,11	truly (4) 13:19;23:15;281:9, 19	
	traffic (1)	treated (3) 35:20;115:16; 116:12	trust (3) 195:14;266:11;	
		treating (3) 95:10;297:3;327:3		
		treatise (4) 232:12,13,14;		

<p>32:3;33:22;46:7; 81:19;88:21;90:10, 11;93:22;94:12; 98:11;111:21; 128:22;138:15; 146:19;157:19; 162:15;167:16; 170:14;189:15,17; 190:6,13;208:12; 216:5;235:11;269:1; 283:2;306:3</p> <p>type (15) 47:9;93:7;104:20; 109:13;131:6; 137:10,18;138:21; 139:4,6;152:17; 154:16;162:18; 182:7;199:15</p> <p>types (15) 21:15;121:21; 126:4;128:1;137:6; 138:19;148:20; 154:19;156:19; 157:19;159:9; 166:16;170:16; 198:1;235:21</p> <p>typically (6) 29:2;37:3,16,17; 85:14;86:15</p>	<p>61:11;66:11;94:6; 104:5,12;119:2; 147:16,20,20;155:12; 205:2;226:4,6; 240:13;257:18; 268:9;304:5</p> <p>underinsured (1) 192:5</p> <p>underlying (3) 56:7,13;261:4</p> <p>undermine (4) 21:4;110:11; 266:11;274:19</p> <p>undermines (1) 78:19</p> <p>undermining (1) 78:21</p> <p>underneath (1) 51:12</p> <p>underscore (1) 285:15</p> <p>understandable (2) 203:1;204:1</p> <p>undertake (2) 44:20;45:12</p> <p>undertakes (1) 327:9</p> <p>undertaking (1) 45:11</p> <p>underwent (1) 115:22</p> <p>undue (1) 161:17</p> <p>unduly (1) 25:22</p> <p>unfair (8) 25:9;29:20;30:6; 94:2,3;235:4;240:13, 14</p> <p>unfamiliar (1) 136:10</p> <p>unfettered (1) 302:3</p> <p>Unfortunately (4) 20:15;168:12; 171:15;308:15</p> <p>uniform (2) 228:21;296:5</p> <p>uniformly (2) 158:1;262:17</p> <p>unions (1) 278:20</p> <p>unique (14) 43:12;51:19;59:10; 103:17;120:20; 121:1;172:16; 183:10;194:21; 219:4;246:22; 254:12;276:5;293:22</p> <p>uniquely (2) 239:2;240:12</p> <p>unit (1) 143:17</p>	<p>United (18) 16:6;43:13;45:21; 46:8;49:17;72:15; 177:21;181:2; 183:10;242:21; 265:16;266:17; 275:3;276:18;308:7, 17;315:11;320:16</p> <p>units (3) 143:15;149:14; 305:15</p> <p>University (6) 11:7;23:7;124:20; 158:18;260:1,5</p> <p>unlawful (1) 280:15</p> <p>unlawfully (1) 327:10</p> <p>unless (2) 76:18;327:13</p> <p>Unlike (2) 186:6;188:17</p> <p>unlikely (1) 237:5</p> <p>unmet (2) 16:22;268:16</p> <p>unmuted (1) 173:1</p> <p>unnecessarily (1) 277:19</p> <p>unnecessary (2) 280:1;326:16</p> <p>unprecedented (2) 16:4,7</p> <p>unrealized (1) 21:6</p> <p>unreasonable (1) 235:5</p> <p>unregulated (1) 302:3</p> <p>unsafe (1) 200:8</p> <p>unsubstantiated (2) 97:4,18</p> <p>untitled (5) 81:7;85:10;86:9, 14;90:19</p> <p>untold (1) 31:5</p> <p>unwarranted (1) 25:21</p> <p>unwavering (1) 297:10</p> <p>up (52) 10:11,13;16:15; 17:21;34:14;41:4; 54:3;72:22;85:2; 120:12;122:20; 129:6;130:3;133:18; 134:2;135:2;136:13; 139:16;153:10; 160:14;166:22; 167:19;180:1;</p>	<p>183:11;184:21; 185:5;187:1;188:10; 190:19;192:20; 194:20;204:18; 212:15;215:2,6,13; 216:3;222:4;226:21; 238:1;244:1,19; 255:18;263:6;268:5; 270:6;276:15; 288:11;290:20; 318:14;319:13,14</p> <p>up-and-coming (1) 168:7</p> <p>upcoming (1) 312:22</p> <p>update (1) 119:17</p> <p>updated (1) 206:13</p> <p>updates (2) 326:22;327:3</p> <p>updating (1) 273:3</p> <p>uphold (1) 284:10</p> <p>upon (6) 8:16;22:9;82:8; 93:18;326:5;329:5</p> <p>uptake (31) 31:22;56:1,18; 57:16;58:11;59:13; 60:1;67:8;68:14; 71:7,15;99:14;135:8; 141:15;147:14; 150:1,4;156:9; 171:14;172:4; 190:13;258:10; 259:12;261:5; 273:20;286:9; 295:13;306:10,20; 314:3;315:7</p> <p>uptick (2) 58:3,5</p> <p>urge (9) 205:1;263:10; 268:14;277:18; 279:21;280:15; 285:10;296:22; 302:13</p> <p>urgency (1) 193:10</p> <p>urgent (1) 16:22</p> <p>urges (1) 326:21</p> <p>usage (1) 270:10</p> <p>US-Canada (1) 177:19</p> <p>use (49) 7:9;8:7;50:16; 55:8;59:3;60:17,17; 63:3;64:4;73:22;</p>	<p>77:18;83:2;88:5; 98:5;106:11;107:18, 22;126:15;128:21, 22;141:3;148:8,11, 14;149:11;150:20; 170:5;174:20;175:5; 181:21;182:16; 183:3,22;186:5; 197:19;211:10; 222:19;251:3;256:8; 270:1,9;279:18; 280:18;309:1; 310:22;317:10,12,13; 326:6</p> <p>used (25) 16:11;49:5;62:13; 64:8,9,11;84:17; 89:9;93:9,19;97:21; 106:14;114:17; 117:7;128:20; 134:11;148:1;209:8; 210:21;211:8; 241:19;280:5; 311:15;319:15; 321:14</p> <p>useful (12) 35:10;43:22;45:14; 68:1;129:22;132:19; 136:14;137:3;152:7; 157:14;251:4;300:3</p> <p>uses (3) 106:6;175:15; 309:21</p> <p>using (18) 20:22;61:6;64:14; 69:16;76:9;77:12; 90:15;99:10;100:2; 127:2;143:8,20; 144:4;187:9;194:6; 238:13;267:14; 280:16</p> <p>USP (11) 320:16,18,19; 321:5,12,16;322:6, 10,13;323:2,21</p> <p>USP's (1) 321:13</p> <p>usual (1) 92:4</p> <p>usually (7) 140:3;151:17; 187:6;221:1;228:10; 229:14;253:11</p> <p>utilization (13) 57:10;58:10;64:5; 68:14;139:2;148:19; 149:12;157:22; 158:1,3;161:20; 166:15;296:9</p> <p>utilize (1) 272:1</p>
U				
<p>UK (1) 261:12</p> <p>Ulrich (3) 311:19,21,22</p> <p>ultimately (11) 7:12;21:4;36:17; 52:17;68:2;78:21; 153:18;160:1;258:9; 259:18;290:3</p> <p>unanticipated (1) 153:15</p> <p>unavailable (1) 21:6</p> <p>unaware (1) 274:19</p> <p>unbiased (1) 183:4</p> <p>uncertain (2) 159:17;163:11</p> <p>uncertainties (4) 163:9,20;164:1,5</p> <p>uncertainty (11) 20:21;36:15,19; 44:11;162:21;163:1, 1,18;164:8;272:2; 281:11</p> <p>unclear (1) 165:5</p> <p>under (23) 26:7;43:16;55:10; 56:9;57:14;59:19;</p>	<p>unduly (1) 25:22</p> <p>unfair (8) 25:9;29:20;30:6; 94:2,3;235:4;240:13, 14</p> <p>unfamiliar (1) 136:10</p> <p>unfettered (1) 302:3</p> <p>Unfortunately (4) 20:15;168:12; 171:15;308:15</p> <p>uniform (2) 228:21;296:5</p> <p>uniformly (2) 158:1;262:17</p> <p>unions (1) 278:20</p> <p>unique (14) 43:12;51:19;59:10; 103:17;120:20; 121:1;172:16; 183:10;194:21; 219:4;246:22; 254:12;276:5;293:22</p> <p>uniquely (2) 239:2;240:12</p> <p>unit (1) 143:17</p>	<p>United (18) 16:6;43:13;45:21; 46:8;49:17;72:15; 177:21;181:2; 183:10;242:21; 265:16;266:17; 275:3;276:18;308:7, 17;315:11;320:16</p> <p>units (3) 143:15;149:14; 305:15</p> <p>University (6) 11:7;23:7;124:20; 158:18;260:1,5</p> <p>unlawful (1) 280:15</p> <p>unlawfully (1) 327:10</p> <p>unless (2) 76:18;327:13</p> <p>Unlike (2) 186:6;188:17</p> <p>unlikely (1) 237:5</p> <p>unmet (2) 16:22;268:16</p> <p>unmuted (1) 173:1</p> <p>unnecessarily (1) 277:19</p> <p>unnecessary (2) 280:1;326:16</p> <p>unprecedented (2) 16:4,7</p> <p>unrealized (1) 21:6</p> <p>unreasonable (1) 235:5</p> <p>unregulated (1) 302:3</p> <p>unsafe (1) 200:8</p> <p>unsubstantiated (2) 97:4,18</p> <p>untitled (5) 81:7;85:10;86:9, 14;90:19</p> <p>untold (1) 31:5</p> <p>unwarranted (1) 25:21</p> <p>unwavering (1) 297:10</p> <p>up (52) 10:11,13;16:15; 17:21;34:14;41:4; 54:3;72:22;85:2; 120:12;122:20; 129:6;130:3;133:18; 134:2;135:2;136:13; 139:16;153:10; 160:14;166:22; 167:19;180:1;</p>	<p>183:11;184:21; 185:5;187:1;188:10; 190:19;192:20; 194:20;204:18; 212:15;215:2,6,13; 216:3;222:4;226:21; 238:1;244:1,19; 255:18;263:6;268:5; 270:6;276:15; 288:11;290:20; 318:14;319:13,14</p> <p>up-and-coming (1) 168:7</p> <p>upcoming (1) 312:22</p> <p>update (1) 119:17</p> <p>updated (1) 206:13</p> <p>updates (2) 326:22;327:3</p> <p>updating (1) 273:3</p> <p>uphold (1) 284:10</p> <p>upon (6) 8:16;22:9;82:8; 93:18;326:5;329:5</p> <p>uptake (31) 31:22;56:1,18; 57:16;58:11;59:13; 60:1;67:8;68:14; 71:7,15;99:14;135:8; 141:15;147:14; 150:1,4;156:9; 171:14;172:4; 190:13;258:10; 259:12;261:5; 273:20;286:9; 295:13;306:10,20; 314:3;315:7</p> <p>uptick (2) 58:3,5</p> <p>urge (9) 205:1;263:10; 268:14;277:18; 279:21;280:15; 285:10;296:22; 302:13</p> <p>urgency (1) 193:10</p> <p>urgent (1) 16:22</p> <p>urges (1) 326:21</p> <p>usage (1) 270:10</p> <p>US-Canada (1) 177:19</p> <p>use (49) 7:9;8:7;50:16; 55:8;59:3;60:17,17; 63:3;64:4;73:22;</p>	<p>77:18;83:2;88:5; 98:5;106:11;107:18, 22;126:15;128:21, 22;141:3;148:8,11, 14;149:11;150:20; 170:5;174:20;175:5; 181:21;182:16; 183:3,22;186:5; 197:19;211:10; 222:19;251:3;256:8; 270:1,9;279:18; 280:18;309:1; 310:22;317:10,12,13; 326:6</p> <p>used (25) 16:11;49:5;62:13; 64:8,9,11;84:17; 89:9;93:9,19;97:21; 106:14;114:17; 117:7;128:20; 134:11;148:1;209:8; 210:21;211:8; 241:19;280:5; 311:15;319:15; 321:14</p> <p>useful (12) 35:10;43:22;45:14; 68:1;129:22;132:19; 136:14;137:3;152:7; 157:14;251:4;300:3</p> <p>uses (3) 106:6;175:15; 309:21</p> <p>using (18) 20:22;61:6;64:14; 69:16;76:9;77:12; 90:15;99:10;100:2; 127:2;143:8,20; 144:4;187:9;194:6; 238:13;267:14; 280:16</p> <p>USP (11) 320:16,18,19; 321:5,12,16;322:6, 10,13;323:2,21</p> <p>USP's (1) 321:13</p> <p>usual (1) 92:4</p> <p>usually (7) 140:3;151:17; 187:6;221:1;228:10; 229:14;253:11</p> <p>utilization (13) 57:10;58:10;64:5; 68:14;139:2;148:19; 149:12;157:22; 158:1,3;161:20; 166:15;296:9</p> <p>utilize (1) 272:1</p>

<p>V</p>	<p>vibrant (1) 78:2 vice (8) 257:8;267:19; 283:4,6;288:15; 311:20,22;320:15 victories (1) 27:5 video (3) 8:4;176:14;207:15 videos (2) 207:12,18 videotape (1) 9:15 view (8) 13:14,14;126:11; 133:21;134:3,12; 182:15;269:22 viewers (2) 11:2;95:20 viewpoint (2) 95:6;294:1 views (1) 8:8 vigorous (1) 295:5 vigorously (1) 26:20 violate (2) 29:11;81:9 violation (6) 81:12;85:5,12; 229:4;238:20;239:12 violations (3) 85:17;90:19;91:2 violative (2) 84:13;86:16 virtual (1) 94:17 virtually (5) 12:1;67:10;155:15; 294:7;299:22 virtuous (1) 20:9 visit (3) 83:20;119:3;176:8 visits (1) 210:1 Vizient (9) 288:12,17,19; 289:3,9,15,19;290:4; 291:15 voice (5) 70:17;197:8; 281:13;288:8;298:8 voices (1) 316:18 volume (5) 125:22;128:20; 134:9,22;135:4 volume-based (1) 310:1 voluntarily (2)</p>	<p>118:16;319:4 voluntary (1) 82:17 volunteer (1) 178:21 volunteering (1) 178:6</p>	<p>227:13;233:12; 239:17;241:8; 249:10;260:20; 317:20;318:17 ways (15) 19:9;31:5;42:5; 47:18;48:10;72:17; 77:16;78:6;97:3; 128:15;138:15; 174:18;193:18; 196:20;293:6 weaken (1) 21:3 wear (1) 71:9 web (4) 175:11;203:18; 206:13;214:10 webcast (3) 11:1,2;328:11 webpage (1) 207:3 website (13) 9:19;83:21;86:15; 119:3;175:14; 178:19;185:13; 207:12;208:2; 216:10;299:7,20; 329:4 website's (1) 176:17 week (3) 39:18,19;144:3 weekend (1) 264:13 weeks (2) 39:20;189:17 weigh (1) 186:15 weighing (1) 28:1 WEINSTEIN (22) 213:2,3;214:2; 218:6;225:10,11,15; 226:3,20;229:1; 237:21;239:19; 240:18;242:19; 245:19;246:13; 247:16;248:13; 250:21;251:17; 253:16;254:21 weird (2) 222:20;254:6 Welcome (5) 6:3,7;12:3;213:2; 281:21 welcoming (1) 23:13 well-being (1) 309:13 well-developed (1) 244:2 well-informed (1)</p>	<p>29:2 weren't (1) 77:15 Western (1) 261:10 whack (1) 250:3 whack-a-mole (3) 250:1;282:20; 283:2 what's (28) 34:17;42:6;52:14; 59:5;62:2;72:12; 77:19;124:4;126:11; 128:9,19;130:17,17; 142:10;147:7;155:2; 170:2,12,18;172:16; 179:1;180:2;221:21; 223:22;233:8,16; 247:1;250:2 whereas (1) 57:12 whereby (1) 310:20 wherein (1) 265:10 Where's (1) 225:16 Whereupon (4) 74:19;123:3; 212:22;329:12 whichever (2) 140:5;187:1 White (9) 12:3;44:18;56:22; 62:16;63:20;66:5; 88:5;181:10,10 white-cell (2) 61:14,20 whole (15) 45:3;47:1;49:5; 64:3;99:21;122:9; 142:14;152:22; 160:6;181:10;186:2; 214:19;225:21; 239:16;282:3 whole-disease (1) 183:7 wholesale (1) 301:20 wholesaler (1) 142:16 wholesalers (3) 126:3,16;142:12 who's (6) 12:5;79:13,18; 206:6;221:19;240:7 whose (1) 190:18 who've (1) 12:10 wide (3) 139:4;262:11;</p>
<p>valid (4) 158:14;159:9; 287:17,19 validate (1) 56:20 validated (1) 144:3 validity (3) 70:2;144:7;292:21 valuable (3) 165:12;284:14; 321:17 value (13) 46:8,12;47:17; 77:21;128:16;134:6, 14,18;135:20;152:5; 157:15;268:3;320:7 value-added (1) 271:17 variability (1) 292:7 variable (1) 293:1 variables (2) 192:3,8 variance (1) 296:3 variation (2) 262:11;292:14 varieties (1) 235:3 variety (5) 35:9;52:11;82:12; 121:8;126:3 various (5) 121:8;174:19; 175:10;196:7;252:22 vary (2) 61:4;63:7 varying (3) 60:16;195:6; 319:15 vast (2) 85:13;300:18 version (3) 63:16;66:14; 132:22 versus (15) 14:3;57:2;59:16, 17;65:1,6;147:9; 212:1;222:3;223:15; 224:1;225:3;251:18, 20;317:6 via (3) 68:18;300:3; 328:11 viability (2) 270:17;306:12 viable (1) 41:13</p>	<p>W</p> <p>wade (1) 50:15 wait (8) 164:6,9,13;166:4,4, 5,6;190:17 wait-and-see (1) 52:13 waived (2) 226:13;290:18 walk (3) 33:10;229:3;259:9 wall (3) 309:19,19;310:7 walls (4) 308:20,21;311:14; 318:21 wants (4) 107:10;116:16; 146:6;251:2 warning (11) 81:7;85:10;86:9, 13;87:7,9;90:19; 97:21;220:7;255:21; 299:10 warnings (1) 87:18 Washington (2) 214:22;260:11 wasted (1) 269:20 watch (2) 62:2;135:7 watching (3) 52:22;170:18; 185:12 waterfront (2) 99:22;100:4 way (51) 15:18;22:5;25:15; 26:2,19;32:2;37:3; 45:13;51:5;52:16; 59:16;64:15;69:14, 15,17;85:14;88:11; 103:6;105:6;109:15; 132:9;136:16,16; 139:5;140:22; 141:18;161:14; 163:16;180:15; 181:19;182:5; 184:20,20;185:2; 186:10,19;198:17; 202:12;210:11; 214:13,15;217:12,14;</p>	<p>W</p> <p>wade (1) 50:15 wait (8) 164:6,9,13;166:4,4, 5,6;190:17 wait-and-see (1) 52:13 waived (2) 226:13;290:18 walk (3) 33:10;229:3;259:9 wall (3) 309:19,19;310:7 walls (4) 308:20,21;311:14; 318:21 wants (4) 107:10;116:16; 146:6;251:2 warning (11) 81:7;85:10;86:9, 13;87:7,9;90:19; 97:21;220:7;255:21; 299:10 warnings (1) 87:18 Washington (2) 214:22;260:11 wasted (1) 269:20 watch (2) 62:2;135:7 watching (3) 52:22;170:18; 185:12 waterfront (2) 99:22;100:4 way (51) 15:18;22:5;25:15; 26:2,19;32:2;37:3; 45:13;51:5;52:16; 59:16;64:15;69:14, 15,17;85:14;88:11; 103:6;105:6;109:15; 132:9;136:16,16; 139:5;140:22; 141:18;161:14; 163:16;180:15; 181:19;182:5; 184:20,20;185:2; 186:10,19;198:17; 202:12;210:11; 214:13,15;217:12,14;</p>	<p>227:13;233:12; 239:17;241:8; 249:10;260:20; 317:20;318:17 ways (15) 19:9;31:5;42:5; 47:18;48:10;72:17; 77:16;78:6;97:3; 128:15;138:15; 174:18;193:18; 196:20;293:6 weaken (1) 21:3 wear (1) 71:9 web (4) 175:11;203:18; 206:13;214:10 webcast (3) 11:1,2;328:11 webpage (1) 207:3 website (13) 9:19;83:21;86:15; 119:3;175:14; 178:19;185:13; 207:12;208:2; 216:10;299:7,20; 329:4 website's (1) 176:17 week (3) 39:18,19;144:3 weekend (1) 264:13 weeks (2) 39:20;189:17 weigh (1) 186:15 weighing (1) 28:1 WEINSTEIN (22) 213:2,3;214:2; 218:6;225:10,11,15; 226:3,20;229:1; 237:21;239:19; 240:18;242:19; 245:19;246:13; 247:16;248:13; 250:21;251:17; 253:16;254:21 weird (2) 222:20;254:6 Welcome (5) 6:3,7;12:3;213:2; 281:21 welcoming (1) 23:13 well-being (1) 309:13 well-developed (1) 244:2 well-informed (1)</p>	<p>29:2 weren't (1) 77:15 Western (1) 261:10 whack (1) 250:3 whack-a-mole (3) 250:1;282:20; 283:2 what's (28) 34:17;42:6;52:14; 59:5;62:2;72:12; 77:19;124:4;126:11; 128:9,19;130:17,17; 142:10;147:7;155:2; 170:2,12,18;172:16; 179:1;180:2;221:21; 223:22;233:8,16; 247:1;250:2 whereas (1) 57:12 whereby (1) 310:20 wherein (1) 265:10 Where's (1) 225:16 Whereupon (4) 74:19;123:3; 212:22;329:12 whichever (2) 140:5;187:1 White (9) 12:3;44:18;56:22; 62:16;63:20;66:5; 88:5;181:10,10 white-cell (2) 61:14,20 whole (15) 45:3;47:1;49:5; 64:3;99:21;122:9; 142:14;152:22; 160:6;181:10;186:2; 214:19;225:21; 239:16;282:3 whole-disease (1) 183:7 wholesale (1) 301:20 wholesaler (1) 142:16 wholesalers (3) 126:3,16;142:12 who's (6) 12:5;79:13,18; 206:6;221:19;240:7 whose (1) 190:18 who've (1) 12:10 wide (3) 139:4;262:11;</p>

289:6 widely (1) 31:6 widespread (1) 280:18 willing (3) 180:1;203:21; 219:18 win (1) 242:8 winner (1) 170:5 winner (1) 152:20 wish (1) 210:6 withholding (1) 327:12 within (13) 60:6,11;74:3; 79:20;114:16; 138:20;142:1;194:3; 196:21;276:1; 299:19;307:4;329:4 without (22) 32:6;37:9;55:5; 67:3;77:1;80:4; 151:19;184:18; 187:7;193:10;220:7; 222:12;224:11; 232:8;233:21; 266:19;276:2;281:5; 16;309:12;326:2; 327:15 Wonderful (4) 173:3;236:1; 238:12;254:18 wondering (2) 138:6;144:7 wonky (1) 67:20 word (4) 62:5;96:20;106:7; 208:8 words (10) 34:15;38:11;46:21; 181:22,22;182:3,16; 282:16;283:2;308:5 wore (1) 191:3 work (47) 13:5,8,18;14:14; 18:21;19:8;21:18; 22:2;24:12;42:5; 45:8;55:6;72:10; 82:9;85:16;91:8; 152:17;156:17; 160:14;163:3; 172:10;173:8;189:1, 4;191:21;196:1,8; 202:8;203:21;211:1, 3,20;213:17;233:12; 259:1,2;263:11;	264:3;275:20;276:7; 289:13;297:6;298:5, 15;307:18;309:19; 318:3 worked (10) 12:17;22:20;23:18; 69:4;78:10;223:19; 273:5;291:11;321:3; 328:15 working (30) 13:21;14:4;15:4; 16:15;18:10;28:12; 73:12;136:21; 141:20;171:20; 174:15;175:20; 178:6;196:16; 209:12;211:14; 212:3;236:2;246:16; 254:9,16,19;258:20, 20;260:15;268:6; 277:15;293:9;305:9; 322:20 works (10) 29:5;89:6,13; 101:3;141:18;156:2; 217:11;316:16; 317:15;322:10 Workshop (25) 6:7,14;8:5,22;9:3, 11,17,20;10:13;11:1, 17;14:15;23:22; 24:10,11;255:5; 268:5;288:14;312:3; 328:1,10;329:3,4,8, 12 workshops (1) 39:12 world (18) 12:12,21;16:5; 34:10;36:3;45:15; 138:17;169:19; 170:19;186:6;188:2; 224:20;242:20; 260:16;273:6,21; 274:4,8 worldwide (2) 45:22;274:6 worried (2) 232:20;243:9 worry (1) 73:11 worse (1) 223:22 worth (3) 162:19;166:9; 218:1 wrap (3) 122:20;133:18; 166:22 wrist (1) 236:8 write (1) 174:1	written (5) 10:20,22;96:15; 188:3;282:8 wrong (6) 106:1;182:19; 205:18;231:6,8,16 Y year (14) 11:6;17:3;44:8; 50:6;52:21;101:13; 146:6;163:3;184:3; 261:9;276:1;278:10; 286:14;287:13 years (50) 17:8;25:16;27:19; 44:9;47:13;54:17; 62:1;63:22;64:10; 78:11;90:20;133:4; 145:8,17;150:9; 155:5,6;156:18; 158:21;167:2; 173:12;178:5,5,11; 189:15;197:21; 198:2;234:5;236:9; 259:1,3;260:6,8; 261:20;263:10; 265:6,7;266:15; 272:19;274:11; 278:9;283:18; 286:10;300:11; 303:21;304:12; 308:8;312:21;317:1; 323:5 Yep (1) 177:11 yield (1) 304:11 yielding (1) 159:21 young (1) 277:20 yous (1) 23:21 Z Zarxio (3) 39:18;144:13; 198:3 zero (2) 149:18;159:1 1 1 (6) 22:20;131:21; 184:3,5;243:13; 286:17 10 (14) 10:15;17:4,8;33:8; 89:10;132:17;133:2;	230:6;261:12; 272:19;274:11; 304:18;308:7;312:20 10:16 (1) 74:19 10:30 (1) 74:17 100 (2) 149:11;190:14 10-month (1) 326:7 11 (11) 40:6,9,19;49:19; 50:19;52:10;54:17; 132:5;183:15;260:8; 266:17 11:21 (1) 123:3 12 (9) 94:1,4,7;130:5,7; 131:13;132:6; 185:21;278:8 12:15 (2) 122:22;124:2 13 (2) 132:3;261:20 13b (1) 98:5 140 (1) 264:1 15 (8) 39:15;40:4;47:4; 49:18;194:14;221:3; 276:20;312:18 1504 (1) 8:2 17 (3) 10:4;131:16;255:9 17.5 (1) 134:18 1-855-RXB-ADAD (1) 84:21 19 (1) 286:12 1984 (2) 71:7;77:9 1991 (1) 79:22 2 2 (9) 18:15;67:19; 127:17;131:20; 132:4;184:4;229:7; 286:18;308:2 2:04 (1) 212:22 2:15 (1) 212:21 20 (4) 194:14;245:8; 289:8;306:5	20.2 (1) 135:4 2002 (2) 26:4;54:10 2003 (1) 26:11 2006 (1) 71:9 2008 (1) 28:1 2009 (1) 28:5 201 (1) 82:6 2013 (6) 134:13;144:11; 145:7,8,13;286:14 2014 (4) 129:6,12;130:4; 134:4 2015 (6) 17:4;90:20;91:3; 144:13;198:3;305:11 2016 (2) 181:3;191:12 2017 (1) 80:10 2018 (10) 22:20;25:3;26:15; 45:2;129:5,12; 141:22;148:20; 279:9;324:16 2019 (9) 129:5;130:2; 132:18,22;134:4; 196:14;210:19; 215:1;305:20 202 (1) 82:6 2020 (6) 10:22;17:6;40:12; 196:16,19;304:12 2023 (1) 135:22 2026 (1) 308:11 2034 (1) 55:4 20-year-old (1) 316:13 21 (3) 82:7;129:6;196:12 2253 (1) 119:2 23-year (1) 22:21 24/7 (1) 12:18 25 (3) 245:9;281:22; 282:3 26 (8) 17:5;39:8,13,16;
---	---	--	--	--

40:5;49:16;131:15; 266:18 27 (1) 194:14 270 (1) 278:18 2-minute (1) 255:21 2-week (1) 190:14		8 (5) 67:19;131:19; 166:17;258:18; 270:22 80 (3) 262:3;304:2; 308:15 800 (1) 274:5 82 (1) 261:22 84 (1) 262:14	
3	5		
3 (10) 41:22;89:7;106:19; 117:10;132:2; 170:15;190:11; 274:11;277:3;286:20 30 (4) 9:20;27:19;173:12; 329:4 31 (3) 178:5,5;286:4 340b (1) 143:19 351 (1) 104:12 351a (1) 34:1 351i (1) 37:7 351k (2) 34:6;37:4 35-36 (1) 17:21 360 (1) 126:11 38 (1) 38:21 39 (1) 300:11	5 (9) 54:10;94:1,2; 131:17;189:10; 217:15;240:13; 266:15;277:4 50 (3) 130:6;135:20; 289:4 50,000 (1) 178:14 500 (1) 278:19 501c3 (1) 316:14 502a (1) 81:21 502n (1) 82:1 55 (1) 277:1 56 (1) 71:11 579 (1) 261:9 58 (1) 129:8 5-minute (1) 207:15 5-year (1) 129:9	9	
4	6	9 (4) 10:22;17:5;170:15; 189:5 9:02 (1) 6:2 90 (6) 61:10;71:12; 186:22;229:14; 230:7;245:11 93 (1) 262:1 95 (2) 18:2;289:5 96 (1) 230:6 96.5 (1) 134:10 99 (2) 187:7;262:3 9th (1) 328:20	
4 (5) 10:6;106:19; 190:11;255:11;277:3 4:18 (1) 329:12 40 (9) 18:17;25:16;66:13; 130:12;131:10; 134:4,6;260:5;308:4 42-second (1) 99:17 45 (1) 208:7 46 (1) 262:5 49 (1) 274:7	6 (12) 17:22;67:17,17,19, 22;170:15;216:15; 217:5;262:14; 267:11;271:16;287:9 60 (2) 130:13;131:9 63 (1) 286:14 65-year (1) 31:2 6-month (1) 326:6		
	7		
	7 (2) 114:14;312:19 70 (2) 129:8;229:16 700 (2) 187:18;210:15 76 (2) 38:20;262:5		
	8		