

1 UNITED STATES FOOD AND DRUG ADMINISTRATION

2 CENTER FOR DRUG EVALUATION AND RESEARCH

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7 The Nonprescription Drug Facts Label in a Changing
8 Consumer Marketplace 2021

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10 Virtual Public Workshop
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13 DATE: Wednesday, June 9, 2021

14 TIME: 8:30 a.m.

15 LOCATION: U.S. Food and Drug Administration

16 Adobe Connect

17 Silver Spring, MD 20993

18 JOB No.: 4389669

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

2 DR. DELLIBOVI-RAGHEB: Good morning.

3 Welcome, and thank you for joining FDA's virtual
4 public workshop, "The Nonprescription Drug Facts Label
5 in a Changing Consumer Marketplace 2021." My name is
6 Teegan Dellibovi-Ragheb. I am an interdisciplinary
7 scientist in FDA's Office of Nonprescription Drugs,
8 and I am the workshop host and moderator.

9 Before we begin, there are a few housekeeping
10 items I want to mention. If you have any technical
11 issues during the meeting, you can submit questions
12 directly into the Q&A chat window or email a link that
13 we will provide there. If you have questions for our
14 speakers during the workshop, please enter them in the
15 same Q&A chat window and, time permitting, we will try
16 to address your questions during the panel discussions
17 at the end of each session.

18 In addition, FDA invites any interested
19 parties to submit research, data or information
20 relevant to the workshop topics to the public docket.
21 You can find a link to the docket on the workshop
22 webpage. The docket will remain open until August 10,

1 2021.

2 Following the workshop, meeting materials
3 including recordings, speaker slides and transcripts
4 will be available on the workshop webpage.

5 Moving on to our agenda, I'm thrilled to
6 announce that we have three incredible sessions
7 featuring experts invited to speak on many exciting
8 topics related to the nonprescription Drug Facts
9 label. I would like to welcome each of our speakers
10 and panel moderators. Please refer to the speakers'
11 full biographical summaries posted on the workshop
12 webpage to learn more about their remarkable work and
13 research.

14 Without further ado, I am delighted to
15 introduce our first two speakers who will deliver the
16 opening remarks. Please welcome our first speaker
17 from FDA, Dr. Peter Stein, director of CDER's Office
18 of New Drugs.

19 AV SUPPORT: Hi, Dr. Stein. I'm sorry to
20 interrupt. I believe you're muted on your cell phone.
21 This is AV support.

22 DR. STEIN: Okay. We'll try that again.

1 Thank you. Hopefully you can hear me now.

2 AV SUPPORT: Yes, sir. Thank you.

3 WELCOME And OPENING REMARKS

4 DR. STEIN: Okay. The challenges of our
5 virtual world. Well, I just want to again, I want to
6 welcome you to this important workshop. I know we've
7 been looking forward to learning and participating in
8 the presentations and discussions that I know will be
9 very rich today.

10 Two hundred and forty million Americans use
11 over-the-counter drugs every year, and these products
12 have long provided an efficient, low cost way for
13 consumers to manage everyday health needs. And they
14 play an increasingly vital role in our healthcare
15 system.

16 There are, of course, a vast array of over-
17 the-counter drugs including cough and cold medicines,
18 fever reducers, sunscreens, pain relievers, antacids
19 and many more. And for more than 20 years now,
20 consumers have relied on the information in the Drug
21 Facts label to allow them to appropriately self-select
22 which over-the-counter drug to use, how to take the

1 drug and what side effects they should look for. The
2 information allows these drugs to be used safely and
3 effectively without the intervention of a healthcare
4 professional.

5 While the DFL format has been a huge advance
6 when it was first proposed, a lot has changed in
7 medicine, in the American population and in the
8 consumer marketplace over the time. As the last year
9 during the pandemic in particular has shown us,
10 consumers no longer purchase their OTC drug products
11 just in a traditional brick-and-mortar pharmacy.

12 In addition to multiple different types of
13 retail outlets such as groceries and convenience
14 stores, consumers are increasingly purchasing drugs
15 online and are looking to digital tools and the
16 Internet to get their health information and a lot of
17 other information.

18 As these things change, it's important for
19 nonprescription drug labeling to keep up, and that's
20 why this workshop is so important. It's a start of
21 what we expect will be an ongoing process to take a
22 look at nonprescription labeling to see if it can be

1 further optimized for consumer use in a way that's
2 robust, user-friendly, compatible with traditional
3 text, paper-based presentation and adaptable to use
4 with new technologies.

5 So again I want to welcome you to what I know
6 will be a valuable and important meeting, and we
7 certainly appreciate your participation and look
8 forward to the discussions. And I'll turn it over to
9 Dr. Terri Michele, who's the director of CDER's Office
10 of Nonprescription Drugs. Terri?

11 DR. MICHELE: So thanks so much, Dr. Stein.
12 We really appreciate all of the support that we've
13 gotten from CDER and from OND to hold this workshop.
14 And we're looking to some really fantastic
15 presentations. So we're very excited that everyone
16 could join us this morning.

17 So this workshop's really all about the
18 future, which is the future of nonprescription drugs.
19 So I have a bit of an echo. Tech support, do you hear
20 an echo? No? Okay.

21 So basically when we first started
22 approaching speakers about this workshop a number of

1 months ago, the very first question that everyone
2 asked me was, well, why are you doing this now? And
3 that's a very good question, and I suspect that many
4 of you may share it.

5 So I wanted to talk a little bit about that.
6 The answer really comes down to preparing for the
7 future. So the idea for this workshop grew out of a
8 discussion I had with Dr. Woodcock several years ago
9 now while we were working on OTC monograph reform.
10 And as you heard, we're now living in a world that has
11 changed drastically from when we started thinking
12 about the Drug Facts label more than 20 years ago.

13 So seeing this, we started asking ourselves
14 what FDA could do to really help ensure better health
15 impact of over-the-counter, nonprescription drugs. So
16 these questions included how can the regulatory
17 process support safety and innovation while also being
18 more agile, timely and predictable, how can technology
19 impact on self-selection and use and expand the
20 availability of certain drug products and how can the
21 delivery of information for correct self-selection and
22 use be improved.

1 So based on these questions, we've been
2 working on several major initiatives to answer them.
3 So first to improve the regulatory process to support
4 safety and innovation, in March of 2020, so just over
5 a year ago now, Congress passed some really landmark
6 legislation for nonprescription drugs which reformed
7 the over-the-counter monograph system in the CARES
8 Act.

9 Monograph reform modernizes the OTC drug
10 review, taking it out of the slow and burdensome
11 regulation process into a new and more agile
12 administrative order process. Importantly the
13 legislation also gives FDA a new user fee program to
14 provide the funds that we need to implement this
15 program. So currently we're working very hard on
16 implementation to bring the promise of monograph
17 reform into fruition.

18 Second, the nonprescription safe use
19 regulatory expansion, or NSURE program, is an effort
20 to establish innovative approaches to increase access
21 to a broader selection of nonprescription drug
22 products for consumers. And these approaches include

1 applying innovative tools like digital health
2 technologies that would support consumers in
3 appropriately self-selecting and using certain drugs
4 to permit more complex prescription-to-over-the-
5 counter switch programs to proceed. And so far we
6 have a draft guidance out and we're working to publish
7 a proposed rule to further codify the process.

8 And that brings us to the third question, and
9 with these two major efforts ongoing, the time is now
10 right to begin looking at nonprescription drug
11 labeling, especially the Drug Facts label, to make
12 sure that we apply the learnings from the last 20
13 years of doing switches and looking at labeling to
14 make sure that we have an optimized label format to
15 better support safety and efficacy of products in
16 today's changing marketplace.

17 So we are very much looking forward to the
18 presentations today. We greatly appreciate the input
19 of our speakers as well as everyone attending from the
20 public, and we look forward to a very robust
21 discussion. So thank you, everyone, and I'll turn it
22 back to Teegan.

1 SESSION 1: THE CURRENT LANDSCAPE OF THE DRUG FACTS
2 LABEL And BARRIERS TO CONSUMER COMPREHENSION

3 DR. DELLIBOVI-RAGHEB: Thank you very much,
4 Dr. Michele, for your remarks. We will now begin our
5 first session, which is entitled, "The Current
6 Landscape of the Drug Facts Label and Barriers to
7 Consumer Comprehension."

8 Our first three speakers are from the Office
9 of Nonprescription Drugs at the FDA. So I will
10 mention here that these presentations reflect the
11 views of the authors and should not be construed to
12 represent FDA's views or policies.

13 Starting off our first session, I'd like to
14 introduce Dr. Kevin Lorick, from FDA's Office of
15 Nonprescription Drugs. The title of his presentation
16 is, "A Brief History of the Drug Facts Label for
17 Nonprescription Drugs."

18 A BRIEF HISTORY OF THE DRUG FACTS LABEL FOR
19 NONPRESCRIPTION DRUGS

20 DR. LORICK: Sorry. My name is Kevin Lorick,
21 and I'll be speaking today about the history of the
22 Drug Facts label for nonprescription drugs. Any

1 discussion of consumer labeling has to begin with what
2 existed before there was effective regulation.

3 This is an example of a patent medicine
4 label. Typical of a snake oil of the time, there are
5 outrageous claims and no directions for use. The
6 product claimed to be a cure-all for vague diseases or
7 symptoms that appeared similar but were not
8 necessarily related. It was billed as a reliable
9 treatment for epilepsy, St. Vitus dance, convulsions
10 hysteria, nervous prostration, insomnia, neurasthenia
11 and disorders of the nervous system. We don't know
12 what's in Dr. Guertin's nerve syrup, but we do know
13 that it is guaranteed free from alcohol, opiates and
14 other dangerous drugs.

15 The quackery was one of the factors that led
16 Dr. Harvey Wiley, the chief chemist of the FDA Bureau
17 for Chemistry and a member of the AMA's Council on
18 Pharmacy and Chemistry, to encourage Congress' passage
19 of the 1906 Pure Food and Drugs Act, also known as the
20 Wiley Act.

21 This law prohibited interstate commerce in
22 misbranded and adulterated foods, drinks and drugs.

1 The act provided some of the first definitions of
2 misbranded. Misbranded shall apply to all drugs, the
3 package or label of which shall be false or misleading
4 in any particular -- it's still our number one
5 definition, if it be an imitation or offered for sale
6 under the name of another article or if its contents
7 shall have been removed and other contents shall have
8 been placed in that package or if the package fails to
9 bear a statement on the label of the quantity or
10 proportion of any alcohol, morphine, opium, cocaine,
11 heroin or other dangerous drug.

12 However it was expected that safety would be
13 achieved by guaranteeing that drugs were what they
14 purported to be. The focus of this law was on
15 deceptive practice. For example, the definitions of
16 misbranding describe false claims, counterfeit or
17 falsified medicine through labeling, counterfeit or
18 falsified medicine through tampering or that the
19 product is intoxicating without informing the patient
20 or consumer; that is, material facts have been
21 omitted.

22 But there were some improvements. For

1 example, the Kickapoo Indian Medicine Company patented
2 Sagwa in 1882 as a cure-all. In 1908, they're selling
3 Kickapoo oil and the claims are more limited to aches
4 and pains. It also has directions for use.

5 However among its numerous shortcomings, the
6 1906 provisions for misbranding were not adequate.
7 The words safe and effective don't appear in the text
8 of the Wiley Act, and penalties were also limited.

9 Famously, elixir sulfanilamide was
10 responsible for at least 100 deaths and was recalled
11 and seized due to the presence of diethylene glycol, a
12 solvent which the manufacturer had not tested prior to
13 use. The product was misbranded because it contained
14 no alcohol, as required for a product labeled elixir.
15 However, despite the damage done, the company
16 responsible for only required to pay a small fine.
17 Even this fine wouldn't have been required had the
18 product been labeled solution.

19 And so Congress passed the more modern 1938
20 Federal Food, Drug and Cosmetic Act, greatly expanding
21 FDA authority over drug adulteration and misbranding,
22 and it authorized premarket approvals and inspections.

1 This new act went beyond saying that drugs had to be
2 what they said they were. It also stated that
3 products had to be safe. The law expanded the
4 definitions for misbranding to include if any
5 information required to appear on the label or
6 labeling is not placed with conspicuousness under the
7 consumer conditions for purchase and use. The
8 interpretation of this clause especially with regard
9 to therapeutic effectiveness claims varied.

10 It also includes the definition that the
11 label does not provide adequate directions for use
12 and, importantly, warnings against misuse that are
13 necessary for the protection of users or if it's
14 dangerous to health when used as suggested in the
15 labeling thereof.

16 In 1938 though it was up the pharmacist to
17 decide if an individual could simply walk in and buy a
18 drug or if a prescription from the doctor was
19 required. This could mean that consumers may receive
20 drugs with dangerous side effects containing complex
21 instructions at a time when many people couldn't even
22 read.

1 So later talks today will discuss the impact
2 of low literacy on label comprehension. This
3 confusion regarding when a doctor's advice may be
4 needed to safely use a drug led to the passage of the
5 1951 Durham-Humphrey amendment to the FD&C Act. This
6 meant that the FDA recognized two classes of drugs,
7 those available only with a prescription, the Rx only
8 or legend drugs, and those whose packaging did not
9 suggest the need for a prescription, the over-the-
10 counter or nonprescription drugs.

11 Here you see a label for an NSAID product
12 that I recreated from an actual product available in
13 1957. You'll notice that even when the directions are
14 clearly printed on the outside container, the warnings
15 are only found on the inside. So purchase decisions
16 that a consumer might make even for simple medicines
17 could still be uninformed of necessary warnings and
18 the drug could be potentially unsafe for them.

19 In 1962, the Kefauver-Harris amendments
20 required drugs to demonstrate effectiveness as well as
21 safety, and it was focused really on the protection of
22 human subjects. This amendment to the act created

1 FDA's modern NDA system, new drug application system.

2 The change in law also required review of the safety
3 and effectiveness of drugs already on the market.

4 While focused on prescription drugs, this led to the
5 OTC drugs review in 1972. In order to deal with the
6 large number of OTC drugs, the FDA created the
7 monograph system for classes of drugs that were
8 generally recognized as safe and effective, or GRASE.

9 Monograph regulations began requiring certain
10 warnings on labels for the GRASE drugs. For example,
11 21 CFR §331.30, which is the monograph for antacids,
12 requires the labeling for some products to contain a
13 warning, "May cause constipation." Similar to the
14 NSAID label I showed previously, there was not a
15 specific requirement that warnings be visible prior to
16 purchase.

17 So the way the information was presented
18 could vary from drug to drug and from manufacturer to
19 manufacturer. As a result, labels could still be
20 crowded with promotional material or have information
21 not relevant to use of the drug -- the safe use of the
22 drug mixed within the directions and the warnings.

1 Then in 1990, our colleagues in the Center
2 for Food Safety and Nutrition worked with the USDA and
3 Congress to pass the Nutrition Labeling and Education
4 Act of 1990, or NLEA. The agencies required
5 nutritional label paneling, which is described in 21
6 CFR §101.9 and shown here, provides standardized
7 graphic presentation for food nutrients, allowing
8 consumers to judge the significance of the levels of a
9 particular nutrient in a product in the context of a
10 total daily diet.

11 Since its implementation in 1993, the agency
12 has received very positive feedback from consumers and
13 nutritionists, noting the impact and utility of the
14 standardized food label. This also led FDA to
15 recognize that OTC drug labels needed to have
16 standardization and simplification to provide
17 consumers easier access to the information needed for
18 the safe use of their drugs.

19 In the Federal Register of February 27, 1997,
20 FDA proposed to establish a standardized format for
21 the labeling of OTC drug products that included
22 specific subheadings -- headings and subheadings

1 presented in a standardized order, standardized
2 graphical features such as Helvetica type style and
3 the use of bullet points to introduce key information
4 and minimum standards for type size and spacing or
5 whitespace. In a later talk, Amanda Pike-McCradden
6 will discuss the studies that evolved from this effort
7 and their significance.

8 So fast-forward two years. On March 17,
9 1999, FDA published a final rule that standardizes
10 format and content requirements for the labeling of
11 OTC drug products. This Drug Facts rule is codified
12 in 21 CFR §201.66 and states that the content and
13 format requirements within it apply to the labeling of
14 all OTC drug products.

15 This includes products marketed under a final
16 drug OTC monograph, products marketed under an
17 approved new drug application, or NDA, or an
18 abbreviated new drug application, ANDA, under section
19 505 of the act and products for which there is no
20 final drug OTC monograph or approved NDA or ANDA.

21 And so now, in order to better convey
22 adequate directions for use and appropriate warnings

1 against misuse to the layperson, the Drug Facts label
2 is required to be on the package at the point of
3 purchase and looks like this. Dr. Betsy Scroggs will
4 discuss the details of the Drug Facts rule, its
5 content and format requirements in a later talk.

6 So here we are a little bit more than 20
7 years later. And have things gotten better? Well,
8 with the DFL, consumers can make informed purchase
9 choices before taking the product home. Most serious
10 warnings are presented first and multiple label
11 comprehension studies have shown that this is helpful
12 in conveying the most important safety messages to
13 consumers.

14 Many consumers know directly where to look
15 for information relevant to their individual health
16 situation and standardization of the format the Drug
17 Facts has permitted ease of understanding for
18 physicians and pharmacists who may be advising
19 consumers on their self-treatment choices.

20 But of course not everything works the first
21 time out. Drug Facts labels have changed
22 incrementally for specific products as new warnings

1 arise. And, in general, they also have changed for
2 all OTC drugs. For example, in 2000, certain changes
3 in formatting were allowed to accommodate stronger
4 warnings. In 2007, a sexually transmitted disease
5 warning was added. In 2008, an FDA contact number for
6 adverse event reporting was added.

7 Well, what still needs work? For
8 prescription to OTC switches, the prescription labels
9 were always available. This is no longer the case,
10 especially for older drugs. This may be remedied only
11 with DFL content that is extensive, especially the
12 fixed-dose drug combinations.

13 Consumers usually only keep the immediate
14 container, despite instructions to keep the outer
15 package. Small type size is typically hard to read
16 and key warnings may be buried under flaps that
17 consumers won't or can't open. This is a three-panel
18 DFL that you only see the first panel at the point of
19 purchase.

20 Too many messages to read and understand can
21 lead to consumer fatigue and that fatigue can cause
22 consumers to miss, forget about or simply ignore

1 critical safety warnings.

2 So as we move forward, we have other things
3 to consider, right? The DFL rule is focused on
4 printed media, which makes some sense for a rule
5 written between 1999 and 2000 before the Internet
6 really took off the way that we know it today.

7 But the marketplace is changing. The DFL
8 rule does not consider the challenges related to
9 commerce in a digital world. In the simplest of
10 examples, we look at the use of nontraditional sales
11 outlets. Consumers still need access to proper label
12 information for informed purchase decisions.

13 But this is not always available. What you
14 see on the left here is an image that I constructed.
15 But it's typical of what you may find for OTC drugs
16 sold online today. Notice that there's a Drug Facts
17 label. But you can't pick up the bottle to read it.

18 On the other hand, access to digital
19 information is increasing. A focus on self-care in
20 the Internet Age has led to a desire for access to
21 more drugs that were previously available for
22 prescription or by prescription only. This creates

1 complex problems to solve if we want to accomplish
2 many of the newer prescription-to-OTC switches.

3 The DFL rule may not necessarily be
4 compatible with the very technologies that could be
5 used to convey complex messages or concepts that could
6 actually benefit consumers, right? We have access to
7 smartphones. We have access to our Internet websites.
8 We have access to social media that could be used to
9 provide better information.

10 These new considerations may require more
11 large-scale changes to regulation going forward. We
12 talked about the NSURE program, and we'll get to that
13 a little bit later on. These challenges will be
14 considered in our afternoon session.

15 So finally, as to the future, this workshop
16 is the beginning of the future of the DFL. As we move
17 into the future, let's not repeat the errors of our
18 history. Thank you. And I'll turn it back over to
19 Teegan.

20 DR. DELLIBOVI-RAGHEB: Thank you very much,
21 Dr. Lorick, for your talk. It is my pleasure to
22 introduce our next speaker, Dr. Betsy Scroggs, from

1 FDA's Office of Nonprescription Drugs. And the title
2 of her presentation is "Overview of the Drug Facts
3 Labeling Regulatory Requirements."

4 OVERVIEW OF THE DRUG FACTS LABELING REGULATORY
5 REQUIREMENTS

6 DR. SCROGGS: Hello. Hi. I'm Dr. Betsy
7 Scroggs, and I'm the associate director for labeling
8 in the Office of Nonprescription Drugs. The purpose
9 of my presentation today is to provide you with an
10 overview of the Drug Facts labeling content and format
11 requirements described in the Code of Federal
12 Regulations, or CFR, found under 21 CFR §201.66.

13 To jump right in, it is important to
14 understand the scope of the DFL regulations. The drug
15 fact regulations in §201.66 cover all OTC drug
16 products. The DFL provides for standardized content
17 and format requirements. The regulation itself, 21
18 CFR §201.66, is divided into two main parts. The
19 first is content requirements and the second are those
20 pesky format requirements.

21 So where do we find the Drug Facts label?
22 The Drug Facts label must appear on the outside

1 container of wrapper of the retail package, for
2 example, a carton, or on the immediate container
3 label, and for example, a bottle that would be in a
4 carton. But if there's no outside wrapper, then it
5 must be on the bottle.

6 This slide shows you on the left side a list
7 of the nine main topical content headings, which I
8 will describe to you during my presentation. The
9 colorful graphic image to the right is a
10 chlorpheniramine label which illustrates where the
11 headings, subheadings and information are located in
12 this carton.

13 The content requirements cover what
14 information is contained in the DFL, its organization
15 and how it must be presented in a certain order as
16 described in paragraph 201.66(c)(1) through (c)(9).
17 Please note that the nine headings, eight are required
18 whereas the last heading, questions or comments, is
19 optional. But we do recommend it.

20 Next we'll cover the headings, subheadings
21 and required content starting with the Drug Facts
22 title. The first required heading is the title "Drug

1 Facts." The title appears at the top of the Drug Fact
2 box. If the Drug Facts labeling appears on more than
3 one panel or side of the labeling, the title "Drug
4 Facts (Continued)" must appear at the top of each
5 subsequent panel containing the DFL.

6 Just below the Drug Facts title, we would
7 find the heading "Active ingredient (in each dosage
8 unit)." For example, the heading might state "Active
9 ingredient in each tablet," tablet being the dosage
10 unit. The heading is followed by the established name
11 of each active ingredient and the quantity of each
12 active ingredient in the dosage unit, such as
13 loratadine 10 mg or ibuprofen 200 mg.

14 Unless otherwise provided in an applicable
15 OTC drug monograph or approved drug application,
16 products marketed without discrete dosage units, for
17 example, topicals, will state the proportion rather
18 than the quantity of each active ingredient.
19 Proportion is generally expressed as a percentage.

20 Third up is the heading "Purpose" or
21 "Purposes," which is followed by either the general
22 pharmacological category or the principal intended

1 action of the drug or where the drug consists of more
2 than one active ingredient, the general
3 pharmacological categories or the principal intended
4 actions of each active ingredient. When an OTC drug
5 monograph contains a statement of identity, the
6 pharmacological action described in that monograph's
7 statement of identity is the stated purpose of the
8 active ingredient.

9 Fourth, the "Use" or "Uses" heading. That is
10 followed by the specific indications or approved uses
11 for the drug product. So this is fairly
12 straightforward.

13 Next up are the "Warnings" which I will cover
14 in the next 11 slides. The "Warnings" heading may be
15 followed by one or more special topics warnings; for
16 example, labeling a topical product with a warning,
17 "For external use only." Slide ten lists more special
18 topics warnings, Reye's syndrome warning, allergic
19 reaction and asthma alert warnings.

20 Slide 11 continues the special topics
21 warnings. Oh, I guess on this it said slide 34.
22 Okay. So for the sake of time, I will not run through

1 the regulations. But this is a list of more special
2 topics warnings. We're now on slide 35, which covers
3 contraindication labeling in the Drug Facts label.

4 The "Do not use" subheading is followed by
5 all contraindications for use with the product. These
6 contraindications are absolute and are intended for
7 when consumers should not use the product unless a
8 doctor has made a prior diagnosis or when certain
9 consumers should not use the product under any
10 circumstances.

11 Here we cover how we label for preexisting
12 conditions in the DFL under "Ask a doctor before use."
13 This subheading provides for two versions, one
14 directed to adults and one directed to a child's
15 caregiver. The subheadings read either as, "Ask a
16 doctor before use if you have," or, "Ask a doctor
17 before use if the child has."

18 These warnings are directed to consumers with
19 certain preexisting conditions and consumers with
20 certain symptoms. Warnings under the "Ask a doctor
21 before use" subheading are intended only for
22 situations where consumers should not use the product

1 until a doctor is consulted.

2 Now we are covering how we label for drug
3 interaction warnings under, "Ask a doctor or
4 pharmacist before use." This subheading also allows
5 for two versions, one directed to adults and one
6 directed to a child's caregiver. The subheadings read
7 either as, "Ask a doctor or pharmacist before use if
8 you are," or, "Ask a doctor or pharmacist before use
9 if the child is."

10 This subheading is followed by all major
11 drug-drug and drug-food interactions. And in today's
12 environment, that's becoming more challenging to list
13 all the known drug-drug interactions with a drug
14 product.

15 Consumers are warned about possible side
16 effects under the subheading, "When using this
17 product." The subheading, "When using this product,"
18 is followed by the side effects consumers may
19 experience or what to avoid while using the product.

20 Then we come to adverse reactions. If a
21 consumer would experience an adverse reaction to the
22 OTC drug product, the DFL directs the consumer to stop

1 use and ask a doctor. The "Stop use and ask a doctor
2 if" subheading is followed by words that tell a
3 consumer how to recognize signs of an adverse
4 reaction, to immediately discontinue use of the drug
5 product and, in some drug products, we have added a
6 redundancy to tell consumers to seek attention
7 immediately.

8 Now what this says is that if there are
9 required warnings that do not fit elsewhere, the
10 "Warnings" regulations to provide some flexibility to
11 include warnings that do not fit into one of the other
12 "Warnings" categories.

13 The DFL includes a pregnancy/breast-feeding
14 warning that directs the pregnant or breast-feeding
15 consumer to ask a health professional's advice before
16 use of the OTC product. There is an additional
17 warning for products containing aspirin or carbaspirin
18 calcium, and also the specific pregnancy and breast-
19 feeding warning found in some approved drug
20 applications for products containing ketoprofen,
21 naproxen sodium and ibuprofen.

22 We also warn consumers to keep out of the

1 reach of children, and that -- overdose, to get
2 medical help or to contact a poison control center
3 right away.

4 We will now shift gears and move on from this
5 important but extensive list of warnings. Following
6 the warnings are the directions for the drug product.
7 The heading, "Directions," is followed by the
8 directions for use described in an applicable OTC drug
9 monograph or approved drug application.

10 Following the directions, we have the "Other
11 information" heading. The heading "Other
12 information," is followed by a various set of
13 additional information that is not included elsewhere
14 but may be required or optional. Examples of
15 requirements are listed on the slide.

16 If an OTC drug product contains certain
17 cations such as calcium, magnesium, potassium or
18 sodium, depending on the amount that could be ingested
19 per day from the drug product, then the information
20 about the cation amount contained in the dosage unit,
21 such as the quantity of sodium in a tablet, must be
22 listed. Also, if applicable, what would follow is the

1 phenylalanine/aspartame content, then any information
2 that is authorized to appear would follow under this
3 heading.

4 We have inactive ingredients of course in the
5 drug product. The "Inactive ingredients" heading is
6 followed by a list of the drug product's inactive
7 ingredients. Each inactive ingredient is stated by
8 its established name.

9 And last, but not least, we have the
10 "Questions?" or "Questions or comments?" heading which
11 is optional. It's followed by a telephone number of a
12 source to answer questions about the product. Even
13 though it is an optional heading, we do recommend its
14 inclusion in the label and that the days of the week
15 and the times of the day when a person's available to
16 respond to the question is included.

17 This slide concludes my overview of the one
18 optional and eight required Drug Facts labeling
19 content headings. I will wrap up my presentation
20 shortly with a brief overview of the DFL format
21 requirements.

22 Now in slide 47 of the series, what the

1 format requirements state under §201.66(d), as
2 delineated, the following are some of the highpoints.
3 The text must be legible using any single, clear,
4 easy-to-read type style.

5 Other characteristics that are specified by
6 regulation are type size, style and use of bolding.
7 The DFL layout aligns text using left justification.
8 It specifies the amount of space between two lines of
9 text, referred to as leading. Other space is also
10 specified.

11 And it also specifies use of uppercase and
12 lowercase letters, bullets, bar lines and hairlines.
13 For small packages, the DFL allows for a modified
14 format if more than 60 percent of the total surface
15 area available for labeling is taken up by specific
16 required labeling.

17 And this concludes my talk on the DFL content
18 and format requirements. Thank you very much for
19 listening. At this time, I will pass you off to our
20 next presenters, and I believe it's Dr. Amanda Pike-
21 McCrudden to talk about the social science aspect or
22 the studies that were used to get to this point.

1 Thank you very much.

2 DR. DELLIBOVI-RAGHEB: Thank you very much,
3 Dr. Scroggs, for your talk. And I'd now like to
4 introduce our next speaker, Amanda Pike-McCradden,
5 from the FDA's Office of Nonprescription Drugs. The
6 title of her presentation is "Rationale for the
7 Current Drug Facts Label Format."

8 RATIONALE FOR THE CURRENT DRUG FACTS LABEL FORMAT

9 MS. PIKE-MCCRUDDEN: Good morning. My name
10 is Amanda Pike-McCradden, and I am a social science
11 analyst in the Division of Nonprescription Drugs I.
12 Today I'm going to discuss the historical rationale
13 for the DFL format we are currently using.

14 When this was all under consideration in the
15 1990s, FDA had become concerned about how adequately
16 OTC labeling communicated the information necessary
17 for safe and effective use of products. As the number
18 of OTC drugs increased, consumers were being asked to
19 make more sophisticated decisions regarding treatment
20 of conditions. It was known that there was a large
21 population of consumers of low health literacy and
22 there was a growing number of elderly consumers who

1 were the heaviest users of OTC medications.

2 So there was a need to present information in
3 the most effective and approachable way to ensure
4 consumers could adequately understand and utilize all
5 of the information on the label.

6 As the proposed new format was being
7 developed, several main ideas were employed to shape
8 the new format. The first was to utilize information
9 chunking. People tend to organize similar information
10 together to facilitate memory. So grouping relevant
11 information together should help boost retention.

12 Secondly, they wanted to decrease the
13 cognitive load on consumers. By lowering memory
14 demands, it should allow for information to be more
15 fully processed. Consumers also tend to rely on
16 heuristic cues to make decisions. They take mental
17 shortcuts, particularly when their attention is
18 divided and will make assumptions or decisions based
19 on appearance, prior knowledge and opinion. And
20 finally, there was the thinking that a less imposing
21 label should increase consumer confidence in decision-
22 making.

1 It was determined that the new DFL format
2 would include a standardized format and content,
3 headings and subheadings for navigation, shortened
4 sentences and less complex terms. The overall goals
5 were that this use of less complex terminology,
6 presented in shorter sentences, within a uniformly
7 organized structure would decrease cognitive load,
8 increase consumers' willingness and self-perceived
9 ability to read and understand the presented material
10 and that the new format should help consumers
11 prioritize the importance of the presented
12 information, such as warnings.

13 Two studies were conducted to evaluate the
14 effects of the FDA proposed format changes and to
15 gather information on consumer preferences for label
16 design. These studies are informally referred to as
17 study A and study B. Study A was called the "Impact
18 on Format Elements on Comprehension of Label
19 Information," and investigated the influence of the
20 new format and the use of highlighting on
21 communication of important label directions and
22 warnings. Study B was called the "Preference for

1 Variations in OTC Label Format," and investigated
2 consumer preferences regarding OTC label format
3 variations and examined comprehension of various
4 methods of communicating the relative safety and
5 effectiveness of OTC products.

6 Study A -- sorry. First I will cover study
7 A. There were 1,202 adult subjects in this study
8 which was conducted in eight geographically
9 distributed shopping malls in the U.S. and examined
10 two levels of each of four independent variables.
11 Label format, old was compared to new. Drug type,
12 there was a cough/cold and a pain reliever label
13 utilized. There was also a difference in highlighting
14 that was examined, five concepts highlighted versus
15 ten concepts. And two groups of attention, either
16 divided attention or focused attention.

17 Highlighting, label format and drug type were
18 manipulated through variations in the design of the
19 presented label. Attention was manipulated through
20 instructions given to the subject.

21 The new format labels were designed following
22 the examples in the OTC proposed rule. Old format

1 labels were designed using the format on the market at
2 the time. All labels in this study were presented --
3 had information presented in the same order: active
4 ingredients, followed by uses and indications,
5 warnings and directions. Labels were developed for
6 two types of products, a cough/cold remedy and a pain
7 reliever.

8 Highlighting was accomplished through bold
9 typeface. So it wasn't actual highlighting, yellow
10 highlighting like we see in some labels today. Half
11 of the subjects were told they would be answering
12 questions on a food label and a drug label, which
13 represented the divided attention subgroup, and half
14 were told that they would answer questions about only
15 one label which comprised the focused attention
16 subgroup.

17 Here are two label examples from the study.
18 The first is in the proposed new format for a
19 cough/cold product. The second is in the old format
20 for the same cough/cold product. As you can see,
21 there's quite a bit of difference in appearance
22 between the two.

1 Subjects were presented with the label or
2 labels they were instructed to read and were allowed
3 as much time as they needed. Each subject received
4 only one drug label. They were not asked to compare
5 different versions of drug labels in this study. The
6 interviewer then asked questions from a standardized
7 questionnaire and the label was removed from view for
8 product knowledge questions.

9 Outcome measures included product knowledge,
10 opinion ratings of the label, willingness to read the
11 label, confidence in using the label and correct
12 decision-making based on the label.

13 Some key takeaway from the study were, first,
14 that the new format took less time to read. The new
15 format allows for better and faster simple search for
16 information. Subjects preferred the new format
17 overall. They had more confidence in the new format
18 with divided attention which reflects a typical
19 shopping experience.

20 Subjects preferred labels with more
21 highlighting, although results were mixed in terms of
22 use of decisions. And that is something we're still

1 seeing in studies. When asked to recall items from
2 the label, subjects mostly recalled items in a pattern
3 suggesting that they read directions first followed by
4 uses and warnings.

5 The old format never outperformed the new
6 format. But there were some places where there were
7 no differences between old and new. Some product
8 knowledge scores were the same between formats. The
9 different scores and mixed results were typically
10 based on the type of drug.

11 Cough/cold labels were more complex and
12 scored differently than the pain reliever label.
13 Cough/cold did not perform differently on product use
14 decisions between the formats, while the pain reliever
15 in the new format performed better than the old format
16 as compared to cough/cold.

17 It is possible that the number of active
18 ingredients impacted success of the new format, which
19 will come as no surprise to anyone involved in DFL
20 research. This is an area where we still have
21 difficulty.

22 Moving along to study B, there were 904 adult

1 subjects in this study, and it was conducted in eight
2 geographically distributed shopping malls in the
3 United States. It examined two levels of each of four
4 independent variables: title, a medication facts title
5 versus no title on the label; the order of warnings
6 and directions, either warnings first or directions
7 first; placement of active ingredients either at the
8 top or the bottom; and type of demarcation lines
9 between sections, either thick lines or thin lines.

10 Two different drug types were used for the
11 labels, a cough/cold and a sunscreen. And 16 labels
12 were developed for each type of drug to incorporate
13 all variables.

14 Here are two label examples from the study.
15 The difference here is the use of medication facts as
16 a title at the beginning, at the top of the label. It
17 sounds like a small difference, but you can see it
18 really does make quite a visual impact.

19 All 16 labels were presented to each subject
20 and they were asked to order the packages from most to
21 least preferred. Subjects were asked why they made
22 their number one and number two rankings, and then

1 subjects were asked attitude questions on one of the
2 new format labels chosen at random by the interviewer
3 and a label based on existing OTC format to measure
4 preference, credibility and readability of the label.

5 Here I'm showing you two charts from the
6 results of the ranking. The two product types,
7 cough/cold and sunscreen, have been combined here with
8 the labels ranked by how many times each was selected
9 as a subject's number one pick. The chart on the left
10 shows the top six labels, and the chart on the right
11 shows the bottom four labels from the ranking. The
12 frequency is how many times the label was selected.
13 The percentages are based on 455 responses for
14 cough/cold and 449 responses for sunscreen.

15 As you can see, title clearly won the day.
16 All labels with a title fared better than no title.
17 There was less of a clear preference between thick and
18 thin demarcation lines and while directions first did
19 perform better overall, outside of the first label,
20 which was a little bit of an outlier, the frequency
21 difference was small in overall selection, a
22 difference of 60 to 59 selections.

1 When asked why they made their top rankings,
2 here are some of the responses. First was that they
3 liked the layout or that it was easy to read, followed
4 by preferences for medication facts and directions
5 first or warnings first.

6 Some key takeaways from study B, the presence
7 of "Medication Facts" as a title was a design element
8 that had the greatest impact. Subjects chose their
9 second label based on how closely it resembled their
10 first choice. So when they established a preference,
11 they definitely stuck to it and felt strongly about
12 it. Subjects generally preferred labels with
13 directions above warnings, active ingredients at the
14 bottom and thick demarcation lines.

15 So I guess it is no surprise that we ended up
16 going with a new format because that's why we're all
17 here today. And we did that because the new format
18 did demonstrate definite advantages over the old
19 format. Subjects located information on the new label
20 format more accurately and could use that information
21 for use-related decisions.

22 Subjects had more self-confidence using the

1 new format with divided attention. And subjects
2 preferred a label with title and headings and cues for
3 navigation such as demarcation lines. And it is
4 important to note that all variables for formatting
5 examples were not investigated. These studies were
6 designed to be a starting point to provide insight on
7 specific variables.

8 So the new format is not perfect. And as I
9 was reading through these studies, I was struck that
10 some of the areas where the labels struggled in study
11 A and study B are the same areas where we still
12 struggle. Multiple ingredients and complex ideas up
13 against subject preference and opinion and
14 preconceived notion.

15 When this new format was created, there
16 wasn't much information to pull from in terms of data.
17 And now we have over 20 years' worth of experience and
18 data to use to design the next DFL format.

19 So I think we're in a really great place to
20 put all of that knowledge for use to us and come up
21 with a DFL that really works to get important
22 information across to consumers in an approachable and

1 comprehensible way. And with that, I'll turn things
2 back over to Teegan.

3 DR. DELLIBOVI-RAGHEB: Thank you very much,
4 Amanda, for your talk. I'd now like to now introduce
5 our next speaker, Dr. Jesse Catlin, from California
6 State University, Sacramento. The title of his
7 presentation is "Drug Facts Label Communications:
8 Successes and Challenges."

9 DRUG FACTS LABEL COMMUNICATION: SUCCESSES AND
10 CHALLENGES

11 DR. CATLIN: Okay. Well, good morning,
12 everyone. Hopefully you all can hear me or you'll
13 chime in and let me know. Yeah. My name is Jesse
14 Catlin. I'm an associate professor of marketing at
15 Cal State, Sacramento. Thanks a lot for tuning in and
16 it's really an honor to be here.

17 Today I'm going to talk a little bit about
18 Drug Facts label communication, a little bit of the
19 good and maybe a little bit more of the challenges
20 that we see associated with the DFL.

21 So to start, I'd like to say that, you know,
22 the DFL success as a communication tool has really

1 been pretty impressive. As we've seen in some of the
2 earlier presentations, the DFL has been a huge
3 improvement over prior labeling practices and brought
4 about several benefits.

5 This includes standardization of formatting,
6 consistency across products and also things like the
7 use of plain language and enhanced readability through
8 bullet points, sectioning, whitespace and so forth.
9 Having been in the marketplace for 20 years, the
10 remarkable safety profile of OTC drugs using the DFL
11 format, I think it speaks for itself.

12 All of that said, while it's important to
13 recognize what I would argue is overall success of the
14 DFL, it remains a static, non-customizable, text-based
15 communication tool. So going forward, I'm going to
16 highlight three main areas related to challenges or
17 barriers to communicating via the DFL which have been
18 demonstrated both in my own research and that of
19 others.

20 The first barrier to DFL communication that
21 I'll point out is that the DFL struggles to
22 communicate complex, multi-attribute criteria.

1 Consumers often struggle to use DFL information when
2 required to simultaneously integrate multiple pieces
3 or components of the information together. For
4 example, a drug that requires a consumer to factor in
5 their medical history, age and/or some other factors
6 in order to make a proper decision.

7 One way to think about it could be
8 visualizing a sort of decision tree where there are a
9 series of nodes or points that represent individual
10 components of the label that need to be considered
11 when evaluating a drug. And you can see on the right
12 side of the slide here, I've got an image of what a
13 decision tree might look like. And in each one of
14 those points, we've got some information or an
15 attribute that a consumer needs to evaluate maybe to
16 reach a proper self-selection decision as an example.

17 The DFL often performs quite well at any
18 given individual node or component when viewed in
19 isolation. But where the DFL struggles is when we
20 look at a combined series of nodes where a consumer
21 needs to factor in multiple items or criteria from the
22 DFL into their decision.

1 An example of this can be seen in some
2 studies for omeprazole. When it comes to individual
3 statements on the DFL in these studies, consumers did
4 pretty well at or greater than 90 percent correct
5 responses to individual comprehension questions.
6 However when we look at correct responses across
7 multiple components of the DFL, for example,
8 considering multiple factors to determine self-
9 selection, there's a much lower level of correct
10 responses.

11 And while this isn't necessarily surprising
12 that there would be a decrease, we can see here a
13 pretty substantial drop-off for some of these
14 measures, comprehension was less than or equal to 21
15 percent. And this has been an issue observed in other
16 studies as well.

17 So this is worth pointing out as an issue to
18 drugs that are already available OTC like omeprazole.
19 But also this is a major factor, of course, that
20 prevents making more complex drugs available over the
21 counter.

22 A second set of barriers to communication via

1 the DFL are individual consumer characteristics,
2 particularly those related to levels of ability in
3 terms of things like literacy, including health
4 literacy, language barriers and cognitive limitations
5 as well. And we know from previous research that all
6 of these things are associated with lower DFL
7 comprehension.

8 The second session today I know will be
9 diving deeper into some of these issues. So I just
10 want to touch on them here relatively briefly. But
11 what I would like to highlight is that the non-
12 adaptive nature of the DFL prohibits customization for
13 individual needs.

14 So for example space limitations prevent
15 additional language options or different modes of
16 communication for individuals with lower visual
17 ability. The ability to customize label information
18 could go a long way toward helping these groups. And
19 I'll mention this again toward the end of my
20 presentation.

21 A third type of barrier that I'd like to
22 discuss in more detail is how consumers' preexisting

1 knowledge, attitudes and beliefs can impact their
2 interaction with the DFL. So to start, research shows
3 that some consumers do not read the DFL at all or they
4 discard the packaging before use. And obviously not
5 reading the DFL is a problem, as is discarding
6 packaging before termination of use.

7 Among various reasons this could be an issue
8 is that someone may be unaware of developments that
9 would make them need to deselect or discontinue use or
10 other users of the drug in the household may not have
11 full information if they consider using the drug. And
12 there are a lot of other issues here as well of
13 course.

14 And one particular result I'd like to
15 highlight comes from a survey of H2 blocker
16 purchasers, and it's in the framed panel on the right
17 side of the screen. When asked how much package
18 labeling influenced their decision in this study, the
19 purchase decision, 68 percent stated not at all. And
20 so this kind of result suggests how important
21 preexisting attitudes or beliefs can be in determining
22 the extent to which a consumer interacts with and uses

1 the DFL information.

2 In many cases, consumers may have a clearly
3 defined motivation, expectation or belief that may
4 drive their behavior outside of any label instruction.
5 And it also reinforces the fact that the DFL labeling
6 is likely one of many potential resources that
7 consumers may use to determine how they make OTC drug
8 decisions. So there's more than just the label that
9 people are being influenced by. And obviously some of
10 the folks in this study might have been told by their
11 doctor to purchase this particular medication.

12 But I think it's probably true that there are
13 also folks in the 68 percent that were operating in an
14 information state that was probably below what we
15 would optimally prefer.

16 Continuing on, even if consumers do read the
17 DFL, they may only read certain parts of it while
18 ignoring others. Research shows that consumers attend
19 to different components of OTC labeling with varying
20 levels of intensity. An example I'm citing here is
21 some eye tracking studies that showed that more
22 attention was paid to the branding on the package

1 compared to other components of the labeling. And I
2 think we'll hear more on some of that work later
3 today.

4 Additionally, in my own work with co-authors,
5 we found that brand names could be used as cognitive
6 shortcuts that impact interaction with the DFL.
7 Specifically we did a study where we looked at how
8 using a branded versus a generic principal display
9 panel, also known as the front of the package,
10 influenced attention to and comprehension of DFL
11 information.

12 As you can see in the framed panel, among
13 participants with a lower need for cognition, so in
14 other words people who are prone to looking for mental
15 shortcuts, we found less time spent reviewing the DFL
16 and lower comprehension of the DFL when the principal
17 display panel featured a brand instead of a generic.
18 In other words you might think of branding as serving
19 as sort of a mental shortcut where some individuals
20 feel like they don't need to read the label as
21 carefully if it's a more familiar brand.

22 And this is something that hasn't been

1 examined quite as much in the literature, as we often
2 focus mostly on the DFL, you know, itself. But I
3 think it's worth thinking about how non-DFL elements
4 of the packaging might interact with preexisting
5 individual characteristics to influence DFL
6 communication.

7 So we've talked about consumers who might not
8 read or only partially consult the DFL. It's also
9 worth noting that even if a person reads the DFL, they
10 may ignore or disregard the need to follow some or all
11 of the instruction.

12 Indeed research shows that some individuals
13 believe they can choose their own dose regardless of
14 what the package label says to do and some work --
15 related work by my co-authors and I suggest that
16 consumers may hold misconceptions about OTC risks that
17 could influence DFL communication; that is, some
18 consumers might perceive OTC drugs as relatively risk-
19 free even if used improperly such as by taking more
20 than one medication with the same ingredient at the
21 same time, which is also known as double-dosing.

22 One of the key results from this work is

1 shown here. This particular study included
2 participants with specialized medical training such as
3 having taken a pharmacology course, so a nursing
4 student or a medical student perhaps, and those
5 without specialized medical training. And we referred
6 to these two groups as experts and novices
7 respectively.

8 Participants were shown different pairs of
9 OTC drug labels. Some of the pairs had the same
10 active ingredient while some pairs did not. So
11 participants were asked to rate their perceived risk
12 of taking both drugs at the same time.

13 What we found was that among participants
14 without medical training, so the novices, as we called
15 them, when evaluating two OTC drugs for concurrent
16 use, double dosing, or taking two drugs with the same
17 active ingredient at the same time was not regarded as
18 being any riskier than taking two medications with
19 different ingredients.

20 And this result is also illustrated in the
21 figure on the right side of the screen. Here the y-
22 axis illustrates the mean risk judgment associated

1 with concurrent use of the two OTC drugs at the same
2 time. And you can see that the bars, the black bar
3 represents when the active ingredient in the two drugs
4 was the same. The white bar is when the active
5 ingredient in the two drugs was different.

6 You can see that for the expert group, risk
7 judgments were higher on average when the two OTC
8 drugs contained the same active ingredient compared to
9 when the active ingredients in the two drugs were
10 different. And this was a statistically significant
11 difference. For the novice group, there was no
12 difference in average risk judgments regardless of
13 whether the active ingredients were the same or
14 different.

15 And this is called out in the red oval here.
16 You can see there was no statistically significant
17 difference between the two bars. So it didn't matter
18 whether the active ingredients were the same. Risk
19 judgments didn't differ for this group.

20 One thing I'd like to point out here, and
21 this is discussed more in the published paper, is that
22 the study had other measures that indicated it wasn't

1 just the case that the novice group simply didn't
2 notice or pay attention to the active ingredient
3 information. It was clear from these measures that
4 the novice participants generally recognized when the
5 active ingredients were versus were not the same. But
6 they just didn't think it mattered from a risk
7 perspective.

8 So again what I'm hoping to convey here is
9 how preexisting knowledge, attitudes and beliefs -- in
10 this case, knowledge and beliefs about OTC drug risks
11 -- can have a role in influencing how consumers
12 interact with the DFL. It could also influence
13 problems like double dosing on OTC ingredients as
14 well.

15 Having discussed some of the barriers to
16 communication, I'd also like to talk briefly about
17 some modifications that have either been considered or
18 implemented to improve DFL communication. This
19 includes use of icons, additional warning information
20 and also highlighting specific information on the DFL.
21 And there's an example of an active ingredient being
22 highlighted here on the screen.

1 I know we'll hear -- we've heard about some
2 of these interventions, and we'll hear more about them
3 in later presentations. But a couple of brief points
4 I'd like to make.

5 The first is that while these efforts may be
6 effective in isolation, what most of these approaches
7 have in common is that they add more information to
8 the DFL. Given that the DFL is an already dense
9 communication format, it's important to think about at
10 what point we overload consumers. And we've heard
11 this theme of cognitive load emerging in some of the
12 earlier presentations.

13 And obviously a clear reason this is a
14 concern is that people might miss information or not
15 be able to find certain information that's important
16 to their particular situation. But it's also
17 concerning because we know from research in other
18 fields that when consumers feel information overload,
19 they tend to look for mental shortcuts which can
20 increase the chance of mistakes.

21 Also it's important to know whether consumers
22 have appropriate knowledge to make use of any proposed

1 intervention or change to DFL labeling. So for
2 example highlighting active ingredient information may
3 help some consumers. But other consumers may not have
4 the existing knowledge to draw from in order to
5 benefit from this kind of intervention.

6 So, for example, someone has to actually know
7 that the active ingredient, you know, is an issue and
8 what to do with that information. In our previously
9 mentioned study looking at risks of double dosing, an
10 icon calling out the active ingredient content alone
11 did not have an impact on double dosing risk
12 perceptions unless it included specific text
13 explaining why double dosage -- double dosing
14 presented risks.

15 Also in the spirit of label modifications or
16 changes to improve DFL communication, I'd like to now
17 talk a little bit about a recently published FDA-
18 sponsored label comprehension study for naloxone. And
19 there are a few unique aspects of this study. But the
20 one I found most noteworthy was the rather unique
21 design of the DFL which included illustrations and a
22 step-by-step diagram.

1 As you can hopefully see on the screen, there
2 is step one, two, there, four and five, illustrated
3 with accompanying explanatory text. And this use of a
4 stepwise diagram with illustrations and text is quite
5 different from what you would typically see on a DFL.
6 But I would argue this is potentially a good thing.
7 And the results of the study were quite intriguing.

8 So moving to the framed panel where we look
9 at the results here, as we might expect, performance
10 on comprehension questions related to single steps
11 listed on the DFL is quite high, so at or above 90
12 percent. Also, perhaps not surprisingly, performance
13 was lower on questions that included multiple steps.
14 So for a composite measure of steps one through three
15 combined, 81.1 percent got all three correct. And for
16 all five steps, 74.6 percent got all five steps
17 correct.

18 But I think what's worth noting here compared
19 to other studies, including the omeprazole studies I
20 discussed earlier, the gap between -- or the drop-off
21 between comprehension of the single and multi-item
22 measures appears smaller. And what this suggests to

1 me is the potential value of using a more flexible DFL
2 design to communicate more complex or multifaceted
3 information.

4 So taking it all together to summarize, I
5 think it's clear that the DFL was a major step forward
6 and has in many ways been a huge success. However
7 it's also clear from publicly available research that
8 there are clear barriers to DFL communication,
9 including the three issues I've highlighted in this
10 presentation, the first being communication of
11 complex, multi-attribute criteria, the second being
12 responding to individual differences and ability levels,
13 so addressing issues like health literacy, visual
14 ability, language barriers, cognitive limitations and
15 so forth, and third, preexisting knowledge, attitudes
16 and beliefs that consumers bring to the interaction
17 with the DFL, especially when these issues limit DFL
18 attention and adherence.

19 I think what's also equally important to
20 consider here is that mitigating these challenges is
21 complicated by the DFL's format as a static, text-
22 based, non-customizable form of labeling. It's really

1 a lot to ask and, dare I say, impossible for a printed
2 package label that is the same for every consumer to
3 be able to overcome all of these obstacles.

4 The DFL does a pretty good job. But we're
5 really asking a lot. Instead it seems like a good
6 idea to think about what I'll call DFL+. I think
7 we've heard this hinted at throughout, you know, this
8 is a theme for today, but a more flexible DFL design
9 including communication that may take place outside
10 the label such as via adjunctive technology such as
11 smartphones or other mechanisms.

12 And while there are naturally a variety of
13 issues that need to be worked out and more research
14 testing are needed, it seems that the increased
15 customization and relevance offered by these kinds of
16 approaches could go a long way toward addressing the
17 DFL communication challenges highlighted here.

18 You know, a fundamental principle in
19 marketing is increasing relevance helps to connect
20 more deeply with consumers and can lead to, you know,
21 we hope more increased attention and compliance with
22 whatever the message being communicated is. And so

1 these are issues that we - I think are important to
2 consider. And also I'd like to point out that this
3 includes not only enhancing communications for
4 existing OTC drugs, but it also potentially opens the
5 door to additional OTC offerings that are more complex
6 in nature.

7 And so with that, I'd like to thank you all
8 very much for your attention. If you have any
9 questions or would like to discuss anything related to
10 this presentation, I've listed my email address here,
11 and I'd love to hear from you to chat more. Thanks a
12 lot.

13 DR. DELLIBOVI-RAGHEB: Thank you very much,
14 Dr. Catlin, for your talk. That brings us to our
15 first break, which will be for ten minutes. We will
16 resume at 9:55 a.m. As a reminder, please enter any
17 questions you have for the speakers into the Q&A chat
18 box. Thank you.

19 (Off the record.)

20 DR. DELLIBOVI-RAGHEB: Welcome back,
21 everyone. Continuing our first session, it's my
22 pleasure to introduce our next speaker, Julie Aker,

1 from Concentrics Research. The title of her
2 presentation is "Consumer Experience with the Drug
3 Facts Label (What's Working and What's Not)."
4 CONSUMER EXPERIENCE WITH THE DRUG FACTS LABEL (WHAT'S
5 WORKING AND WHAT'S NOT)

6 MS. AKER: Thank you very much. Good
7 morning, everyone. Hopefully you can hear me all
8 right. My name is Julie Aker. I'm president and CEO
9 at Concentrics Research. Many thanks to FDA for
10 sponsoring this public workshop on a topic that is
11 near and dear to our hearts and for this opportunity
12 to share what we've learned in our interactions with
13 consumers every day.

14 For the past 35 years, Concentrics has been
15 conducting research on prescription and over-the-
16 counter drugs and devices. And in this work, we
17 capture the voice of the consumer or the patient and
18 represent this feedback in our data. That feedback is
19 the basis of innovative solutions as well. Most of
20 our work is in Rx-to-OTC switch, conducting studies
21 such as label comprehension, self-section, human
22 factors and actual use. And all of these studies

1 clearly rely on the Drug Facts label.

2 So today I'm going to share our observations
3 and feedback from consumers about what's working and
4 what's not relative to the DFL. But before consumers
5 can even access the OTC, they have to find it first.
6 And we've learned about this navigation process. It's
7 very predictable and it's consistent across age groups
8 and literacy levels.

9 We've studied this process of navigation in a
10 study sponsored by CHPA in 2014 where we learned that
11 consumers used the aisle signs to find the therapeutic
12 category they want to treat and then they go to the
13 shelf to find the indication they're looking for by
14 brands they trust. And then they differentiate the
15 products depending on the product ingredients and the
16 symptoms they want to treat. The problem is they're
17 faced with an ever-growing wall of products and the
18 labels have become more and more complex.

19 When we consider the content of the DFL, we
20 find that consumers gravitate towards the purpose and
21 the uses. They ask what does this medicine do. And
22 then they typically go to the directions section.

1 They want to know how do I use this medicine. And as
2 they make their way through the DFL, they focus on
3 what's relevant to them. For example, if someone has
4 a cardiovascular history, they might be scanning for
5 information on heart attack or stroke or certain
6 medications. We've also found that consumers focus
7 more on absolutes on the labeling, and these are
8 typical warnings such "Do not use" or "Stop use" or
9 the directions.

10 For the format, consumers will tell you that
11 they're well aware that there's a standard format.
12 They've seen it on all their OTCs and they know it has
13 certain sections and they know that it's on all the
14 medications that they currently are using. And
15 certainly we see improved comprehension when there are
16 best practices included such as white space,
17 pictograms, special highlighting or bolding. But
18 those treatments need to be used judiciously in order
19 to have the desired effect.

20 So now let's talk about what's not working as
21 well. In over 2 million consumer interviews that
22 we've conducted, consumers have told us a lot. First

1 of all, consumers start by telling us that while
2 they're interested in the ingredients, they can't
3 pronounce them and don't really know what the active
4 ingredient does or how it works.

5 If I could sum up our observations in a
6 phrase, I would say DFL density and the amount of
7 information on a DFL and all of the associated
8 labeling such as leaflets, quick start guides,
9 instructions for use. It's all just over the top.
10 These labels have gotten packed with more and more
11 over the years, and now they're untenable for most
12 consumers.

13 The effects of a dense label are that one
14 doesn't really quite know where to start. Long lists
15 of warnings and medical conditions, drug interactions
16 become overwhelming. Because expectations have grown
17 to add more and more to the label, we now have peel-
18 back and lift-off labels in order to pack it all in.
19 and then we invite confusion by having duplicative
20 language in multiple places, perhaps referenced in a
21 before use and a during use warning.

22 And again the order of the DFL is not

1 intuitive. Consumers want to understand what's
2 involved in taking the medication first. So they
3 often skip to the directions which means that the
4 warnings are scanned.

5 And finally, if we don't do anything else, it
6 would be a huge improvement to simply retitle the
7 heading that's called "When using this product" to
8 "Side effects" for the labeling. Consumers tell us
9 frequently that they wish they could just find the
10 side effects on these labels.

11 The warnings are very important, perhaps the
12 most important part of the labeling. But in packing
13 them with absolutely everything, we sometimes have
14 repeated references to the same condition or drug.
15 Here's an example. Do not use if you have a history X
16 condition. Ask a doctor if you have signs of X
17 condition. And stop use if you have symptoms of X
18 condition.

19 So we've created somewhat of a warning
20 wallpaper which means it looks like one block of
21 overwhelming warnings. And the question is, okay,
22 what's the most important? Interestingly on a recent

1 study in which we had some warnings that were not
2 being heeded, we became curious about how these
3 warnings were being interpreted. And we asked the
4 question do you see these warnings as requirements or
5 recommendations.

6 And most consumers told us that they see
7 these as recommendations. And this is linked to the
8 fact that most people, especially those with chronic
9 medical conditions, have a doctor or see a doctor
10 regularly and they depend on what the doctor tells
11 them over anything they would read on a label. Some
12 have told us that the "Ask a doctor" warnings are only
13 for people who don't have a doctor, and many don't
14 believe they apply to them personally.

15 So what are we missing? Well, people focus
16 on the front of the pack. And it's interesting that
17 Jesse brought this up too, or the principal display
18 panel is what we call that front of the pack, the PDP.
19 It's really the first thing they see. It's a
20 guidepost and the branding is really a trust mark. So
21 there's a lot of preliminary information on that PDP
22 that helps consumers. It tells them what the product

1 treats, the ingredients, the product form, the
2 quantity, sometimes more information about how it
3 works or how to take it. And it begs the question are
4 we leveraging the PDP as much as we could to help the
5 consumers.

6 For the DFL, less is more. Consider your own
7 reaction when you get those annoying terms and
8 conditions and privacy statements that go on for pages
9 when you visit a website. How many of you read every
10 single word? And how about decision-making about
11 medicines that have been purchased?

12 In the past year, this was often influenced
13 by friends and family that found something that worked
14 well. But increasingly consumers are using Google
15 reviews like they do for consumer products and, of
16 course, we all rely on what we've used in the past
17 that we know worked well. And we're also dealing with
18 basic assumptions about OTCs.

19 For example, many consumers feel the DFL was
20 created by attorneys forcing language into labels as
21 recommendations, not requirements. And some consumers
22 consider that OTCs aren't as strong as prescription

1 medicines, even if it says prescription strength on
2 the PDP.

3 If we read more carefully based on what's
4 relevant to us with our friends and family, we know
5 that that shifts as well. So consider that someone is
6 in a caregiver role for a child or for an aging
7 parent.

8 They would be focused on relevant ages and
9 associated dosing while someone with limited literacy
10 or English as a second language might be looking for
11 common or simple words, and those with certain medical
12 conditions might be likely to seek information
13 relevant to their medical condition or even certain
14 drugs they're taking that might interact. Consumers
15 focus on what's relevant to them and then they
16 prioritize what their doctor has told them over the
17 information that's on the label.

18 So why is this not working? Well, in short,
19 the world changed. And as the world changed, more and
20 more technology has worked its way into our world. We
21 have technology with everything that we do now. It's
22 in every part of our life. And it's also fast,

1 convenient and it's targeted and customized. So this
2 issue of a static label and the customization that
3 people are getting used to with doing a quick Google
4 search is really what's changed.

5 So consider that the pandemic only fueled the
6 desire for technology, and not only just the desire,
7 but the absolute necessity for it. This was a wakeup
8 call to people who were not using technology
9 extensively.

10 And when the pandemic hit, the technology
11 became a lifeline for everything from talking to a
12 family member hospitalized with COVID to ordering
13 necessary supplies from Amazon. And the pandemic
14 boosted the technology-dependence and familiarity and
15 now a QR code on a menu at a restaurant is very
16 common. And using a health portal or a telemedicine
17 call is routine.

18 So if I had to sum it up about why people use
19 technology as an adjunct to the labeling, I would say
20 it's because it's searchable and customizable. It's
21 easy to do a search. You can learn specifically what
22 you want to learn about. And more importantly, it's

1 fast and it's on their familiar device.

2 When we direct people to the DFL and we ask
3 for feedback, they tell us they do read the DFL,
4 especially the first time they use a product. And
5 they use the front of the box to guide them.

6 In terms of finding information on the DFL,
7 we universally get feedback about using more color,
8 especially red for more important information, and
9 everyone feels the text is too small. Interestingly,
10 in a recent study, we also found out that people, when
11 they go to the store, they really wish the stores were
12 organized in such a way that's relevant to them. So
13 this gets back to this whole issue of relevancy.

14 For example, some consumers told us they
15 wished that all the products that caused sleepiness
16 would be in one area or all the products that were
17 safe to use when you're pregnant or breast-feeding
18 were in a different area or if you -- what products
19 that you could use when you have high blood pressure
20 would be in a certain area.

21 What about limited literacy? Well, limited
22 literacy consumers do confer with their doctors. And

1 many of them tell us that they use health portals and
2 use them to communicate with their doctor. It's fast
3 and it's easy. Consumers Google it and they do this
4 to check out a medicine online before use or even in
5 the store if they have a specific question.

6 Highlighting key conditions on the front of the panel
7 is really helpful.

8 And recently a participant told us that they
9 were seeking a cold medicine and they found one that
10 actually told them on the front that they could use it
11 if they had high blood pressure. Low literacy
12 consumers want it simple. They're interested in the
13 ingredients. But some struggle to know what the
14 ingredient is or does. And also nearly everyone has
15 this extra tool of a smartphone right in their hand.

16 So it's already a DFL+ technology world. And
17 this is where consumers review the label and use
18 technology perhaps for searching the answer to a
19 specific question. They do this because it's fast and
20 easy. And one low literacy participant recently said
21 this is my phone right here in my hand. I can ask it
22 anything I want, and it will tell me.

1 We talked a bit about how the intention of
2 the flow of the information on the DFL was to have
3 consumers go from top to bottom and to see the uses,
4 then the warnings and lastly the directions. But
5 here's how it really goes. The picture on the right
6 shows that they really start with what the product
7 does, the uses. They drop down to the directions.
8 And then they kind of scan through the directions,
9 really looking for what's relevant to them. So the
10 different ordering of the information might be
11 extremely useful.

12 If you look at Drugs.com, you'll see a couple
13 of different approaches to presenting the DFL
14 information. They use headings that are clickable
15 online to get information. And under that, they have
16 statements from the DFL that they've turned into
17 questions. Again they're doing this online. So they
18 have almost unlimited room to continue to provide
19 information. You just have to scroll.

20 And we find this approach is very important
21 and very useful in turning the DFL into a series of
22 questions when we do our technology program. So if we

1 have a technology involved in an Rx-to-OTC switch, we
2 use this same approach. It's very effective. People
3 seem to focus on a question better than a statement,
4 especially if those statements are buried in long
5 lists on a label.

6 Consumers tell us that if they search online,
7 they can find what they need with a Google search or
8 Drugs.com or they can go to their favorite online
9 store like CVS.com or Walgreens.com or Amazon.com.
10 They tell us they do these searches because I can
11 search for the product I want, it's faster, it's more
12 convenient and they love the idea of a symptom
13 checker. We hear this a lot in our research.
14 Consumers talk about wishing that they could just
15 enter their symptoms on their smartphone and it would
16 tell them what the best products would be to treat
17 those symptoms.

18 And when consumers go to an online store,
19 they use the same approach as they do in person. At
20 the top you see red circles where they've entered that
21 they're looking for allergy medicine. So this would
22 be similar to the aisle sign. And then you see the

1 search bar at the left where they can search by price,
2 by brand, by symptom. Consumers often search by a
3 brand name. And then they get their virtual wall of
4 products to look at to search through similar to an
5 in-store shelf.

6 When they select a product, you can see at
7 the lower right that they can view the DFL as well as
8 the front, top, bottom, sides of the packaging. So
9 you can see the flexibility in the search features
10 that make this selection process much easier.

11 So what alternatives could work for the DFL?
12 Well, fewer words. Fewer words would be very, very
13 helpful as a starting place, and maybe isolated use of
14 pictures or judicious use of icons. Plain language.
15 Search-and-find type of capabilities, and then
16 relevancy for special populations for people seeking
17 information about a certain medical condition.

18 Here are some examples from some recent
19 research. Because we were doing virtual studies, we
20 had this wonderful added benefit of being able to meet
21 someone in their home. And they can show us examples
22 of medicines or products that they're using.

1 In this case, we had one participant that
2 showed us a product that they really liked on the
3 left. It had big words on the front of the box, and
4 she said it was really easy to see the ingredients and
5 what it does. The participant on the right was trying
6 to describe having pictures on the label that would
7 signal key functions. And she showed us a supplement
8 she was taking that had recognizable icons across the
9 bottom.

10 We've experimented with iconography in our
11 research. And we find that using a few recognizable
12 icons with limited text near them is very helpful and
13 highly effective. These are some of the icons we were
14 exploring recently with some consumers with limited
15 literacy. And we got very positive feedback. They
16 liked the plain language such as no and hand signaling
17 stop. And we added side effects. They also asked us
18 after the research was over how could we get these
19 labels. This would be so helpful.

20 And there's lessons to be learned from Rx
21 labeling too. Back in 2013, there were workgroups at
22 FDA that were exploring different ways of presenting a

1 medications guide to patients. And FDA put together a
2 bubble approach which is the one on the right there.
3 And we actually created a hybrid icon-plus-text model
4 which is the one on the left. And then we tested
5 those with three different drugs against the current
6 medication guide. And as you probably can imagine, we
7 got much better scores with either of those two
8 different approaches than to just kind of a wall of
9 text.

10 And we also asked people if the pictures and
11 icons were helpful or distracting. And depending on
12 the label and the density of the label, 75 to 90
13 percent preferred some icons because it helped them
14 target and find information as it was parsed into the
15 category.

16 And Jesse's already brought this up. But
17 I'll also just emphasize that, you know, in 2020 we
18 worked with FDA on a novel label for OTC naloxone
19 using this very same principle of pictures-plus-words.
20 And after many refinements, we found it highly
21 effective in communicating lifesaving information. So
22 interestingly the order of this labeling follows what

1 consumers have told us, that they want the uses, then
2 the directions and lastly the warnings.

3 What was also helpful in this label was that
4 the ordering was clear because the steps were
5 numbered. So it helped the consumer to know how to
6 progress through the labeling. So we can consider
7 these types of learnings and even just numbering the
8 sections of the DFL might help to establish a flow.

9 So as we consider the DFL and possible
10 changes to the future, you might ask can we leverage
11 technology right now to help us. And we say yes.
12 This doesn't have to be all or none. We do believe in
13 DFL+ and we always will need the label. But what if
14 we simplify it and pair it with technology? Eighty-
15 five percent of all Americans right now have a
16 smartphone and they're using it daily, and even more
17 so I think that we've all seen since the pandemic.

18 This has grown somewhat exponentially since
19 2011 when smartphone use was 35 percent. And if
20 you're wondering if those of limited literacy are not
21 included in some of these numbers, I can share that in
22 a recent study where we screened 936 consumers, only

1 18 of them were unable to participate due to the lack
2 of a device or a camera on their device. That's 1.9
3 percent.

4 In another study, we found that 93 percent of
5 limited literacy participants routinely did Google
6 searches and got information about OTCs that way.
7 Seventy-seven percent used YouTube or social media
8 regularly.

9 So when we think about the DFL plus some form
10 of technology, consider a dynamic website in addition
11 to the DFL. A good example is a smoking cessation
12 website at smokefree.gov. You can build a customized
13 plan to stop smoking.

14 What about QR codes? There's almost
15 unlimited information that you can get. And here's an
16 example on a supplement where if you click on that or
17 scan that QR code, you'll get access to recipes and
18 macros and other types of information. You can insert
19 a video or a survey or anything you want.

20 And for a little audience participation, if
21 you hold up your smartphone, if you happen to have it
22 handy, you can try to look at this QR code and you'll

1 see that it holds -- it actually opens a survey. And
2 this is a very cool QR code that was actually
3 developed by the Veterans Administration.

4 And can you believe that this QR code
5 revealed a six-question survey that you can complete
6 in 15 seconds that tells you if you're cleared to work
7 during COVID? Try it. Look how easy it is. It was
8 very simple and easy to answer those questions. And
9 this is the same type of approach that we're using
10 with some of our technology programs.

11 Consider how fast and easy this is and
12 consider using something like this at a store shelf or
13 for online purchase. You could just insert a survey.

14 Here's another example. You can -- this one
15 also works. You can hold your phone up. This is
16 actually a dynamic website that -- where the screens
17 move and give you information. But what's cool here
18 is you can see what I've circled there on the right is
19 that you can print out a PDF. And so imagine if we
20 had a leaflet that someone could print out if they
21 lost it or they wanted to have it for use at home.

22 And so other considerations, as we consider,

1 as we ponder these possibilities with the future of
2 the DFL, let's be creative and innovate. For example,
3 does everything have to be on the DFL? What if we
4 just had before use self-selection criteria on the
5 outer label? What if we had keywords and phrases on
6 the exterior and more in the leaflet?

7 What about our Spanish-speaking consumers who
8 wish that there was a quick way to get a label in
9 another language? And consider the use of consistent
10 and easily identifiable icons that could really be
11 used on a PDP, the front panel, as well as the DFL to
12 signal key warnings or highlight key information.

13 So we know what's not working and we know
14 what is working. We know that the current DFL is too
15 complex and overwhelming to consumers. It's very
16 difficult to find information or even figure out what
17 the most information -- most important information is.
18 And the order is not intuitive with the uses and
19 directions first and the warnings last.

20 So we're missing a clear reference to side
21 effects, and we really could benefit from plain
22 language like no or stop with the ingredients spelled

1 out phonetically, as an example.

2 We also know what could work in the short-
3 term and in the future. Parsed information and icons
4 could really help. And in the short-term, we can use
5 barcodes and QR codes for quick access to information.

6 So the future is really unlimited with self-
7 selection tools and web apps to facilitate a self-
8 selection decision. We have the tools and techniques
9 right now that could make a big difference and really
10 improve the health and quality of life for our
11 consumers. Thank you very much.

12 DR. DELLIBOVI-RAGHEB: Thank you very much,
13 Julie, for your talk. It is my pleasure to introduce
14 our next speaker, Clark Richardson, from PEGUS
15 Research. The title of his presentation is "The
16 Familiar OTC Drug Facts Label: Obstacles and
17 Opportunities."

18 And I do apologize in advance. We had some
19 technical issues with uploading this presentation. So
20 it is in a different format.

21 THE FAMILIAR OTC DRUG FACTS LABEL: OBSTACLES AND
22 OPPORTUNITIES

1 MR. RICHARDSON: Well, good morning. and
2 first, thank you to our FDA hosts for envisioning and
3 arranging this timely workshop. My name is Clark
4 Richardson. I'm the president and CEO of PEGUS
5 Research. And my organization is one that specializes
6 in consumer behavior research.

7 As background for my presentation, we conduct
8 the label comprehension, self-selection, actual use
9 and other consumer studies that support applications
10 for new OTC NDA approvals. The reason that's
11 important is we conduct an average of 4,000 or 5,000
12 individual Drug Facts label-oriented consumer
13 interviews every year. And that kind of experience
14 yields insights about the OTC DFL that can't be
15 obtained in any other way.

16 So please note that all of my comments today
17 will focus on one special class of nonprescription
18 labels, Rx-to-OTC switch DFLs. And this is just one
19 special category. But it's informative and
20 instructive because these are labels -- new labels for
21 consumers that were created from content originally
22 oriented toward physicians. And this is also the

1 category that I'm familiar with as a researcher.

2 So previous speakers have done a great job
3 explaining how the Drug Facts label was created and
4 why and sort of the standardization features which are
5 helpful in many ways. But as a result, the DFL is
6 generally best suited to OTC conditions that are
7 straightforward, meaning symptomatic, self-
8 recognizable, episodic or self-limiting and have
9 straightforward contradictions. So we can think of
10 the DFL as a vehicle, sort of like as a cart or a
11 wheelbarrow that you'd use in your yard. And if the
12 quantity of information fits in that vehicle, then the
13 tool works well.

14 The place where that breaks down, however, is
15 if the extent of information extends the capacity of
16 the tool. So thinking about the DFL, there are clear
17 limitations. The DFL is flat and static, as has been
18 pointed out by previous speakers. It's meant to be
19 printed on a physical package. It's one-directional
20 in its communication with a single medium and has
21 highly structured headings and content with little
22 flexibility.

1 So that rigidity creates obstacles for
2 conditions that are difficult to self-recognize or
3 diagnose, that are chronic, that require external
4 testing or validation and for medications that are
5 preventative or have complex or difficult to recognize
6 contraindications.

7 So in those cases, for those medications, the
8 DFL is like a vehicle that is overloaded and unwieldy
9 and, in this case, precariously ineffective.

10 So let's talk for a moment about what the DFL
11 needs to do, this flat, static tool, to achieve its
12 intended purpose. It needs to communicate and mediate
13 across a chain of steps and behaviors. And from the
14 consumer perspective, those are questions like will I
15 look at it or ignore the label? Will I read it
16 carefully or skim? Do I comprehend what's written
17 there? Is it right for me to use? Do the warnings
18 apply to me? Will I ask a doctor or pharmacist? Will
19 I follow the directions for use? Do I stop use --
20 modify or stop use if conditions change or my symptoms
21 change? And the net result of all of those steps are
22 health outcomes, meaning what we hope will be maximum

1 benefit and minimal risk.

2 But things can go wrong at any point in that
3 chain. People may choose not to read or they may
4 default to other sources. They may read but not
5 understand. And they may understand but not apply.
6 And sometimes that means intentional override, which
7 is a particularly challenging issue when information
8 is presented clearly, but people choose to do
9 something else. And so people may initially comply
10 but then fail to adapt to changing circumstances or
11 symptoms.

12 So let's look at new OTC switch DFLs.
13 According to FDA's count, there have been 41 new Rx-
14 to-OTC switches since 2001, which is shortly after the
15 DFL format was approved. And as you look at these
16 drugs that are very familiar, you realize that they
17 are for familiar categories of conditions.

18 Most are to treat symptomatic, self-
19 recognizable and episodic or self-limiting conditions,
20 which is great and it does really well for that.
21 There are very few conditions within this that are a
22 little bit less traditional, that may be more

1 preventative or may treat conditions that are more
2 chronic or ongoing. But the majority fit that basic
3 pattern.

4 The one question we could ask is have new
5 DFLs been changing over time for OTC switches. So we
6 first looked at the length or the quantity of
7 information in OTC switch DFLs and focused just on the
8 41 on FDA's switch list. And as you can see from that
9 scatter plot there, there's wide variability in the
10 number of words per label. They ranged from just over
11 200 to just over 800 words per label. And there is a
12 general increasing trend, if we fit a line to that,
13 that suggests that they have generally been getting
14 longer over time.

15 The next question, and this was raised by a
16 previous speaker, is what does readability look like.
17 And for us, this is critical and fascinating because,
18 as we know, many consumers aren't good readers. They
19 have low health literacy. So we looked at readability
20 of the new OTC switch DFLs this time using the Flesch-
21 Kincaid grade level. And this is the familiar metric.
22 There are lots of published studies about OTC drugs

1 and the grade level. And when we look at this, we
2 don't see a clear pattern or change in grade level
3 over time.

4 But it is instructive to think about what FDA
5 said in the label comprehension study's guidance
6 document which is that OTC DFLs should be written
7 ideally in a fourth to fifth grade reading level. But
8 in no case should they be written, or generally
9 shouldn't be written above an eighth grade level. And
10 in fact when we look at this, we realize that most do
11 in fact fall within that range. And clearly it's
12 possible to create labels that are written to a higher
13 level that still communicate well, that are clearly
14 written.

15 But those facts and figures may tell us
16 something about the limitations of the DFL and the
17 readability challenges that occur when you try to
18 shoehorn or fit information into that structure.

19 So in summary, for that piece we could
20 conclude that new OTC switch DFLs may be getting
21 longer on average, just based on simple word count.
22 Many new OTC switch DFLs are written to an eighth

1 grade level or lower. But about the quarter of the
2 ones that we've looked at have reading grade levels
3 ninth grade or higher and up to 10.6 grade. So those
4 findings suggest that we may in fact be stretching the
5 boundaries of the DFL in its current format.

6 So we've been talking about past OTC switch
7 products, things that are on the market that are
8 approved. But let's talk for a moment about
9 additional categories that could provide a public
10 health benefit, fill unmet needs, increase access to
11 safe and effective medicines. And these have been
12 talked about in many venues and settings.

13 One could be cholesterol-lowering drugs and
14 naloxone, which of course has been discussed here.
15 and those were mentioned when FDA released the draft
16 NSURE guidance as potential candidates. There are
17 oral contraceptives and erectile dysfunction drugs
18 such as PDE-5 inhibitors, migraine drugs and others.
19 And some of these have been carefully developed and
20 tested but encounter challenges or obstacle when
21 attempting to portray clearly all of the needed
22 information within the confine of this DFL -- familiar

1 DFL tool.

2 So I'll note that some sponsors and programs
3 are significantly ahead of what I will describe in
4 terms of OTC labeling innovation. But the information
5 is not yet in the public domain. And so we'll focus
6 on what's mostly in the public domain here.

7 In terms of case studies, I'd like to talk
8 about three categories and what obstacles or
9 challenges the DFL poses for those categories.

10 Statins are an interesting and informative example.
11 There is a clear public health case to expand access
12 to safe and effective medications for dyslipidemia.
13 And Merck Mevacor had three separate OTC applications
14 and advisor committee meetings.

15 In each case, the panels who reviewed those
16 expressed concern about elements like the one you see
17 here. Can consumers understand the indication
18 cholesterol well enough? Can they correctly diagnose
19 themselves? Do they make appropriate decisions about
20 whether to take the drug? And can they avoid adding a
21 statin to or replacing their current Rx therapies?
22 All important issues. And Merck, to be fair, made

1 valiant efforts to innovate with labeling. But they
2 were constrained by limitations of the DFL.

3 So when we think about obstacles or
4 challenges on the DFL to creating an effective
5 labeling for something like a statin for high
6 cholesterol, there are limited opportunities to
7 portray information to help people self-diagnose and
8 decide if a drug is appropriate to use. And those
9 headings are really up at the top of the DFL.

10 We may be limited to the purpose. There are
11 parts about do not use and ask a doctor. But in fact
12 Merck realized that it would be essentially impossible
13 to portray what they needed just within the confines
14 of those simple boxes.

15 So they added new panels or elements around
16 the traditional DFL to supplement. And there's a
17 great deal of creativity here. They had a PDP that
18 explains age and sex requirements. They added another
19 panel that explained what you needed to do before you
20 select or take the drug in terms of getting your
21 numbers tested. They added a flowchart that had age
22 and sex criteria and other critical contraindications.

1 And all of those were great.

2 But as was mentioned previously, it does
3 require consumers to process a lot of simultaneous
4 pieces of information. And so in the end, even with
5 those enhancements, the results of the comprehension
6 studies were judged insufficient. FDA recommended
7 additional development and testing and critically the
8 self-selection results showed that something like
9 between 11 and 38 percent of people with critical
10 contraindications would still select the drugs.

11 And so it was possible to create very clear
12 and creative labeling materials that read at a good
13 grade level. But consumers still struggled to
14 understand because they couldn't integrate all of
15 these pieces of information.

16 So moving on to a different case study, in
17 this case, oral contraceptives, these are used by
18 millions of women in the U.S. and around the world.
19 And there's a clear potential public health benefit in
20 expanding access for women's health. But there are
21 also important labeling challenges. And, for example,
22 the prescribing information, the Rx information breaks

1 instructions into chronological pieces such as what to
2 do before use, when to start, how to use and
3 directions for how to handle dosing errors. And so a
4 label has to do some very interesting and dynamic
5 things.

6 One example I've pulled out here is it needs
7 to convey multiple messages about bleeding at
8 different time points, each with its own individual
9 action. So for example, if women experience
10 unexpected bleeding before use, they should ask a
11 doctor before use. If they experience expected
12 changes in bleeding during use after they've
13 initiated, they should continue taking. And if they
14 have unexpected changes in bleeding during use, they
15 should keep taking and talk to a doctor.

16 And as you can imagine, that last statement
17 is very difficult to portray within a label that
18 really isn't logically arranged to have someone keep
19 taking and talk to a doctor. So there are important
20 conceptual challenges here and some constraints that
21 are difficult to work around.

22 And as you can see, that warning about

1 bleeding could appear logically in multiple different
2 places. But there simply aren't adequate places for
3 some of the elements that need to be communicated.

4 Let's talk about a third case study, and one
5 that's important, PDE-5 inhibitors for erectile
6 dysfunction. There could be significant demand for a
7 drug to provide true symptomatic relief to men with
8 erectile dysfunction.

9 But from the prescribing indication, a key
10 contraindication is to avoid concurrent use with
11 nitrate drugs because of potential hypotensive
12 effects. And there are also key warnings about using
13 with heart disease. And these need to be clearly
14 represented on an OTC DFL to ensure, number one, that
15 people can select correctly and, number two, that they
16 can use it safely in an ongoing fashion.

17 So when you think about those challenges
18 within the confines of the DFL, nitrates are a
19 particular challenge because many people may either
20 not recognize that name or they may not recognize that
21 their medications fall in that category. And so the
22 Drug Facts label needs to not only identify that term,

1 but it may also need to educate consumers about what
2 those medications are.

3 And further, because that warning is so
4 important, the standard do not use language may not be
5 strong enough to convey what consumers need to know.
6 And additionally, the DFL must direct potential users
7 who are, number one, diagnosed with heart disease and,
8 number two, not diagnosed but have signs and symptoms
9 of possible heart disease to ask a doctor before use.

10 And so now you can see that we may be asking
11 the flat, static DFL to even help people recognize
12 undiagnosed conditions, which is a very tall order but
13 certainly possible with the adjunct technologies and
14 other things that we've been talking about in this
15 section. And in fact some of these obstacles that
16 I've described are very easy to overcome I think with
17 some simple technology. And I wish we had more time
18 to talk about that in this presentation.

19 Sponsors often use workarounds. They
20 recognize that they need to fit the DFL format. But
21 they try to do things kind of within and around that
22 to supplement or to make it more effective. So for

1 example there may be colored text inside a DFL to draw
2 attention. But what we find in our research is that
3 adding those emphasis items actually causes elements
4 to compete for attention. And so they don't always do
5 what's intended.

6 As we know, the format and headings are also
7 somewhat rigid and can't be altered much. So there
8 are things that can be added outside. And you've
9 already seen things in this presentation that do that.
10 There are principal display panels that add graphics,
11 claims or warnings.

12 You can add icons, and Julie mentioned that.
13 You can add pictograms, which Jesse displayed before
14 as on FDA's model naloxone label. And you can add
15 other elements. So these techniques I think all help
16 to improve comprehension or self-selection.

17 But in our experience, in many, many studies,
18 those things may not be enough on their own to
19 generate the kinds of comprehension results and the
20 accuracy of self-selection that are needed to give
21 reassurance for approval of all new drugs. And so
22 that puts sponsors in a position where they need to

1 even think outside of those possibilities.

2 So let's talk for a moment about label
3 opportunities. We've been focusing on how to extract
4 every last drop of utility out of the flat, static
5 DFL. That's been the exercise for these last years.
6 But there are, as we've already seen, endless media
7 already available for delivering health information
8 that are evolving rapidly.

9 And we could extemporize on how those can be
10 applied to DFLs. In fact, we've envisioned in our
11 minds somewhat as previous presenters how that could
12 be laid out as sort of a flat DFL plus an adjunct
13 website or an app.

14 But the use of media would be an obvious
15 enhancement to labels. People understand better when
16 they see or hear. You can add algorithmic support for
17 decision-making, quizzes to test knowledge and you can
18 actually connect to existing health records and data
19 to validate or verify that they could or should be
20 using.

21 So think of all the things OTC labeling could
22 do if we could free it up and use other possibilities,

1 other technologies. There is a hierarchy of possible
2 actions. The DFL can inform, which I think it does
3 now in one direction. It can educate by adding maybe
4 some supplemental workarounds or some multimedia. And
5 then it could also interact. It could accept inputs
6 from consumers that would allow the content to be
7 customized for them to see what they need to see.

8 Next it could persuade. You could administer
9 quizzes. You can allow people to make decisions and
10 then reeducate if they make a wrong decision. And
11 finally it could actually intervene which means it
12 could validate decision-making. It could actually
13 mediate access, and it could redirect to a healthcare
14 professional when needed.

15 So if we ask the question where are we today
16 with the DFL, I guess I would say that based on things
17 that are currently approved, we're probably still down
18 somewhere around the educate stage, although there are
19 clearly sponsors who are working in these upper stages
20 now. And I think that's what the future of the DFL
21 looks like and what it can do.

22 But the key message is that to achieve higher

1 possibilities, we need to liberate ourselves from a
2 rigid, flat DFL and begin to add additional
3 innovations and ancillary capabilities.

4 So a question. What is the state of the art
5 in sort of mass production, interactive, public-
6 facing, self-directed education and decision-making
7 tools? I had the experience, like almost all of you,
8 of trying to do my taxes recently. And I used an
9 online tax preparation service and was amazed by how
10 simple it is, how intuitive and the fact that it can
11 walk average taxpayers through a process that could be
12 very complicated, that has endless possibilities.

13 And so these guided services have become very
14 capable and are getting very good at it. And in fact,
15 last year, this service said it processed 35 million
16 people's returns. And to be able to do that, that
17 number, and help people do that reliably is
18 remarkable.

19 But the question I would ask is why do
20 services like that work and is there a pattern here
21 that we could leverage for a DFL. These services such
22 as tax preparation services reduce complex tasks to

1 simple distinct steps driven by an algorithm in the
2 background. And at every step, they ask just one
3 question, usually yes or no. They also offer an
4 explanation of what the question means. They give
5 readily available educational material for those who
6 want to dig deeper. And at any point you can link out
7 to get additional help. And so it almost can't fail
8 if you answer honest values.

9 So the key takeaway points here at that the
10 current DFL has been a good tool to standardize and
11 inform. For many drugs with sort of simple
12 characteristics, it does a good job of helping people
13 to navigate. And we've already heard that people
14 scan, as we've heard previously.

15 We find that people will look at the purpose
16 and they'll look at the directions and think the rest
17 basically not apply to them. But we know that
18 especially for complicated candidates this format
19 simply can't accommodate nontraditional drug
20 candidates. And we've really stretched it to its
21 limits. There's not a lot more that we can do within
22 that format. And examples of technology to make

1 education and decision tasks simple, reliable and safe
2 are all around us. There are a myriad of
3 possibilities.

4 So these utilities and tools could provide --
5 the ones that we've looked at, could provide a model
6 for what OTC labeling could be and really must become
7 to keep up with the changing needs of the OTC consumer
8 marketplace.

9 So with that, I will stop. Thank you so much
10 for your attention today. And it's been a pleasure to
11 talk with you. We wish we had more time to talk about
12 additional things to go along with this. But here is
13 my contact information, and we would love to
14 correspond with any of you who have questions.

15 DR. DELLIBOVI-RAGHEB: Thank you very much,
16 Clark, for your talk and thank you for bearing with us
17 with the technical difficulties with these slides. It
18 is my pleasure to introduce our next speaker, Dr.
19 Shonna Yin, from New York University school of
20 Medicine. And the title of her presentation is
21 "Strategies to Improve the Nonprescription Drug Facts
22 Label: A Review of the Literature."

1 STRATEGIES TO IMPROVE THE NONPRESCRIPTION DRUG FACTS
2 LABEL: A REVIEW OF THE LITERATURE

3 DR. YIN: Great. Thanks so much. I'm
4 waiting for my slides to load. Okay. Perfect. Okay.
5 So today I'll be focusing on the published literature
6 on research focused on OTC products to highlight
7 potential strategies to consider for improving the
8 nonprescription DFL.

9 I definitely want to acknowledge the
10 fantastic team that's worked with me in preparing for
11 this, including Yuxiao Lei, who's one of my project
12 coordinators, and Carlita Anglin, our librarian at
13 NYU. And I have no -- nothing to disclose.

14 And I just want to briefly share the search
15 strategy on the screen before we start and the
16 different databases that we looked at and search
17 terms.

18 Great. So to give you an overview of what
19 I'll be covering today, we'll go through some potential
20 strategies including looking at readability and
21 clarity of language, chunking and organization of
22 information, font size, headers, titles and eye-

1 catching features, iconic and pictographic information
2 and then end with a little summary.

3 Okay. So we'll start first with readability
4 and clarity of language. There were not a lot of
5 studies, published studies that have looked at
6 readability of OTC labels. This study by Trivedi and
7 team sought to assess readability of 40 OTC products
8 and used three different readability formulas. They
9 found that labels were, on average, written at a
10 college level, at a 16 or 17 grade level and
11 notably no labels were less than an eighth grade
12 level and the average U.S. reading level is thought to
13 be around the eighth grade level. So this was
14 certainly concerning.

15 This is another study from King, et al. This
16 is from Mike Wolf's team. So this was done focused on
17 OTC acetaminophen labeling. They conducted focus
18 groups with participants in two different cities who
19 were asked to give feedback about active ingredient
20 and dosing information as opposed to plain language
21 text and icons for OTC acetaminophen. We'll talk
22 about icons a little bit later. But what we'll talk

1 about here, preferences for plain and explicit
2 language.

3 So researchers found that most people
4 preferred warning language that was more explicit and
5 in more plain language like do not take more than six
6 pills in 24 hours versus do not exceed six tablets in
7 24 hours unless directed by a doctor. The word
8 exceed, for example, is not easy to understand and the
9 part about the phrasing unless directed by a doctor,
10 vague and confusing and thought that it could be
11 misinterpreted in many ways.

12 In addition participants expressed that they
13 felt it was very important for labels to explicitly
14 state that it's not safe to take two products
15 containing acetaminophen and to explicitly state why
16 that liver damage is the reason for this.

17 Moving to chunking and organization of
18 information, we talked a little bit about chunking
19 earlier. It's been shown to reduce the load on
20 working memory. Some researchers have looked at how
21 the order of the chunks in the DFL could be
22 reorganized to help users.

1 There have been two studies by Bhansali that
2 looked at this. These were both experimental studies
3 where participants were randomly assigned to either
4 the current DFL label versus two experimental label
5 formats that varied in the order of the information
6 that was presented.

7 Both studies used a validated questionnaire
8 to measure variables from the OTC label evaluation
9 process model looking at label comprehension, ease of
10 use, attitudes, product evaluation and purchase
11 intention. This is the different labels that they
12 showed.

13 So label A, where warnings were placed under
14 uses, that's how currently -- on the current DFL, like
15 that in that order. Label B was where warnings were
16 placed before uses. And then label C, where warnings
17 were placed after uses and directions.

18 So they found that label C, and this is
19 consistent with what other presenters have said, when
20 warnings were placed after the uses and directions,
21 the participants scored significantly higher in all
22 the domains assessed. And interestingly label D did

1 the worst because it seems to be the most dissonant in
2 terms of logical order.

3 And so the study is pointing to the fact that
4 if we can have the chunked information in a logical
5 order with uses, directions and other information,
6 that may improve information processing, at least for
7 some OTC users.

8 And I want to point out that this study was
9 done with more highly educated population who were
10 involved in the health-related fields. So it may not
11 necessarily be reflective of the general U.S.
12 population.

13 A second study was also done by Bhansali
14 looking at the same labels as well. This one was done
15 with college students, and they also found very
16 similar results as the first study.

17 Okay. I'm going to move now to font size.
18 Current regulations allow for a minimum of 6-point
19 font size on nonprescription DFLs. Prior studies have
20 shown this 6-point font may impede consumer
21 comprehension, especially among visually impaired
22 population.

1 This study from Mullen, they did a secondary
2 analysis of data collected as part of a larger study.
3 They looked at the association between visual acuity
4 and the risk of misuse of nonprescription
5 acetaminophen products. The potential for misuse was
6 assessed through a functional assessment of product
7 self-dosing and by testing patients' understanding of
8 concomitant use risk.

9 These were their findings. Compared to
10 individuals with normal vision, those with mild to
11 moderate vision loss, a visual acuity of 20/30 or
12 20/100 were more likely to have demonstrated errors
13 compared to those with normal vision, and that was
14 true for all three of the acetaminophen products that
15 they tested.

16 One of the interesting things that they also
17 found from this study was that the vision-related
18 medication errors were seen irrespective of literacy
19 skills, suggesting that the two things are different
20 risk factors with different pathways for contributing
21 to nonprescription product misuse.

22 This study was done by my team at NYU working

1 in collaboration with Mike Wolf. We systematically
2 looked at the top 200 pediatric OTC liquid products
3 using a health literacy perspective. And we looked
4 both at the PDP as well as the Drug Facts label and
5 one of the things we looked at was font size.

6 So you can see here that the font sizes on
7 Drug Facts panels were on average between 5.5 and 6.5,
8 smaller when it was on the bottle versus when it was
9 on the box. And then we can see on the main principal
10 display panel, font sizes are much larger and the font
11 size for critical information like active ingredients
12 are much smaller than other things such as flavor.
13 And this may influence how people are -- the attention
14 that people are paying to this information.

15 Okay. The research on nonprescription
16 medication labels indicates that consumers are better
17 able to read and demonstrate product knowledge when
18 letters are at least 10-point font. Tong has done a
19 narrative review on studies looking at design and
20 comprehensibility of nonprescription Drug Facts labels
21 and they also found that small font sizes impact the
22 ability of older consumers to read and comprehend DFLs

1 and larger font sizes were associated with improved
2 consumer medicine knowledge.

3 This study by Tong and Sansgiry compared
4 three nonprescription Drug Facts labels, the old FDA
5 label, the new FDA label and simulated labels with
6 simulated labels printed in a 10-point font, with 11-
7 point headings in bold. And the only difference
8 between these labels was font size. And you can see
9 here that there was -- that the simulated label
10 performed the best in terms of all of these different
11 categories, ease of use, product knowledge, attitudes,
12 product evaluation and purchase intention.

13 And this is -- you can see on the next slide
14 -- oh, I'll show you later the different -- what the
15 different products look like.

16 So in general I think we know that larger
17 font sizes are consistently preferred by consumers.
18 And even when you look at Drug Facts labels being
19 tested in other languages, that holds true. So this
20 study by Sansgiry was done conducted with a largely
21 Hispanic population. They looked at these different
22 labels. They looked at three label formats, the old

1 FDA, the new FDA and the new bilingual label for
2 acetaminophen, ibuprofen and aspirin in random order.
3 And they found the ease of use scores were highest for
4 the format for the bilingual labels with the increased
5 font sizes.

6 Great. So I'll move on now to -- this is
7 where it shows the ease of use scores being better in
8 that category of labels.

9 Okay. So headers and titles and other eye-
10 catching features. I'm going to talk about a few
11 interesting studies. This one is by Tong which was
12 done in Australia who was interested in making
13 improvements to their OTC drug labeling.

14 They first did a qualitative exploratory
15 study looking at consumer opinions on three groups of
16 nonprescription labels, existing Australian
17 nonprescription labels, the FDA DFLs and post-
18 standardized medicine information box that they had
19 created. And interestingly the FDA DFL was their most
20 preferred label from their participants.

21 The headers they thought contributed to a
22 good and clear layout. The use of the additional

1 descriptive subheadings within the warnings section
2 was very helpful. And the high contrast of the FDA
3 DFL label also contributed to clarity.

4 An additional follow-up study was done by
5 Tong as well where they looked at four prescriptions,
6 labels for diclofenac, which is an NSAID, two labels
7 developed based on the existing and proposed
8 standardized label formats in the U.S. and Australia
9 and then two labels developed by applying good
10 information, design and findings from prior consumer
11 needs analysis. And I'll show you snapshots of those
12 labels in the next slide.

13 The participants recommended more bolding of
14 key terms or points of information, for the use of
15 color for highlighting and differentiation of
16 information, recommended adding the side effects as a
17 heading.

18 These are the four different labels that were
19 looked at, just the Drug Facts panel based one and then
20 this one next to it here shows how you can use
21 different colors to really highlight points of
22 attention.

1 Okay. And then in dual language
2 comprehension studies, participants also respond
3 positively to eye-catching features that emphasize
4 components of the DFL. This study from Sansgiry that
5 I mentioned earlier, they looked at the three label
6 formats, the old, the new and newly created bilingual
7 labels. And the participants really preferred the
8 highlighting of the warnings. You can see that here,
9 highlighting of warnings and active ingredients, which
10 would alert them to important information within those
11 sections.

12 Okay. And then I'll just present one last
13 study. Just to provide some context, there are new
14 regulations from the FDA that acetaminophen and the
15 class NSAIDs be highlighted on labeling.

16 So this study from Harben is an experimental
17 study with 65 adults that were 65-plus. They looked
18 at the effectiveness of this regulation on
19 attentiveness to critical warnings and active
20 ingredient information on nonprescription DFLs and
21 PDPs.

22 They ended up conducting two experiments, one

1 focused on changes to the active ingredients portion
2 of the DFL and one focused on changes to the warnings
3 on the DFL. And you can see these are snapshots of
4 what they used.

5 They used a method called detection, change
6 detection to objectively evaluate whether the novel
7 OTC drug labels increase attention to critical health
8 information among older adults. They were --
9 participants were asked to look for changes between
10 flickering displays, highlight, no highlight and --
11 when they detected a change when they were -- and
12 asked to identify the location of the change.

13 And you can see experiment one compared the
14 standard DFL with active ingredient that's highlighted
15 versus non-highlighted. And then the other experiment
16 looked at the addition of this warning that's
17 highlighted.

18 And overall for both experiments, both
19 highlighting and adding front-of-package warning
20 seemed to improve the attentional allocation to
21 critical OTC medication information by older adults.
22 And I'm not going to go through in depth the slide.

1 But they did find that highlighting seemed to really
2 help.

3 We'll talk about this last area, icons and
4 pictorial information. Studies incorporating icons
5 and pictograms on the DFLs have had some positive
6 results. The study that several have mentioned
7 already, so I won't go into too much depth, looked at
8 naloxone and incorporating pictures within there. And
9 so I'll just splash through that.

10 But I think what's exciting, one thing that
11 was exciting about the study was that they did look at
12 this -- they included a good number of folks with
13 limited literacy as part of it. And they also
14 included people from the target populations, the
15 opioid users, their families, their friends who were
16 users were included in this -- in this study. And
17 others have shown this already. But overall the label
18 was thought to be adequate for use in the development
19 of naloxone products intended for OTC sale.

20 I'll move on to the next study. So
21 pictograms may also be helpful for supporting
22 understanding of dosing information. But they're not

1 often used. This is going back to an earlier study
2 that I mentioned where my team worked on looking at
3 the top 200 OTC pediatric labels. And one thing we
4 looked at was the presence of pictograms to support
5 dosing. We saw that this was only seen on four of the
6 200 products. And I'll illustrate how this might be
7 potentially used.

8 This was another study our team had done at
9 NYU. We conducted an experimental study looking at
10 the effectiveness of adding pictograms to dosing
11 instructions for infant acetaminophen. That's back
12 when we used to have two versions of acetaminophen,
13 just two different concentrations. And they had these
14 droppers which were quite confusing for parents to
15 use.

16 And so we did the study to see if we randomly
17 assigned participants to get dosing instructions with
18 a pictogram versus text-only instructions, if that
19 might be helpful. And we found that indeed pictograms
20 did help. Overall people did pretty poorly with
21 dosing though. But as you can see in the center of
22 this graph are no errors and then there are the

1 overdoses on the right and the underdoses to the left.
2 Definitely a lot of errors happening, but more
3 overdoses, especially with the group that did not have
4 the pictogram. And thankfully that infant
5 concentration and dropper is no longer being used in
6 the market.

7 My team is currently working on another study
8 funded by FDA to look at OTC cough and cold medication
9 labeling trying to see how we can optimize parent
10 understanding of age restriction and active ingredient
11 information and dosing instruction.

12 And we have done a series of randomized
13 controlled experiments with parents and just to show
14 you another example of how pictograms might be
15 incorporated into a Drug Facts label, we did assign
16 parents to one of six different groups who got varying
17 labels, pictographic or non-pictographic labels and
18 different dosing tools.

19 And we found that there was increase in
20 preference for the tool that's shown on the pictogram.
21 So amongst parents who received the pictographic
22 chart, they were more likely to choose the tool that

1 was visually shown. We saw more dosing errors with
2 cups versus syringes. We did not see an added benefit
3 of pictograms in this experiment, although this was
4 not really a real-world experiment where parents had
5 access to all sorts of tools. So we're interested in
6 trying to do more studies to look more in depth at
7 this.

8 So finally, this is the last study. This is
9 from King, et al., the study I mentioned earlier where
10 they sought to elicit feedback about plain language
11 text and icons. And just to briefly show some of the
12 icons that they had tested and participants really
13 liked having an icon to identify products that
14 contained acetaminophen.

15 However consistency in adoption of this same
16 icon by all manufacturers of acetaminophen products is
17 needed in order for this icon to be meaningful. And
18 participants also favored using an icon to highlight
19 the maximum number of pills per day, which is shown on
20 this slide.

21 Okay. So I'm just going to end because I
22 know we're out of time. There are a number of

1 potential strategies included in the literature for
2 improving the nonprescription DFLs. And I know this
3 is really focused here on the static labels, which is
4 what's the focus of a lot of the research.

5 So in terms of addressing readability and
6 clarity, having more mandatory readability and grade
7 level criteria and, you know, the current guidelines
8 are nonbinding recommendations. There should be
9 greater attention paid to the use of explicit, clear
10 language. In terms of chunking and organization of
11 information, more research on how to do that most
12 effectively.

13 With font size, considering whether it's
14 possible to change that minimum font size to something
15 a bit larger. For headers, titles and eye-catching
16 features, more research on effective strategies to
17 highlight information would be helpful and to do this
18 consistently across products.

19 For icons and pictograms, considering adding
20 pictorial information to the Drug Facts label
21 essentially to support direction might be a good idea,
22 and then considering standardizing icons and use of

1 pictorial information that can be used in DFL and in
2 other parts of the packaging to support the DFL.

3 Finally I think it's important to make sure
4 that the studies that we're doing to assess
5 comprehension are done across different populations,
6 populations with low literacy, those with limited
7 English proficiency and, as many have talked about
8 before, using technology to go beyond the static label
9 to really support parents and patients and families
10 would be really important.

11 Thank you very much. And I'm happy to answer
12 questions later. And I think we're moving to the
13 panel discussion now. So thank you.

14 DR. DELLIBOVI-RAGHEB: Thank you very much,
15 Dr. Yin, for your talk. It is my great pleasure to
16 introduce our moderator, Dr. Ruth Parker, from Emory
17 University, who will be moderating our first panel
18 discussion. Welcome, Dr. Parker.

19 Our panelists will be Amanda Pike-McCradden,
20 Jesse Catlin, Julie Aker, Clark Richardson and Shonna
21 Yin. Our panel discussion will last for about 30
22 minutes and will conclude at 11:25 a.m.

1 PANEL 1: THE CURRENT LANDSCAPE OF THE DRUG FACTS
2 LABEL AND BARRIERS TO CONSUMER COMPREHENSION

3 DR. PARKER: Well, thank you. And my thanks
4 to the presenters for a lot of information, a lot of
5 good information. And I think that the questions, at
6 least the ones that I have so far, are really an
7 opportunity for us to underscore a lot of what you
8 have covered. But it allows us to synthesize it and
9 sort of underscore some of these key points that you
10 all have made from your different perspectives.

11 So I'm going to ask some of these to specific
12 presenters. But I'm going to ask the others that were
13 part of the panel to also let me know and they can
14 chime in as well so that we can try to get sort of a
15 consolidated approach to the responses to a few
16 questions that I'll begin posing now.

17 So let me begin, and as I said, some of this
18 is a consolidation and just underscoring of what we've
19 heard. But hopefully that can be helpful to the
20 agency and the audience.

21 So I'll ask those who just presented,
22 according to your experience and past consumer

1 research studies, what aspects of the DFL are actually
2 working pretty well right now? And it would be
3 helpful, I think, if we could, where possible, to say
4 these are successes as they relate to content and
5 these are successes as they relate to format, since
6 often we look at the labels and think of both content
7 and format.

8 So Julie, I know you've spent some time very
9 specifically thinking about that. Could I ask you to
10 begin to answer that for us know?

11 MS. AKER: Sure, sure. So in terms of the
12 content, I think that we've said, and there's been
13 kind of additive effect here with all of the speakers,
14 that, you know, the uses and the directions, how do I
15 use this. That seems to be working, and it's
16 targeted.

17 And then things that are more absolute, when
18 we are being really absolute, do not use, stop use are
19 precise instructions that are very clear and very
20 direct. Those things work and those things really
21 speak to the fact that this sounds more like a
22 requirement than a recommendation. So that's what

1 they're tuning in on.

2 One other thing that I would just mention,
3 and I didn't have this in my presentation, but we've
4 noticed this in a recent program, is that there's this
5 additive effect of not -- using the carton, but going
6 beyond the DFL.

7 So, for example, if you've got really
8 important information that you have to put in the DFL
9 by regulation, you can also amplify that information
10 by putting it outside the DFL on a side panel or above
11 the DFL and again on the PDP. We've got one program
12 where we actually had to put it in all three places.
13 And the fact that you're queuing into the PDP and then
14 moving over to the panel and then into the DFL really
15 helps.

16 DR. PARKER: Let me get you to again just --
17 you spoke to this fairly concisely I think in your
18 presentation. So maybe you could underscore for us
19 the points that you made about what's working.

20 MS. AKER: Uses, the directions and
21 absolutes.

22 DR. PARKER: And Jesse, anything that you

1 want to add to that?

2 DR. CATLIN: Sure. You know, I think from an
3 overall perspective, as I mentioned in my
4 presentation, the DFL has proven itself in the
5 marketplace. The remarkable safety profile we see for
6 most OTC drugs over the past 20-plus years is a
7 testament to the success of the DFL as a communication
8 tool.

9 I'd venture to say the DFL does a decent job
10 sort of serving the typical case or maybe the typical
11 consumer. But I think it's also clear that there are
12 limitations to this too.

13 DR. PARKER: Okay. And I think you also
14 underscored standardization that was offered by the
15 DFL compared to what we had before that and that the
16 standardization was actually one of the successes.

17 I underscore that because when I think of
18 this and when I think of all of the opportunities that
19 we have technologically moving forward, I think we
20 need to underscore the importance of standardization
21 because, you know, the analogy I've used that many of
22 you have heard many times is we don't need another 200

1 bottles of ketchup in the grocery store to try to
2 choose from. And there's something about orientation
3 and the repetitive nature and thinking about a stop
4 light works because stop lights tend to look alike.
5 And so I think you underscored that standardization,
6 compared to what we had prior to that.

7 And Shonna, you did such an exhaustive and
8 helpful look into the published literature about some
9 empirical studies. Anything you want to add to that
10 from your review, from your lit review about the
11 successes, content format-wise, that we could
12 underscore here so that as we think about the future,
13 we begin by what is it about this that's not broken?

14 DR. YIN: Yes. I think the form -- there's
15 some definite successes around the formatting, so in
16 terms of the chunking of information. I think that's
17 something that everybody agrees it was a good thing
18 was to have the information chunked. You know, having
19 the headers and the sub-headers really flagging
20 different sections I think is another success.

21 I think also the bulleting is helpful as
22 well. So I think there's quite a number of formatting

1 successes in the current DFL.

2 DR. PARKER: Any additions from the others
3 that you want to add to the list before we move on, so
4 that we sort of have that out there? Okay. Great.
5 So let's go to the limitations. You know, it's always
6 easier to talk about all the challenges and the
7 limitations than it is the successes. But we
8 certainly want to underscore from your research and
9 your experiences recommendations for redesigning both
10 content and format. And a lot of that came up.

11 But let's just -- let's go back to that, and
12 I think it's probably helpful to hear from each one of
13 you sort of the main points you saw from your own work
14 and from the studies that you've been a part of about
15 recommendations for redesigning content as well as
16 format. So let's start with you, Clark, if you'll
17 lead us off here.

18 MR. RICHARDSON: Sure. Great, great
19 question. I think there are both sort of short-term
20 redesigns that could be applied and then there are
21 more fundamental redesigns that could shape the DFL of
22 the future. So in terms of kind of short-term

1 incremental changes, there could be flexibility to
2 allow sponsors more liberty in defining their headings
3 based on the clinical characteristics of the drug
4 product. And we talked -- I talked in my presentation
5 about some categories like oral contraceptives and
6 PDE-5s where that flexibility would make a big
7 difference in terms of consumers' ability to
8 understand.

9 There were also mentions about icons and
10 icons could be a great tool if they're familiar enough
11 and standard enough for people to recognize across
12 conditions. And we've worked with things like GI and
13 CV icons. The question again is can people sort of
14 pick up on those between products so that they're
15 familiar and recognizable.

16 But ultimately a more complete redesign of
17 the DFL might be to focus primarily on the things that
18 people need to know at the point of sale. And it's
19 important to know that people make decisions when they
20 buy. They make decisions when they're getting ready
21 to use. And we could probably divide information up
22 between those points in a way that would be a little

1 more like a guided tour, as I said before. But again,
2 the idea of standardization may still apply. There
3 may still be things that need to be common between
4 drugs, even if they employ these adjunctive technology
5 means.

6 DR. PARKER: I'm going to -- I'm going to try
7 to -- try to get each one of you in here on this.
8 Jesse, what are your thoughts about recommendations
9 for redesigning content and format?

10 DR. CATLIN: Sure. I think I definitely echo
11 what Clark has said. I think one thing that is to
12 consider what's important for most people or for a
13 given user of a product actually in a given situation.
14 So what stage of the purchase decision are they at?
15 Is it pre-purchase? Are they about to use the
16 product? Are they already using the product? And
17 what's most important to communicate then for that
18 person?

19 And I highlighted in my presentation the
20 issue of relevance and I think any way you can find to
21 increase relevance gets the consumer engaged, right?
22 That connects with the consumer and they're more

1 likely to listen to that kind of information or pay
2 attention to it when they actually think it's relevant
3 to them, right?

4 When everybody's getting the same
5 standardized, flat box of information, it's very easy
6 to sort of use your own beliefs, well, that applies to
7 other people and not me or miss things versus when you
8 think the information is actually being directed or
9 has been sort of, you know, organized in a way that's
10 most important to you.

11 DR. PARKER: So Julie, take us -- take us to
12 your DFL density here and walk us through some of your
13 thoughts about redesigning content and format.

14 MS. AKER: Sure. I think one thing that a
15 lot of consumers don't just intuitively get when they
16 look at that DFL, and we're all talking about it
17 because we work with it every day, is there is a
18 before use part and there is a during use part.

19 And so if you almost think about
20 daytime/nighttime, you know, when people look at
21 products where they can see that this is what you do
22 in daytime and this is what you do in nighttime, it's

1 super clear. But it's really not, you know, until we
2 point it out or we have a conversation about it that
3 there is a clear before use, do not use, ask a doctor,
4 ask a doctor or pharmacist and a during use which is
5 the area, the side effects which is one big thing that
6 if I could wag a flag there, it would be let's please
7 replace when using this product with side effects.
8 That would be so useful to people.

9 But that's a during use as well as stop use
10 interaction. So it's almost like you've got a book
11 and you've got the left page and the right page and
12 it's before use and during use. I don't know that
13 that's necessarily super clear to most consumers. And
14 there might be something that we could do to make that
15 more clear.

16 I think the other thing is this issue of
17 hierarchies. If everything's important, then
18 nothing's important. And I think that's where it can
19 be easy for consumers to get dismissive. You know, if
20 you've got a list of 13 different warnings that all
21 say don't use, don't use this, don't use if, talk to a
22 doctor if, you know, it just becomes such wallpaper

1 that it's just -- it's very difficult for people to
2 understand, okay, but what do you really mean. Where
3 am I really -- you know, which of these are really,
4 really important.

5 So I think that we invite perhaps some
6 dismissiveness when it's just everything is painted
7 with the same brush. So this idea that Clark brought
8 up about maybe, you know, having some flexibility with
9 headings, I love that. We've seen that with our
10 research as well, that there's an immediacy to some
11 warnings where you need to do something right now.

12 And there's also a difference between I
13 really mean it when I say do not use versus, you know,
14 someone who maybe could use if there were certain
15 circumstances that were in place. So it's all right
16 now with the same brush, and I think that makes it
17 really hard to understand what is really important.

18 DR. PARKER: Yeah. I've heard the real
19 estate. I hadn't heard the wallpaper before. I'm
20 going to add that one to my lexicon. Many of us have
21 talked about the real estate on the label. But I'm
22 appreciating your wallpaper construct as well. So

1 okay, Shonna, from your thoughts and from your lit
2 review, redesign?

3 DR. YIN: Sure. I mean, I think from a
4 content perspective, I think we all are in agreement
5 that there's a lot of content. And so, I think there
6 needs to be some coming together and really trying to
7 hash out which parts are really the essential pieces
8 we need to include, which pieces we might actually be
9 able to leave off of that main DFL label so that
10 people can focus.

11 I think the other thing is, you know, in
12 terms of content, I think explicitness and clarity of
13 the instructions goes under content. I mean, I think
14 that there's a lot of improvements that we can do in
15 terms of the explicitness and the clarity of existing
16 DFL labeling. And, you know, I think there's a lot of
17 overlap across OTC labels.

18 And so if we could come together and say,
19 okay, well, we never want to use the word exceed,
20 there's a simpler way to say it, if there's some way
21 to have some sort of consensus set of plain language
22 for certain common phrases that could be hashed out

1 and then disseminated to manufacturers, having that
2 menu I think might be really helpful. In terms of
3 format and improvements there, I think again the
4 order, I think it's been brought up many times that
5 people prefer to, you know, have those directions
6 higher up and they don't have to sift through all
7 those warnings to finally get to the directions for
8 use.

9 There's a lot of important things in that
10 directions for use that are important also for self-
11 selection, like the ages that it's meant to be for, et
12 cetera. So thinking about that order again, can we
13 move some things up, that makes sense kind of
14 logically in the mind of users.

15 I think the other thing is color. I don't
16 know if we use color as maximally as we could with the
17 formatting, in terms of formatting. So maybe there's
18 some ways we can do that. Typically, you know, it's
19 like they might highlight something in yellow or it's
20 just black and white. But more color could help. It
21 could also be distracting. So we'd have to really
22 test it.

1 The font size issue keeps getting brought up.
2 So could we do something about it? I know we already
3 have limited real estate. So upping the font size
4 means it's even more limited. But just to think
5 about, I think that's something to consider.

6 And then, you know, standardizing how thing
7 are highlighted. So I know there's new rules about
8 the highlighting of the active ingredients, certain
9 active ingredients.

10 So thinking about other things that we might
11 could standardize in terms of highlighting so that
12 it's not everybody deciding which one, you know, for
13 themselves and then leading to cacophony but that we
14 all kind of take a unified approach and so it's easy
15 for everybody to navigate and know what to expect will
16 be highlighted.

17 DR. PARKER: So let's switch gears just
18 slightly here. And Amanda, I might get you to chime in
19 on this one for us first.

20 Based on available data and also experience,
21 input from your own perspective, let's talk about
22 which specific types of nonprescription drug products

1 present the biggest challenges for consumers as it
2 relates to self-selection and use since, you know,
3 those are the two things. You've got to be able to
4 pick it. You've got to be able to use it.

5 What do we know about the types that present
6 the biggest challenges for both of those, self-
7 selection and use? If you can start us off, Amanda,
8 and then we'll hear from some of the others. Thanks.

9 MS. PIKE-MCCRUDDEN: Well, I think, if I had
10 to put it into two categories, I would say first of
11 all more complex products with more than one active
12 ingredient are definitely -- there's definitely an
13 area where we see trouble.

14 In particular overlap of active ingredients
15 especially as there are more products available under
16 the same like brand umbrella. We notice difficulty
17 there with people unintentionally double dosing with
18 certain actives.

19 And I think another area where I spend a lot
20 of time, and I know everyone on this panel also spends
21 a lot of time, are first in class switches which are
22 just by nature more complex.

1 Either these are products that are not
2 currently available over-the-counter. They are more
3 difficult products to self-diagnose, self-administer,
4 to understand really what all's going on there and the
5 warnings that they carry.

6 Excuse me. and those are -- those are areas
7 where -- I know Clark and Julie were also mentioning
8 this in their presentation. These are more complex
9 products. There's a lot more information that needs
10 to be on that label. At the same time, you know, we
11 do run up against there's too much information on a
12 label and people just kind of don't know what to do
13 with that.

14 So it's sort of -- we're trying to balance
15 these different aspects. And I agree that we've
16 stretched the current format to its limit. We're just
17 looking at more complex drug therapeutic categories
18 now which would be wonderful in a lot of ways if we
19 could get these over-the-counter.

20 But we need to make sure that we do it in a
21 safe manner and that there's just -- the nature of it,
22 there's a lot of information that we need to get

1 across. And the thing is, we can put all this
2 information out there. We can make sure that all the
3 correct information is on that label. But if people
4 don't see it, they don't read it, they don't
5 understand it, that doesn't do anyone any good.

6 So that's part of why I'm really excited that
7 we're here today. We're talking about all these
8 things because, you know, we're just at this point
9 where we really need to I think look at making some
10 changes so that we can expand the amount of over-the-
11 counter offerings.

12 DR. PARKER: So Clark, I want to ask you to
13 chime in here as well. So we've got the multi-
14 ingredient, first in class as two categories. And you
15 spoke to this a little bit in your presentation as
16 well. So what from your lens presents the biggest
17 challenges for self-selection and use?

18 MR. RICHARDSON: Sure. I think from our
19 perspective the biggest challenges would really
20 revolve around three things. One of them is drugs
21 that are to treat conditions that are more challenging
22 to diagnose or that are chronic or ongoing. And for

1 example, a statin doesn't really have a defined
2 stopping point. You know, there's nothing that says
3 you're done, you should stop taking.

4 There are also drugs that are intended to be
5 preventative rather than therapeutic -- as we said,
6 contraceptives. And that really suggests a whole
7 different mindset about what the -- you know, the
8 indications and the warnings should look like.

9 And then as we said before, there are others
10 that have critical contraindications that aren't
11 easily understood by consumers or that may require
12 more education to accomplish. And I mentioned PDE-5s
13 as one where some people will need education about the
14 drugs that they're taking.

15 So I think those -- you know, those, and many
16 other examples, for drugs that could be a great
17 benefit suggest basic product types that represent the
18 biggest challenges for self-selection and use.

19 DR. PARKER: Very helpful. Shonna, Jesse, do
20 you have anything you want to add to this? I think
21 that's a -- that's a really nice summary. Other
22 specific ones or types?

1 DR. YIN: I mean, I think in terms of the
2 multi-ingredient and the one that, you know, in kids
3 we think about a lot is cough and cold medicine, so
4 just to bring that up as a category of concern that
5 can lead to a lot of confusion. And a lot of those
6 cough and cold products also have anti-pyretic
7 medicines like acetaminophen in them.

8 And so there's confusion when someone's
9 already being treated for fever with a different
10 medicine and then they don't realize that there's, you
11 know, acetaminophen also in their cough and cold
12 medicine, which leads to problems. So I just want to
13 raise that as an issue, especially in pediatrics.

14 DR. CATLIN: Yeah. I would also mention --

15 DR. PARKER: Jesse? Yeah.

16 DR. CATLIN: And Clark talked about this too,
17 is we've talked a lot about complexity. And one area
18 where complexity matters is when we're looking at
19 having to extract and evaluate multiple decision
20 criteria at the same time.

21 So, you know, in order to properly self-
22 select, we need to satisfy a series of different

1 conditions. We saw, you know, even with omeprazole
2 and also for the statin, people had a hard time making
3 it all the way through that process to the level we'd
4 like.

5 And so I think it really adds to the
6 discussion of like the idea of a guided tour, right,
7 and being able to really walk consumers through each
8 of those steps because I think that's one of the
9 clearest, at least to me, issues where we see the DFL
10 get tripped up.

11 DR. PARKER: So let me push a little bit to
12 ask you all to help us think through what are the
13 components. So I'm going back to the wallpaper, DFL
14 density, Julie, and your thought there. Based on data
15 and also on your expertise, I want you to help us
16 think about which of the DFL components are most
17 essential for adequate consumer self-selection or use.

18 I don't know if any research drives, this,
19 Shonna. You can start by telling us if we know from
20 published studies. Let's say you can't put it all on
21 there. Let's just assume that. And we're going to
22 make sure we get the stuff that you must have on it.

1 DR. YIN: Yeah.

2 DR. PARKER: Let's make the -- let's just --
3 using experience lens and research, what are the
4 elements that must be on the DFL or whatever it
5 becomes for adequate self-selection and use? You want
6 to start us, Shonna, with anything that you may have
7 noticed in the literature? And then I really want to
8 hear from everybody on this.

9 DR. YIN: I don't know if there's -- I don't
10 know if there's a lot of experimental studies that
11 have identified exactly which is the must versus -- I
12 mean, if we knew those answers, it might be really
13 easy to answer.

14 But I think instinctively there are some
15 categories obviously. Directions are important. If
16 someone's going to -- you know, to know how to give a
17 medicine, you need to have the directions.

18 I think, you know, active ingredients, and
19 those are kind of big areas that people have tried to
20 focus on that are considered very important. That's
21 why people have done these experimental studies on
22 them. But Julie, definitely jump in.

1 DR. PARKER: And Shonna, I'm assuming by
2 directions you mean dosing instructions?

3 DR. YIN: Dosing instructions. Yeah.

4 DR. PARKER: Okay. So let me just sort of
5 make sure we're in agreement. In order to self-select
6 and use adequately a nonprescription drug product, you
7 need to be able to understand and find the active
8 ingredient. Is there anybody who disagrees with that?
9 So you know what you're taking?

10 So there seems to be an agreement that that's
11 one of them. Dosing instructions has come up as well.
12 Is there anybody who wouldn't put that on your hitlist
13 of absolutely must-have? Okay. Let's add to that.
14 What else would you put on that list of, you know --
15 yeah.

16 DR. YIN: Just like, I just --

17 MS. AKER: Yeah. I -- oh.

18 DR. YIN: -- and warnings I think is the
19 other big area people focus on, the warnings. But
20 that's a big category. So how many warnings, which
21 warnings, I think that that's a question. But
22 warnings I think is another big area. They do need to

1 be on there. The question is in what capacity. I'm
2 sorry, Julie. Go ahead.

3 MS. AKER: No, no. All good. You know, from
4 a self-selection, you asked about self-selection and
5 use. So let's break it down a little bit. From a
6 self-selection perspective, you're really talking
7 about this process of ruling in and ruling out. And
8 that's a functional way to look at it. It's an
9 objective way to look at it. What must you have? So
10 you must have the conditions, so the ruling-in
11 criteria.

12 DR. YIN: Right.

13 MS. AKER: And of course that's what
14 consumers focus on the most. I have this problem, and
15 so this is for me. What we wanted to also look at is
16 to balance the ruling-out criteria. That's where the
17 differential diagnosis comes in, you know, in consumer
18 terms, if you want to look at it that way. So the
19 ruling out is there.

20 But, you know, there's another concept that
21 we could put on the table here about what's the most
22 important or, in looking at all of this, what's the

1 most essential. And that -- you know, we do a lot of
2 work in devices too. And there's already well-
3 established methods there and failure modes and
4 effects analysis. And it really says, okay, let's
5 take all the things that are here, all these elements
6 and then let's look at the frequency. What's the
7 worst that can happen? What's the worst that can
8 happen? And you look at frequency and severity, and
9 you can get a score. And you can rank order these.

10 So then you get a hierarchy that can start to
11 form. And it goes back to that comment I made about
12 how if everything is important, then nothing is
13 important. This ability to discriminate which ones
14 are really more important that are absolutely
15 necessary, which may need a special treatment like an
16 icon or highlighted. And we all know that we need to
17 use those carefully and judiciously.

18 But there may be times where that particular
19 warning, someone could die or that particular warning
20 has really severe implications. That's different
21 maybe than the five warnings that are beneath it.

22 So how do we amplify that just a little bit?

1 That very simple took of a failure modes and effects
2 analysis can be a very objective means for doing that
3 and it's really how risks are assessed in the device
4 world.

5 DR. PARKER: Okay. Clark, Jesse, can I hear
6 your thoughts on these, the essentials that must be
7 there or any thoughts you have on this?

8 MR. RICHARDSON: Yeah. I would offer just
9 one thought, which is that question is actually
10 probably product-specific. I don't think we could
11 look and say these headings are always the most
12 important. For different drugs, you know, it may be
13 the warnings.

14 And we always go through this exercise of
15 saying if people fail to see this or fail to
16 understand it or fail to follow it, which statements
17 will have the greatest clinical implications. I think
18 that's the lens to look through when we ask that
19 question.

20 DR. PARKER: And I might, just as a
21 conversation response to you, say I think the notion
22 of a safety signal, you know, what about this can lead

1 to a safety signal because that's really, you know,
2 such a high bar and so critically important when you
3 don't have the learned intermediary in the over-the-
4 counter setting.

5 So, and I guess I -- as I think through this,
6 I have a very hard time thinking that people should
7 not be aware of what medication they're taking. So
8 I'm back to I think people do need to know the active
9 ingredient. And that's a big list, given the chemical
10 compounds and how hard it is to understand and how
11 many multi-ingredient products there are and the
12 challenges that you have with doing the math to figure
13 out how much if some of these multi-ingredient
14 products you're really taking. So I fall back into
15 that zone in terms of critical challenges myself when
16 I think about it. Jesse, thoughts?

17 DR. CATLIN: Yeah. And I think I agree with
18 what's been said. I would also say it depends not
19 only on the drug itself but also on the user, or the
20 potential user. So the person situation. If you're
21 one of the people that falls into the, say, one in a
22 million who, you know, really shouldn't take this

1 medication because it would have serious -- it'd
2 create serious problems, well then the most important
3 piece of information for you would be that warning,
4 right, that piece of information letting you know
5 you'd better stay away.

6 For somebody else, for the rest of the people
7 in that, you know, the 999,000, what might be most
8 important for them would probably be different. And
9 if you're clearly somebody who should be using the
10 drug, then the most important information for you
11 might be the dosage instructions and how to make sure
12 you're taking it properly and what to look for if you
13 should stop taking the drug or talk to your doctor.

14 So I think it's definitely an it depends kind
15 of question to me.

16 DR. PARKER: So we're winding up the time we
17 have as a panel. So let me just turn to you all and
18 ask you if there's anything else you'd like to add as
19 comments to those that we've already made in covering
20 this because when you hear your colleagues speaking,
21 you know, things pop into your head. So let me just
22 ask if there are any other comments. I really

1 appreciate the time and the presentations. I learned
2 a lot. And I really appreciate what you all have done
3 to bring this forward to the agency today. So thank
4 you for what you've done. Any other comments?

5 MS. AKER: Just one that I would like to
6 mention is that while we have over-the-counter drugs
7 where the consumer is the primary end-user, they're
8 the ones that are making the decision before use and
9 also during use, then -- can you still hear me?

10 DR. YIN: Yes.

11 DR. PARKER: Mm-hmm.

12 MS. AKER: Okay. Sorry. I don't know what
13 happened to my video. I think it's really important
14 to recognize that consumers, whether they're normal
15 literacy, lower literacy or in any special population,
16 they don't get a divorce from their doctor once they
17 start. And we need to remember that all -- most
18 people are still seeing their doctor. And people with
19 chronic medical conditions even more so are seeing
20 their doctor.

21 DR. PARKER: Other comments? I'll just say I
22 wish everyone in America did have a doctor. But

1 that's through my own lens. I spend many, many hours
2 trying to connect people to primary care physicians
3 and to a front line of care. But I agree with you. I
4 think, you know, many things would go better if
5 everybody does, you know, maintain and have that
6 contact point. But I appreciate what you're saying.

7 Anything else anyone wants to underscore?
8 Well, thank you, Teegan and those at the agency. We
9 appreciate the opportunity to be a part of this, and
10 we look forward to seeing what our colleagues have to
11 say later. Thanks so much, guys. I appreciate it.
12 Be well.

13 MS. AKER: Thank you.

14 MR. RICHARDSON: Thank you.

15 DR. DELLIBOVI-RAGHEB: Thank you, Dr. Parker,
16 and thank you to all of our panelists for the engaging
17 and informative panel discussion. We will now break
18 for lunch for one hour and resume at 12:25 p.m. for
19 our next session.

20 (Off the record.)

21 SESSION 2: HEALTH LITERACY And INDIVIDUAL LEVEL
22 FACTORS IN DRUG FACTS LABEL COMPREHENSION

1 DR. DELLIBOVI-RAGHEB: Welcome back,
2 everyone, from lunch. We will now begin our second
3 session, entitled, "Health Literacy and Individual
4 Level Factors in Drug Facts Label Comprehension."

5 To start our second session, I'd like to
6 introduce you to our first speaker, Cindy Brach, from
7 the Agency for Healthcare Research and Quality in the
8 Department of Health and Human Services. The title of
9 her presentation is, "Pharmacy Health Literacy: Making
10 Labels Easier to Use."

11 PHARMACY HEALTH LITERACY: MAKING LABELS EASIER TO USE

12 MS. BRACH: Thanks very much. I'm going to
13 start with a disclosure which is I have no financial
14 disclosures. But I do work for the Agency for
15 Healthcare Research and Quality. We are part of the
16 U.S. Department of Health and Human Services. And
17 anything that I say is my own opinion and not the
18 government's. And I realize I should add another
19 disclosure here which is the picture that you are
20 seeing of me is five years old.

21 So for those of you who aren't familiar with
22 AHRQ, our work falls into three buckets. We invest in

1 research to understand how to make healthcare safer
2 and improve quality. We create materials to teach and
3 train healthcare professionals and systems to improve
4 care for their patients, and we generate measures and
5 data used to track and improve performance of the U.S.
6 health system.

7 So my role on this panel is to sort of
8 introduce those of you who are not familiar to health
9 literacy. And I'm going to start off with these new
10 definitions for health literacy that came out last
11 year with the launch of Healthy People 2030. Health
12 literacy has been an objective of Healthy People since
13 2000. And this is the first time we've changed the
14 definition.

15 You'll see that they parallel each other, and
16 together they constitute health literacy. So the
17 personal health literacy definition is very similar to
18 the previous one. It talks about health literacy as
19 being characteristic of a person and measures their
20 ability to find, understand and use information and
21 services to inform health-related decisions and
22 actions for themselves and others.

1 With the development of the organizational
2 health literacy definition, we're recognizing
3 something that we've known in the field for many, many
4 years, which is whether people understand and can use
5 information and services depends not only on their own
6 abilities but also on how easy the information is to
7 access and process, how difficult it is to navigate
8 the system, to find the services, et cetera.

9 So in developing this new organizational
10 definition, we're recognizing and trying to raise
11 accountability for what AHRQ works on which is helping
12 reduce the demands on people and meeting them where
13 they're at. So formally organizational health
14 literacy is the degree to which organizations
15 equitably enable individuals to find, understand and
16 use information, et cetera.

17 So I'm going to present some very old data.
18 This is from 2003. And this is our only national data
19 on health literacy. So this is measuring personal
20 health literacy. And you'll see there under the
21 definition of intermediate that it's considered an
22 intermediate level task to be able to interpret

1 prescription and over-the-counter drug labels.

2 And you'll see in the graph that fully a
3 third, more than a third of adults are not able to do
4 that. And I'm not going to present the data. But
5 health literacy is not evenly distributed across the
6 population. There are many minority groups, people
7 with public insurance, older people, as Mike will tell
8 us about more in a minute, who have much greater rates
9 of limited health literacy.

10 So, you know, although those data are old,
11 the problem persists. So while we haven't fielded
12 another national health literacy assessment, these
13 data are from 2017 from the U.S.'s fielding of an
14 international adult literacy assessment. And it's a
15 little -- you know, they used different levels and
16 measures. So you can't strictly compare one to the
17 other.

18 But in PIAAC language, they term people who
19 are level two or below as limited skills. So on the
20 left bar graph, you see that we have only, you know,
21 fewer than 50 percent who are performing at level
22 three and above. In the numeracy, it's 37 percent.

1 So our mathematical skills are worse than our reading
2 skills. And these are just adults aged 18 to 65
3 because the PIAAC focuses more on workplace issues and
4 the workforce. So the figures in the title actually
5 include adults up to age 74.

6 So it's still not the eldest of our elderly,
7 but 52 million adults with limited literacy skills, 74
8 million with low numeracy skills. We clearly, you
9 know, have a segment of the population that we can't
10 ignore.

11 And I also want to make that point what when
12 we talk about health literacy, although it can be
13 personal health literacy, it can be measured at a
14 single point of time, in fact it's not static, that
15 when I'm tired, when I'm stressed, when I'm feeling
16 sick, that is all going to affect my ability to
17 process information.

18 And that is why I preach the gospel of health
19 literacy universal precautions. And the idea here is
20 very much the same as blood safety universal
21 precautions. You don't know whose blood is infected.
22 You treat everyone as if they may be. So with health

1 literacy universal precautions, we want to structure
2 the delivery of care and information as if everyone
3 may have limited health literacy. And the good news
4 is that everybody likes clear information. So we're
5 not disadvantaging anybody by doing that.

6 So in the next several slides, I want to
7 share with you some things that we've learned about
8 patient-centered labeling from the prescription
9 labeling process. And this is something that's been
10 worked on for many years. Mike Wolf and Ruth Parker
11 and many other people -- I know I participated a
12 number of years ago in an advisory panel that was
13 convened by U.S. Pharmacopeia to think about making
14 labels that patients could understand better. And the
15 result was what we call Chapter 17.

16 And on this slide, this lays out the sections
17 of Chapter 17 which became a standard for a patient-
18 centered label. And I think that you've heard a lot
19 about these kinds of things in this morning's
20 presentations as well. So it shouldn't come as any
21 surprise to you.

22 But organizing the label in a patient-

1 centered manner, emphasizing information important to
2 patients, simplified language, give explicit
3 instructions, include the purpose for use, limit
4 auxiliary information because it's distracting and
5 confusing, address limited English proficiency.

6 We have over 25 million people who do not
7 speak English very well in this country. Improve
8 readability which has to do with sort of the
9 typography and being actually able to read the letters
10 and then finally addressing visual impairment. And I
11 think you also heard this morning and will hear more
12 about alternative access methods.

13 So various parts of the country have kind of
14 taken the idea of patient-centered labeling onboard.
15 And one of them is Wisconsin where a group called
16 Wisconsin Health Literacy has embarked on a multiphase
17 project to implement the patient-centered label. And
18 they started in the first phase with talking to
19 consumers. And the results of their focus groups
20 really confirm the attributes, the elements of what we
21 have in Chapter 17.

22 You know, consumer likes having color and

1 bolding and large fonts to draw their attention, to be
2 readable, white space. They want to know what the
3 drug is for, you know, that important information on
4 the top, what it's called. And they don't like
5 unclear directions and clutter. So, you know, it
6 seems like we have a confluence here. There's
7 agreement.

8 And so their next phase of their project was
9 to have a pilot study to actually try and produce a
10 patient-centered labeling. And you can see on the top
11 left what the labels looked like before and on the top
12 right, a much more streamlined and patient-centered
13 version.

14 And they're next going to be working on
15 getting these evidence-based SIGs [ph] up here that
16 are according to the uniform medication schedule onto
17 all labels throughout the state. And they're going to
18 be working with Epic, the electronic health records
19 system, to actually back it up to the prescriber.

20 So you might ask, well, what difference will
21 it make if we actually improve these labels. And
22 these are the results of a study that Mike Wolf led.

1 Terry Davis, Ruth Parker also participated and that my
2 agency, AHRQ funded. And they used a patient-centered
3 label that prioritized information, used larger fonts,
4 more white space and used that UMS, that Uniform
5 Medication Schedule with explicit, evidence-based
6 instructions. And they kept it to see whether it
7 would have an impact on adherence.

8 And I have to confess that I was a little
9 dubious. I thought it was an awful lot to ask of a
10 label to make a measurable change in adherence because
11 we know so many factors affect adherence. And what
12 was really remarkable was they did find a difference
13 for specific populations.

14 So when they looked at subgroups, they found
15 that for patients with limited literacy and patients
16 who were taking medicines that had to be taken two or
17 more times a day, there actually wasn't an improvement
18 in adherence.

19 Now when they looked at the overall
20 population, the rest of the population swamped those
21 effects. And so you didn't see a change in adherence.
22 And that's an important lesson that I'll come back to

1 in a moment.

2 So the final part of my talk, I'm going to
3 take you on a romp through a label. And I know you've
4 seen a number of these Drug Facts labels up on your
5 screen today. This one I found on a public health
6 website that was instructions on how to read a Drug
7 Facts label. So that in itself is sort of telling
8 that you need instructions. And when you just sort of
9 look at the gestalt of the label, you see that this
10 doesn't fair very well on the, you know, white space
11 and, you know, overwhelming wall of typeface.

12 So I'm going to now give you some reactions
13 that are a health literacy perspective of takes on
14 these different parts of this label. And while I am a
15 relatively well-educated person and would score well
16 on a health literacy test, I have an unusual skill of
17 being able to detect ambiguity in things. This has
18 not served me well when trying to find my way on a
19 highway or taking standardized tests. But it's pretty
20 good when I'm trying to identify opportunities for
21 improvement like this.

22 So here we have the uses of acetaminophen

1 which is the drug that this is a label for. And it
2 has a list of things I can use the medicine for. But
3 that caused me to create a question in my mind because
4 they've listed all these things. Does that mean that
5 I can't use the medicine for things that aren't listed
6 there? You know, what about if I have foot pain or
7 shoulder pain? That's not there.

8 So, you know, I think that you can get -- one
9 of the important things about health literacy is being
10 succinct and to the point. And here you could just
11 say this medicine relieves minor aches and pains and
12 reduces fever.

13 On the next part of the label, there's this
14 warning. And warnings are very important. But it's
15 not information if I can't understand it. So it
16 starts off by saying I can get severe liver damage if
17 I take more than 4,000 mg of acetaminophen in 24
18 hours.

19 Now I think there's an implicit assumption
20 that I will know that I'm supposed to look at how many
21 milligrams there are in each of the caplets and divide
22 that into 4,000 so I can figure out how many of these

1 I can take. You know, it's just a mathematical task
2 that we know a lot of people are going to fail at.

3 Then the next item is damage can occur if I
4 take with other drugs containing acetaminophen. So
5 that seems like an all-out prohibition, no other drug.
6 But with the 4,000 -- I think what was really assumed
7 was I was going to look at how much acetaminophen was
8 in my other drugs and how much were in these pills and
9 somehow add up and make sure I wasn't getting over
10 4,000. And that is a complex task that I don't even
11 necessarily know I'm supposed to do and might not be
12 able to do it if I could.

13 And then the last one tells me that I'm in
14 danger if I take three or more alcoholic drinks every
15 day while using this product. And I have to say the
16 every day really kind of stymied me. So, you know, I
17 started thinking, well, you know, if I'm taking
18 acetaminophen for a week and I have four drinks a day
19 for only four of the days, is that okay? And I really
20 don't know. So some of the instructions aren't clear.

21 So this one caught my eye. It tells me if I
22 have a skin reaction, to seek medical help right away.

1 And that's in contrast with other parts of the label
2 that says call your doctor or talk to your pharmacist.
3 It says seek medical help right away. So does that
4 mean I'm supposed to call 911 and go to the ER? And I
5 really -- I'm not a clinician, if you haven't
6 gathered. I really don't know if that is -- if this
7 is an emergency or not.

8 And there is also clearer ways of saying what
9 you're saying in this phrase. I've changed it to if
10 you develop a rash or your skin turns red or blisters
11 while taking this medicine, stop taking it and call
12 your doctor.

13 Now I've bolded rash, skin turns red or
14 blisters because I think that's -- you know, those are
15 the symptoms that you want them to be looking out for
16 and therefore draw attention to them. They did that
17 in the above by using bullets. But, you know, again,
18 just some different possibilities.

19 One of the important things is, you know, we
20 have very little real estate on the label and
21 therefore we don't want to repeat information. So
22 here it tells me again not to take with another drug

1 that contains acetaminophen. But you've already told
2 me to do that, so.

3 So I mentioned emphasis. Here are some
4 examples where I think the emphasis is wrong. I
5 believe the FDA puts it out like this. But if I'm
6 somebody who has liver disease or am taking warfarin,
7 I'm going to be drawn to something that mentions those
8 things because that resonates with me. Oh yes,
9 warfarin. I'm taking warfarin. And this doesn't call
10 your attention to that.

11 I think it's better the way they've done it
12 for the warning about pregnant or breastfeeding. Yes,
13 I'm pregnant and breastfeeding, yes, I'm going to that
14 sentence and seeing what I'm supposed to do.

15 And finally, the directions. And I want to
16 pause for a moment and say I recognize that this is
17 really, really hard work. It is humbling to try and
18 make things easy to understand. But these two bullets
19 have contradictory information.

20 The first one seems to indicate that I should
21 be able to take eight caplets, the next one that I can
22 only take six in 24 hours. And I think it's assumed

1 that I'm going to sort of look at the union of these.
2 But I just see two contradictory pieces, instructions
3 that I'm going to choose one to follow because they
4 don't make sense to me.

5 The perspective I'm sharing with you is very
6 colored by a tool that Mike Wolf and another colleague
7 of ours, Sarah Schumacher, and I developed called the
8 PEMAT. And it's for assessing print and audiovisual
9 materials and provides guidance on some of the
10 comments, along the lines of some of the comments that
11 I made. So you might want to take a look at that.

12 Finally, the gold standard, we all know, is
13 consumer testing. And I think that you had a lot of
14 data presented on consumer testing already today. But
15 I wonder if they told you about the composition of the
16 audiences that they tested with and that it's really
17 important that they be -- they represent people of
18 different ages, ethnicities, races, English
19 proficiencies, literacy and health literacy and in
20 such numbers that you can tease out a separate effect
21 on those people because otherwise if there's just a
22 token number, it'll get swamped by the rest of the

1 population.

2 And therefore you might want to think about
3 using a health literacy screening tool called the
4 Newest Vital Sign which, as you can see, is a
5 nutrition facts label and therefore might help you in
6 including people who will struggle with this
7 information.

8 And thank you very much for your time. I
9 hope you will visit AHRQ's website where we have a lot
10 of health literacy resources, including a pharmacy
11 health literacy center.

12 DR. DELLIBOVI-RAGHEB: Thank you very much,
13 Cindy, for your talk. It's my pleasure to introduce
14 our next speaker, Dr. Michael Wolf, from Northwestern
15 University. And the title of his presentation is,
16 "Addressing Safe OTC Use Among Older Adults."

17 ADDRESSING SAFE OTC USE AMONG OLDER ADULTS

18 DR. WOLF: Thank you very much, and happy to
19 be here today, and it's very, very exciting that the
20 FDA is taking on a revamp possibly of the DFL. That's
21 incredibly important, and I think there's enough
22 evidence today by now that you've heard that really

1 justifies that there are some tweaking opportunities.

2 Before I jump in, I do want to comment
3 quickly. I really appreciate that Cindy brought up in
4 her kind of culminating slide the notion of assessing
5 health literacy and an option being the Newest Vital
6 Sign. I know a lot of industry guidance to kind of
7 ensure that there is diversity by health literacy to
8 ensure comprehension across the most compromised
9 groups with regard to labeling. I think that that
10 might be suggestions using the REALM tool.

11 Just a comment, since I'm focused on older
12 adults, measures like the REALM which capture more
13 kind of crystallized abilities and cognitive function
14 that do not degrade over time are really -- will make
15 a misleading assumption in older patients in
16 particular, it will assume that they have adequate
17 health literacy when they may not because, you know,
18 numeracy and other kinds of problem-solving activities
19 that you might see in something like a Newest Vital
20 Sign would better capture the group. So I hope that's
21 another thing that could be possibly discussed at a
22 later date.

1 Jumping in, again, my name is Michael Wolf.
2 I direct the Center for Applied Health Research on
3 Aging at Northwestern and also I'm the director of the
4 National Institute of Aging Claude D. Pepper Older
5 Americans Independence Center, or the Pepper Center,
6 that I'll represent today.

7 Some disclosures just to share with you, we
8 do have funding from NIH institutes as well as some
9 other foundations. But I do also receive consultation
10 services through other industry partners with regards
11 to health literacy consultation.

12 So coming from a 30,000-foot view first,
13 taking a step back and looking at kind of an aging
14 perspective walking into this kind of OTC use
15 specifically among adults 65 and older, you know, some
16 things to kind of make note of.

17 One, you know, we are in a state of an aging
18 America. The population over 65 is growing at a rate
19 threefold that of younger populations. And we're
20 seeing a considerably large increase that is expected
21 to continue mostly due to the Baby Boomer generation,
22 of course, as they're hitting older age. And so this

1 does kind of present some issues, most importantly the
2 implication being that an older America translates
3 into an increased need for healthcare services.

4 And 9 out of 10 adults over 65 have one
5 chronic condition. Eighty percent have multiple
6 chronic conditions. And that matters for a few
7 things. I'm sorry. I see my slides have not made it
8 through the formatting appropriately.

9 But importantly there's a lot of challenges
10 with regards to for patients in particular that, one,
11 issues around polypharmacy are incredibly common.
12 That includes patients taking as many as five or more
13 medications daily, that they have other factors
14 including high prevalence of functional limitations
15 that could include vision and hearing impairments as
16 well as about estimates range up to about 26 percent
17 of patients over 65 may have a mild cognitive
18 impairment. And that is probably detected less than
19 10 percent of the time in primary care.

20 So these are individuals who are still
21 perceived to be dwelling and living on their own and
22 functionally independent. But it does mean that they

1 do have some limitations that could ultimately affect
2 their ability to properly use medications.

3 Really kind of a quick comment on the side
4 here is, you know, OTCs in particular, you know, when
5 using these medications, they make guest appearances
6 among older patients' multi-drug regimen. So the idea
7 that there's the possibility of drug-drug interactions
8 that would be important to understand or medications
9 that just simply shouldn't be used among an older
10 adult population is common. And so understanding that
11 is quite important.

12 And just in general, you know, about a third
13 of patients over 65 routinely use at least one over-
14 the-counter medication that may populate in their
15 multi-drug regimen that they're taking.

16 And the problem with this and that what we've
17 studied with many AHRQ studies that we had funded in
18 prior times is that medication reconciliation is
19 pretty poor, and it has continued to do so in terms of
20 the differences between what the patient says and
21 knows they're taking and whether or not all those
22 medications are known by their primary care doctor or

1 any of their physicians that are involved in their
2 care.

3 And with that, what we've also found is that
4 over-the-counter medications in particular are not
5 often reported by patients in terms of the need to
6 tell their doctor that they're taking a Tylenol PM
7 every night, or let alone, even when they are told, we
8 have shown that over-the-counter medications are not
9 prioritized to be put onto the medication list in the
10 electronic health record, even if they do know that.

11 So even if you report it, we see physicians
12 often not putting them on there because they don't
13 think they're important to note. And from that end of
14 it again, these medicines just kind of are ghosted.
15 Nobody really know they're taking them and the
16 conversation oftentimes can fall apart.

17 And finally another comment that's
18 interesting around and, you know, unique around for
19 older adults in particular is oftentimes a lot of
20 patients have caregivers, whether it be an adult child
21 or a spouse, who are helping to manage their
22 medications, including any over-the-counter

1 medications. And it's -- you know, it's not as known
2 how proficient the caregiver may be in understanding
3 over-the-counter medications or even if they know the
4 full expanse of medications in the patient's regimen
5 that they may be taking.

6 So again, there's lots of opportunities where
7 things could go wrong, especially if information is
8 not readily available to clearly articulate that.

9 You know, one thing I wanted to call out in
10 particular that is very, very common and, you know,
11 it's been talked about a little bit today but low
12 visual acuity and I'm not talking about visual
13 impairment completely. But whether it be what's very
14 common in older adults, obviously, you know, as we
15 age, we have visual issues, vision issues that kind of
16 start to form or at least increase. And that means
17 that you still may be within a normal vision range.

18 But even people within a normal range who are
19 not visually impaired, we've shown both with my
20 colleague Rebecca Mullen, or now it's Rebecca Lovett,
21 and also Rachel O'Connor have both shown in studies
22 that low vision, people who would still be perceived

1 as having vision with a normal range, older adults
2 with lower vision would have significant increases in
3 their risk for OTC dosing areas and double-dipping or
4 concomitant use, using two products with the same
5 ingredient.

6 And that's pretty important especially given
7 that, you know, how common it may be that not only
8 people just have vision loss over time but or it's the
9 possibility, especially in individuals who are more
10 socioeconomically disadvantaged who may have
11 correctible lenses but have not, you know, gotten a
12 more updated prescription.

13 So they're using old glasses that's not
14 adequately accommodating it. And given, as we can
15 imagine with labeling, the patient becomes incredibly
16 important. Stacy Bailey also at Northwestern did a
17 recent study and founded dosing accuracy declined with
18 age over time. And she looked at our LACOG study
19 funded by NIA over a 10-year window of time, just how
20 there's a doubling of dosing errors that older adults
21 were making unintentionally.

22 And that was in line with also with declines

1 in poorer vision -- you know, with poorer vision and
2 worse cognitive functioning over time, both of which
3 were undetectable declines in cognition and vision,
4 but important.

5 In getting back to my earlier comment about
6 medication reconciliation, our colleague at Penn,
7 Marina Serper, found that 86 percent of patients
8 believed their doctor was aware of all over-the-
9 counter medicines that they were taking regularly, but
10 only 46 percent reported they routinely tell their
11 doctor about these over-the-counter drugs which in
12 some ways kind of envisions that, again, the problem
13 is quite important, that, you know, it's putting more
14 emphasis on having a very, you know, strong label that
15 can help patients understand whether or not it's right
16 for them to take it, the self-selection activity, as
17 well as knowing especially if this is medicine that,
18 because of what else they're taking, they shouldn't
19 take.

20 And it's kind of this omnipotence that
21 there's this notion that because of electronic health
22 records, which also was found among practices that had

1 electronic health records, that's where the patients
2 were more likely to report that they thought their
3 doctor knew what they were taking, even if they
4 weren't telling them.

5 Bringing it down to more of a 10,000-foot
6 perspective at this point and getting into the weeds
7 of this panel, taking a health literacy perspective,
8 you know, the big issue around health literacy and
9 aging, what I have been very interested for many years
10 in studying is this notion of this confluence of two
11 age-related problems.

12 So as we get older, you know, we start to
13 develop more health issues that have to be attended to
14 and see more healthcare providers or at least be more
15 engaged with the healthcare system. You know, as I
16 mentioned earlier, just the prevalence of not just
17 having a chronic condition but multi-morbidity
18 dramatically increases with age.

19 So we have increasing healthcare demands
20 precisely at the moment in which we are also having
21 age-related cognitive decline. So those fluid
22 cognitive abilities that are more better captured,

1 just to kind of tie back to Cindy's presentation, that
2 are more captured with the NVS whereas, you know,
3 crystallized abilities which are those basically are
4 acquired world knowledge. They tend to stay -- they
5 not only stay preserved but also increase over time.

6 But fluid abilities that you need to do for
7 problem-solving, for recalling doctor's instructions
8 to being able to navigate a label and to make
9 inference from it on proper use, all of those things
10 start to decline. So our self-care skills are waning
11 right when we really need them to be as sharp as
12 possible.

13 You know, a person's cognitive -- you know,
14 so some of the assumptions that are in here is that,
15 one, you know, cognitive skills are a major
16 determinant of health literacy skills. So again, at
17 this point in later life, we start to see that it's a
18 bit little harder to process information as quickly,
19 to be able to navigate and multitask and to recall
20 especially spoken instructions.

21 You know, it's also what we do know and why
22 we care about that is because health literacy, we know

1 it's not the responsibility of the patient. It's the
2 responsibility of us as a healthcare system to design
3 acceptable health information to help support informed
4 decisions. That's our job as the healthcare system,
5 to kind of reduce the cognitive burden that we place
6 on patients.

7 You know, in getting, you know, some unique
8 OTC challenges that we've already been discussed, that
9 we know about, is just the very fact that older adults
10 are kind of flying it alone in terms of the self-
11 selection process, can I take this product safely or
12 not and does the label adequately make it easy for me
13 to find that information.

14 But they're doing this in a sea of product
15 choices that are both brand and generic in their
16 option, that have single and multi-ingredient
17 products. And I'm going to mention the active
18 ingredient in a moment. And that was wonderfully
19 captured in that discussion led by Ruth Parker.

20 You know, that gets us to the labeling
21 challenges of, you know, clarity, understandability,
22 you know, and the focus on symptoms, not on an active

1 ingredient that leads us to not think that we even to
2 know what the active ingredient is, which is
3 incredibly problematic. And that's something that I
4 hope the DFL can do better.

5 But the tie between the front of package to
6 the Drug Facts or the PDP versus the Drug Facts label
7 and how they link in, you know, whether it's placed on
8 a container which has wraparound text versus, you
9 know, a flat back of a package, the size of the font,
10 which again is probably the most critical thing when I
11 think of older adults and the issues that we face with
12 how small can we go and recognizing that there is
13 limited real estate to be had. But maybe going back
14 to that discussion on what is prioritized on the label
15 and where can we outsource the other content and kind
16 of create a system of information.

17 So the changes to the DFL study. So we did
18 an FDA-sponsored study a couple of years ago that
19 wrapped up that was really focused on how people
20 thought and could demonstrate safe use on a range of
21 OTC products. And probably the major finding I would
22 highlight right off the bat was we found that there

1 was a recognition of product brand matching to
2 symptoms but low AI recognition, low active ingredient
3 recognition.

4 So for instance, you know, here's an example
5 of a common product. Adults' understanding of Advil
6 was everybody knew what this product was. Everybody
7 knew what symptom it would treat. But only a third
8 knew what the active ingredient, that it was
9 ibuprofen.

10 Similarly, you know, again high product
11 recognition, match to symptom is very -- was very,
12 very simple. But, you know, only 1 in 20 could
13 actually say what the active ingredient was. And
14 another change -- you know, we're saying we need to
15 think about when revising the DFL is rates of self-
16 selection here, you know, due to contraindications and
17 drug interactions widely range from 40 to 88 percent
18 in our study.

19 You know, confusion was often around the
20 language used for symptoms to treat it. And so what's
21 laxative versus a stool softener? Some of the
22 terminology that we use to frame what the indication

1 of the product is for I think were very, very abstract
2 and problematic for individuals that led them to
3 choose the wrong product.

4 And finally problems with concomitant use due
5 to multi-ingredient products was incredibly high. And
6 this was mentioned before, you know, by Amanda and
7 others, you know, that this is one of the main issues
8 right now is that people really understanding, you
9 know, all of the active ingredients in a product and
10 being able to safely use another product that, you
11 know, avoiding any kind of double-dipping.

12 That was clearly a major issue. And across
13 all of these dosing errors and kind of problem-solving
14 on OTC use, older age was a consistent risk factor for
15 difficulty in OTC understanding.

16 So moving forward now that we're kind of
17 landing onto the real issues of what should we be
18 doing now with regards to what are some explicit
19 requirements or changes that you should be thinking
20 about with the DFL, you know, again, for us, and
21 especially among older adults, you know, addressing
22 the cognitive load of information is incredibly

1 important and, you know, not just issues around
2 readability and, you know, I think making sure that
3 information is definitely explicit, as Cindy mentioned
4 before, and, you know, that's probably why we saw such
5 a benefit when we did something as myopic as creating
6 a Universal Medication Schedule.

7 People appreciate more precise information,
8 not the vagaries that we hear like in the SIGs example
9 where we talk about, you know, saying things like
10 twice daily, you know, just doesn't help. When you
11 actually provide people more explicit guidance,
12 they'll do better. And I think obviously format and
13 organization is one of those things. And that's the
14 beauty of the DFL is that it did create a standard.

15 So over time you get to learn where the
16 content is even though right now maybe we're
17 revisiting where the order of that information should
18 be. But also the distraction of extraneous
19 information, and I think part of that is best exemplified
20 -- is a best example of a distracting label in some
21 regards could be the analogous label for food, you
22 know, when you think of a nutrition facts label where,

1 you know, there's some information that we tell people
2 to kind of really focus in on and some -- you know,
3 you want more of these ingredients. You want less of
4 that. But yet you have all this other stuff in the
5 middle that people really haven't found value or at
6 least many people haven't at the moment.

7 But that I think is some of the issue that
8 we're seeing, making sure that you get rid of any
9 extraneous information, focus on what is the priority
10 of that label and also you could always supplement
11 information in terms of what is secondary and where
12 they can go to get more information.

13 Some aging considerations that I thought
14 about for the DFL, you know, just based on what the
15 evidence states and you heard a lot about that from
16 Shonna this morning in her great systematic review for
17 it. But it is that, you know, first and foremost, I
18 think what we've learned time and time again is that
19 we need to involve older adult stakeholders to make it
20 truly patient-centered.

21 So the people that most need to be here are
22 the consumers and making sure that there's an adequate

1 representation of older adults in that stakeholder
2 development of the label I felt would be important.

3 Just as an aside, another colleague of ours,
4 Rebecca Lovett, who I mentioned before, did a
5 systematic review of patients' information for
6 prescription medications and reviewed 70-plus studies.

7 And one of the things she found is that
8 studies that involved patients on any aspect of
9 labeling for medications that when they used --
10 involved patients, those studies were more likely to
11 report significant findings of improvements with their
12 interventions versus those that did not. And I think
13 that really gets at the heart of it.

14 The next, I think reprioritizing and
15 resequencing the information presented in the DFL is
16 very, very key. And again, Shonna made that earlier
17 and rethinking why are we constantly hearing from
18 consumers, parents when they're thinking about the
19 pediatric medications, that they're having to hunt for
20 the content. And I think that given some eye-tracking
21 studies kind of suggest that you could find a more
22 efficient ordering of the information.

1 Again, getting back to the visual acuity
2 issues, font size is just key. I think reconsidering
3 what is the smallest minimal font size is going to be
4 really important and that may need you need to purge
5 some information or find some other conversations with
6 manufacturers to really recognize that, you know,
7 getting down to some of these fonts is -- it's just --
8 it's almost meaningless.

9 And I think some of the solutions that we saw
10 earlier on a decade ago where we thought we could just
11 give people magnifying glasses as part of the pill
12 bottle, I don't think that's probably a viable
13 solution. Being more explicit. Reinforcing the
14 learning of the active ingredient. That might be the
15 number one priority right now is that we need to give
16 people a recognition of what they're taking and not
17 just the symptom.

18 Getting rid of abstract similar language
19 describe symptoms. And the other thing too I think is
20 we really do need to find ways, and this is maybe
21 beyond what we can expect from the DFL. But how do we
22 make sure that this information is shared with the

1 healthcare provider. That might be more of a
2 healthcare system kind of strategy at this point.

3 I think Ruth has said for years that when we
4 think of patient medication information, we need to
5 think of it as a system of information and not trying
6 to think that anything on -- whether it be on a pill
7 bottle, an OTC box or package that they may dispense
8 of or just on the bottle itself, all of that needs to
9 -- cannot in one semblance adequately convey all of
10 what someone might need to know about a medication.
11 So we really need to work to make sure that we
12 coordinate all of these tools.

13 And I will say the other last bullet was this
14 notion of that I really like that in thinking about
15 kind of very clever strategies, I really commend the
16 FDA for being, you know, very novel and thinking that
17 maybe, yeah, for some products where the safety
18 concern is so prevalent that you try to find something
19 at the point of purchase to have, you know,
20 assessments that might require you to have a teach-
21 back before you can actually get the product is a
22 very, very clever way to think about how you might be

1 able to ensure that patients are leaving with an
2 adequate amount of information. That I think has lots
3 of challenges in its delivery. But I think that is
4 something worth noting.

5 I think that -- again, yeah, I think that's a
6 repetitive slide. But anyway, I will end here. I
7 will want to make one mention of an AHRQ study that
8 did come out that I think that fell out of my slides.
9 But it is this idea of a senior section was also
10 proposed by a team at the University of Wisconsin that
11 I thought was very, very clever.

12 And they just recently piloted it and the
13 Journal of the American Pharmacy Association, I
14 believe it's currently in press, study by Gilson, et
15 al., where they showed, you know, promise for like if
16 you put all the medications for older adults, all the
17 OTCs in one common section of a pharmacy, could that
18 possibly be a better way to kind of communicate and
19 make sure that it supports self-selection of products
20 tailored to older adults, make sure that they're not
21 using products that really are appropriate for an
22 older individual with certain chronic conditions. I

1 thought that was a unique way to again complement what
2 you're doing today with the DFL. Thank you.

3 DR. DELLIBOVI-RAGHEB: Thank you very much,
4 Dr. Wolf, for your talk. Next, I'd like to welcome
5 back Dr. Shonna Yin from New York University to
6 present another talk titled, "Nonprescription
7 Medication Use in Children: A Health Literacy
8 Perspective."

9 NONPRESCRIPTION MEDICATION USE IN CHILDREN: A HEALTH
10 LITERACY PERSPECTIVE

11 DR. YIN: Thank you. I don't see the slides
12 up yet. Oh, here they go. So I'm Shonna Yin. I'm an
13 assistant professor of pediatrics and population
14 health at NYU, and I spend a lot of my research time
15 focused on health literacy and the intersection with
16 child health and physically around medication safety.
17 So I'm really excited to be a part of this
18 presentation today.

19 Is anybody seeing a weird screen right now?
20 Oh, okay. Okay. There we go. Great. So I was
21 seeing a weird blending. And again I want to
22 acknowledge my team members, Yuxiao Lei and Carlita

1 Anglin, who helped in preparing this presentation
2 today. So there's no relevant disclosures.

3 And this is an outline of what I'll be
4 talking about today. We'll be talking briefly about
5 health literacy of parents in the U.S., health
6 literacy and pediatric medication outcomes, a health
7 literacy assessment of non-prescription pediatric
8 medicines and then some of the challenges of giving
9 nonprescription medications in pediatrics ranging from
10 issues around understanding formulations and
11 concentrations to active ingredients, the dosing
12 directions and those dosing charts, dosing tools --
13 measure and cough and cold medications.

14 And I'm really focused on issues involving
15 younger kids who are really at the most risk when
16 errors do occur and also focusing a lot on liquid
17 medicines in particular because that's where most of
18 the errors are occurring and also a lot of the errors
19 are occurring and we're typically relying on liquid
20 medicines in children.

21 Okay. So when we think of the health
22 literacy of parents in the U.S., this is data from the

1 same source that Cindy had mentioned earlier. This
2 was the last time this -- health literacy was assessed
3 at a national level. So the data is a little old.
4 But I don't think that the data has really changed
5 much.

6 We're finding that about one in four parents
7 fall into the lowest two levels of health literacy.
8 That represents about 21 million parents with basic or
9 below basic health literacy. I think the important
10 thing also to note from this slide is that very few
11 parents, about 15 percent, fall into that proficient
12 range. So it's suggesting that a vast majority of
13 parents in the U.S. actually do face health literacy
14 challenges.

15 And so I definitely agree with what Cindy had
16 mentioned earlier about using this universal
17 precautions approach to communication, including and
18 thinking about how we design the Drug Facts label and
19 other ways of supporting safe parent use of
20 medications.

21 There's been a lot of study of health
22 literacy in pediatric medication-related outcomes.

1 Many of these studies have been done by my team at
2 NYU. We've found that caregivers with low health
3 literacy have greater difficulty in understanding both
4 prescription and over-the-counter medication labels.
5 They are more likely to use non-standard kitchen
6 spoons instead of standard dosing tools like oral
7 syringes and dosing cups. They're more likely to
8 misunderstand active ingredient information. I'll
9 talk a little bit more about that in a bit.

10 They're also more likely to be unaware of
11 weight-based dosing which is what we rely on in
12 pediatrics and weight-based over age-based dosing.
13 And we also have found that caregivers with limited
14 health literacy have increased odds, 1.5 to 2.5 is
15 what we found increased odds of making a liquid
16 medication dosing error.

17 When I think about health literacy, I like to
18 think of health literacy using this framework. This
19 comes from Ruth Parker. Many of you here may be
20 familiar with it, health literacy really being at the
21 intersection between the skills and abilities of
22 individuals which is shown here in the yellow arrow

1 and then the demands and complexities of the tasks
2 that the health system places on families which is
3 shown in that red arrow.

4 So a number of years ago we tried to take a
5 little bit of a look at health system demands around
6 OTC medication labeling. And we did a study which I
7 mentioned earlier of the 200 top selling pediatric
8 liquid over-the-counter products, particularly
9 focusing on active ingredients and dosing information
10 and how they were displayed. And I'll highlight a few
11 of those findings.

12 We saw, for example, that all the products
13 listed the active ingredients on the Drug Facts label.
14 But importantly nearly 20 percent did not actually
15 list the active ingredient on the principal display
16 panel which is where many parents rely on for
17 information. Very few used highlighting of active
18 ingredients in the DFL which could support people
19 paying attention to that important information.

20 We saw that in terms of dosing directions,
21 they were typically presented in dosing charts which I
22 think is better than being buried in text which is

1 also seen on Drug Facts labeling. And then we also
2 found that only four products included a pictographic
3 dosing diagram, which I mentioned earlier.

4 In terms of font size, we found again that
5 the font size was quite small, especially the font
6 size on the bottle versus on the box and that on the
7 principal display panel we were seeing that the font
8 sizes for important information like the active
9 ingredient were really being dwarfed by many other
10 things like the flavor or the purpose and symptoms and
11 of course the product name and the brand name, et
12 cetera.

13 So these findings show that the DFL may not
14 be designed in the most optimal way to support
15 families in using OTC products correctly.

16 So there are a number of unique challenges
17 related to medication use of nonprescription
18 medications in children. So I'll just touch upon some
19 of these. We know that nearly 60 percent of parents
20 are reporting difficulty understanding over-the-counter
21 medication labels, with one in three reporting great
22 or moderate difficulty and that those with low health

1 literacy are especially reporting difficulty.

2 One of the unique things about in pediatrics
3 has to do with formulations and concentrations. This
4 can be a real source of confusion. Until more
5 recently there were two different formulations, for
6 example, of over-the-counter acetaminophen that was
7 available. And there's still two different
8 concentrations of ibuprofen available. And the infant
9 versus children's acetaminophen was three times more
10 concentrated. For ibuprofen, the infant was two times
11 more concentrated. And confusion around these
12 different formulations has led to cases of serious
13 morbidity.

14 Many parents are unaware that different
15 formulations exist and parents often think that the
16 children's concentration is more concentrated than the
17 infant version. And so back in 2009 an FDA advisory
18 committee actually voted to recommend only one
19 formulation of acetaminophen and then subsequently the
20 manufacturers voluntarily moved to standardize to a
21 single concentration of liquid acetaminophen, which I
22 think many were very happy about.

1 This study done by Eric Brass looked at a
2 medication errors with single ingredient acetaminophen
3 before and after this change. And you can see that
4 there was really a significant drop in the annual rate
5 of exposures due to medication errors involving liquid
6 acetaminophen in children.

7 One thing to note is that there still are two
8 formulations of ibuprofen that remain and that's
9 another very commonly used medicine -- medication in
10 children.

11 Moving on to active ingredients, this is
12 another source of confusion. And parents have to look
13 at the label to see if the same active ingredients are
14 present in more than one medicine. And as I mentioned
15 earlier, many parents may give acetaminophen and then
16 many cough and cold products, which you may want to
17 give at the same time, also contain acetaminophen and
18 could lead to issues.

19 This was an experimental study that my team
20 had conducted where we presented parents with a
21 hypothetical scenario where they had already given
22 acetaminophen and they had to determine whether any of

1 the three boxes shown could be given safely with it.
2 They got the full medication box to look at, so the
3 front and the Drug Facts label. And what we found --
4 and sorry, a lot of this formatting is not coming
5 through.

6 But we found that one in three parents made a
7 correct choice and this was no different than chance
8 alone. Only one in five who made the correct choice
9 was able to give the right rationale of overlapping
10 active ingredients. And one in five parents who said
11 they were looking for active ingredients actually
12 ultimately made the wrong choice. And parents with
13 low health literacy were at much increased odds of
14 making an error.

15 Dosing directions is another place where
16 there is often confusion. And parents who know about
17 weight-based dosing are more likely to dose correctly.
18 But only about a third to less than half of parents
19 know that the weight should be the primary basis for
20 dosing. And you can see here on the right what a
21 typical dosing chart looks like.

22 And several studies, and some of these are a

1 bit old, but there aren't too many recent studies,
2 have documented that many parents have difficulty
3 determining the correct dose for their child using the
4 dosing chart on the Drug Facts label.

5 We've alluded to this earlier. But
6 pictographic dosing instructions may be helpful. This
7 is again the study around infant acetaminophen where
8 we randomly assigned families to either get text with
9 pictogram format instructions versus text only dosing
10 instructions for infant acetaminophen. And we saw
11 that those in the text with pictogram group had
12 significantly less dosing errors, including large
13 dosing errors. And we also found that pictograms were
14 especially beneficial for those with low health
15 literacy.

16 I'm going to move now and talk about the
17 intersection between Drug Facts label and dosing
18 tools. And this is a study where we looked at 200 top
19 selling OTC products again and this was spurred on by
20 FDA guidance that came out in 2009 where they
21 recommended greater clarity in the OTC directions and
22 tools. And we did this, this study to serve as kind

1 of baseline data.

2 And what we found was that one in four of
3 these products didn't include a dosing tool, even
4 though we know from lots of prior research that when
5 people use a kitchen spoon instead of a dosing tool,
6 there's increased error. And in addition, we noted
7 quite a bit of inconsistency between the DFL label
8 directions and markings on the dosing tool.

9 And I just wanted to show you one kind of
10 example that highlights it. So you can see here the
11 dosing directions on the Drug Facts label look fairly
12 straightforward, right? There's only two doses
13 listed, one teaspoon and two teaspoons.

14 But then the measuring device that came with
15 the tool was not in alignment with those
16 straightforward instructions. Many different units
17 were used, fluid ounces, grams, ccs, milliliters, even
18 two tbs, or two tablespoons as well as one dssp
19 marking but not -- not a marking for two teaspoons.
20 So that was actually missing. So this was a study
21 that we did that Mike Wolf and Ruth Parker were
22 involved in. We ended getting a bit of media

1 attention around this. And there's been follow-up
2 study looking at this showing that there has been
3 improvements in the medication packaging after that.

4 I do want to mention the CDC's Protect
5 initiative here. they've really been a leader in the
6 past ten years in their focus on preventing overdoses
7 and medication errors in children, focusing on both
8 the OTC products as well as prescription products.

9 (Audio break 3:41:26 to 3:42:21)

10 Both prescription and OTC products. Some of
11 the key findings were that mL-only dosing was superior
12 leading to a twofold decreased odds of large twofold
13 dosing errors. There was also a fourfold reduction in
14 odds for the preference for a kitchen spoon.

15 And then with respect to dosing tool, we saw
16 that syringes were associated with a decreased odds of
17 error versus cup and that the optimal tool was the one
18 that was the smallest tool for the dose without
19 requiring multiple instruments. And you can see the
20 example for the 7.5 mL dose that the 10 mL syringe is
21 optimal. That's the smallest tool to fit the dose.
22 This cup has a lot more room to overdose and the

1 smaller tool means that parents have to use their
2 numeracy skills to add the right amount.

3 Interestingly while everyone benefited from
4 optimizing the dosing tool, those with low health
5 literacy differentially benefited. And then the last
6 finding from that study, the pictographic aid on the
7 label led to a twofold -- or was associated with a
8 twofold decreased odds of a large dosing error.

9 Okay. And it's quite exciting. We published
10 a number of these research findings and with all of
11 the work with CDC Protect and with this research, it's
12 been exciting to see the real move toward mL-only
13 dosing across many different organizations and there's
14 also been growing support for standardization around
15 the dosing tool as well.

16 And then I'll end by focusing on
17 nonprescription pediatric cough and cold OTC products.
18 The use of these products in children has been quite
19 controversial. In 2008, the FDA issued a national
20 public health advisory recommending that these cough
21 and cold medicines not be used in children less than
22 two. This was extended to children less than four

1 voluntarily by manufacturers of OTC cough and cold
2 medicines. And the AAP recommends no cough -- no OTC
3 cough and cold medicines for children less than six.
4 But despite this, consumers continue to use cough and
5 cold medicines in young children and consumer
6 confusion is quite common.

7 And we've recently just finished up a study
8 funded by the FDA to look at OTC cough and cold
9 products. I talked about this a little bit earlier.
10 But we sought to test specific labeling and dosing
11 strategies for improving parent understanding,
12 focusing a lot on how we can improve parent
13 understanding of age restriction information, active
14 ingredient and dosing instruction.

15 We've conducted a number of randomized
16 controlled experiments. And just to show you a few of
17 those findings, this is around age restrictions. So
18 for parents, they were -- manipulations on the
19 principal display panel rather than the DFL, but I
20 think still interesting.

21 Parents were assigned to four different
22 groups, one that had no age, one that used standard

1 age info, one with an explicit warning, one was with
2 an explicit warning with pictogram. And what we found
3 was that compared to this group three with the
4 explicit warning and standard age info, people in
5 group one had many more errors. So did group two.
6 And then groups three and four were fairly comparable.

7 And then we also did some manipulations
8 around the active ingredients. And again, this is
9 more focused on the front of the panel but I think
10 still interesting to see. We varied here the font
11 sizes of active ingredients. We also assessed the use
12 of this box inset.

13 We also looked at explicit warnings and again
14 basically the take-home point is that when there's an
15 explicit warning, there was a much more increased odds
16 of being able to determine if two medicines are safe
17 to give together based on active ingredient
18 information. And there was no real difference in
19 terms of looking by font size or the presence of the
20 inset.

21 And then the last one I presented earlier
22 using these pictographic charts. We showed that there

1 was increased preference for the tool shown among
2 those who received the pictogram -- pictographic
3 charts, more dosing errors among those using cups
4 versus syringes. But the pictographic chart didn't
5 seem to help in this experiment.

6 But it really wasn't done real-world. We
7 were giving everybody standard tools, which is not
8 what normally happens. And so we are looking forward
9 to trying to suss that out a little more and how this
10 might be feasible to include labeling and what the
11 impacts might be.

12 So all right, I'm just going to end with a
13 few thoughts. I think there's many health literacy
14 challenges to using pediatric nonprescription
15 medicines, especially liquid medicines. Really I
16 think we should be thinking about specific strategies
17 to address these many -- these common areas of
18 confusion, whether it's concentration or active
19 ingredients, navigating these dosing charts, the units
20 and choosing and using dosing tools.

21 And research is I think really needed to
22 identify the best practices, both the DFL and the non-

1 DFL solutions. I think especially in peds it's
2 important to think about all the aspects of the
3 packaging, the intersection between the principal
4 display panel and the Drug Facts label, the box and
5 the bottle, the dosing tools, et cetera.

6 And I think I'm excited to also think about
7 solutions beyond the DFL and the packaging and
8 thinking about how technology can really help be part
9 of that system of information that Mike was talking
10 about. That's all that I have to say. I'm happy to
11 answer any questions. Thank you.

12 DR. DELLIBOVI-RAGHEB: Thank you very much,
13 Dr. Yin, for your talk. I'd now like to introduce our
14 next speaker, Dr. Jovonni Spinner, from FDA's Office
15 of Minority Health and Health Equity. The title of
16 her talk is, "Bridging the Gap to Address Health
17 Literacy Needs Among Diverse Groups."

18 BRIDGING THE GAP TO ADDRESS HEALTH LITERACY NEEDS
19 AMONG DIVERSE GROUPS

20 DR. SPINNER: Thank you. I'm very excited to
21 be here to share some of the work that we have been
22 doing to address health literacy among diverse groups.

1 I don't have anything to disclaim.

2 Just to give you a little bit of background
3 about the Office of Minority Health and Health Equity,
4 our mission is really to promote and protect the
5 health of diverse populations. And we do that through
6 two programmatic areas. One is focused on research
7 addressing questions that are relevant to minority
8 populations and also through our outreach and
9 communication strategies that also address health
10 disparities.

11 And really what we're focused on is achieving
12 health equity, which is defined as the attainment of
13 the highest level of health for all people. And as
14 the graphic shows on the screen, equality is not the
15 same as equity. Equality really is about giving
16 everyone exactly what they need. In our case, when
17 we're talking about health, making sure they have the
18 materials, tools and resources that they need at their
19 level to make a well-informed decision about their
20 health.

21 While on the other hand, equity is all about
22 giving people exactly the same thing, which is not

1 what you want to do. You want to make sure you're
2 meeting people at their place of need. And we know we
3 can't achieve equity with a one-size-fits-all
4 strategy. It really requires a multifaceted approach
5 to make changes at not only the individual but also
6 the community, the organizational and policy levels.
7 And that's really the crux of our work here in the
8 Office of Minority Health and Health Equity.

9 We have a few focus areas. As I mentioned
10 one is research and collaboration where we work in
11 both internal within the agency and with external
12 stakeholders such as academia to support research
13 studies about minority health and health disparities.

14 And as it relates to health literacy, we have
15 funded different studies on health literacy. And one
16 in particular is one on methods testing among diverse
17 consumers. Our outreach and communications work
18 really is focusing on strengthening FDA's outreach to
19 racial and ethnic minority populations and populations
20 that often experience low health literacy or who may
21 speak English as a second language or not at all.

22 So again we're also making sure that we're

1 partnering with external stakeholders to not only
2 identify some of the issues that are contributing to
3 health disparities but also to find tangible and
4 working strategies to help reduce health disparities.
5 And none of the work that we can do we can do alone.

6 We do rely heavily on our stakeholder
7 engagement and making sure that we are establishing
8 and maintaining and building connections with our
9 public and private stakeholders, and this can range
10 from academia to nonprofit organizations, industry and
11 of course patients. And then we also have
12 professional development training for our internal
13 staff which really helps to support workforce
14 diversity and capacity-building efforts.

15 So we've collaborated with some of the other
16 presenters today. So I won't go into too much detail.
17 But health literacy really is important to the work
18 that we're doing. And as we've heard earlier, it
19 really results between a mix-match between the health
20 information and services created for the public.

21 And really it's about their ability to be
22 able to find the information. Once you find it, can

1 you understand it. Can you make decisions based on
2 that information that you've gotten and how to
3 actually use that information. So it really is at the
4 intersection between the individual capacity and the
5 organizational choices to promote understanding.

6 And so health literacy results from the match
7 between the health information and services created
8 and the public's ability to find and use the
9 information. And it really is important for us to
10 keep this concept at the forefront because at some
11 point in time in life we're all going to find
12 ourselves in need of managing our health.

13 And that's whether it is to prevent a
14 disease, treat or manage a disease or a condition or
15 even just to lead a healthy lifestyle, for example.
16 And we're really thinking about extending beyond the
17 walls of the doctor's office.

18 So it's not just when you're in a doctor's
19 office that you need to be thinking about health
20 literacy. It really impacts a lot of different areas,
21 so ranging from your ability to be able to understand
22 nutrition food labels to make decisions about what

1 you're going to eat, Drug Facts labels, which we're
2 here talking about today, being able to understand
3 medical terms and, most importantly, being able to
4 evaluate the risks and benefits of a particular
5 medical decision.

6 So health literacy can impact your ability to
7 get the medical care that you need, how do you take
8 your medications correctly to avoid misuse or injury,
9 how are you managing a particular disease that you may
10 have and, again, just to make good decisions about
11 leading a healthy lifestyle.

12 So we've heard that, you know, health
13 literacy definitely is complicated. It requires a lot
14 of different skill sets from reading to listening,
15 analytical and decision-making skills as well as the
16 ability to really be able to apply these skills to
17 different health situations or scenarios.

18 So being able to understand the instructions
19 on a prescription drug bottle, your appointment slip,
20 medical education brochures, consent forms, et cetera.
21 And also really to be able to navigate the healthcare
22 system as a whole.

1 So this slide really reinforces what we heard
2 from Cindy earlier about, you know, not a lot of
3 adults are considered proficient in health literacy
4 and having the actual skills to be able to manage
5 their health and prevent disease.

6 And without this essential knowledge, it
7 really can be hard for many people to know how to
8 manage their health and/or to improve their health.
9 And there are a lot of reasons why health literacy may
10 occur among diverse populations. It could be that,
11 you know, healthcare providers are using words and
12 terminology that people don't understand. They're
13 talking a lot of medical jargon.

14 It could also be low educational skills.
15 There are cultural barriers to obtaining healthcare.
16 And then of course it's also limited English
17 proficiency as well. So not only can low health
18 literacy limit a person's ability to understand health
19 information, but it can also lead to negative health
20 outcomes.

21 Limited health literacy is linked to higher
22 rates of hospitalization and less frequent use of

1 healthcare services. So people may not be coming in
2 to get treated for their issues. It's also been
3 associated with poor chronic disease self-management
4 and treatment adherence which are both factors that
5 contribute to poor health outcomes.

6 So what's the connection between health
7 literacy and health equity? So we know that research
8 consistently shows that members of racial and ethnic
9 minorities and other diverse groups, they do actually
10 have lower health literacy than white people.

11 And limited health literacy is more likely to
12 be observed among adults who are over the age of 65,
13 definitely among racial and ethnic groups such as
14 African-Americans, Hispanics, Asian Americans, et
15 cetera. People who are recent refugees or immigrants,
16 people who have less than a high school degree or a
17 GED, people at lower incomes or below the poverty
18 level or people who are non-native speakers of
19 English.

20 So for example there is one study by the
21 Department of Education that found that African-
22 Americans, foreign-born Hispanics and Latinos and

1 native-born Hispanic and Latino adults had health
2 literacy scores that were significantly lower compared
3 to white adults in a model that controlled for both
4 demographic and socioeconomic factors.

5 Another factor that's important is that one
6 in five people in the United States speak a language
7 other than English at home. So for these people,
8 health literacy issues may be compounded by limited
9 English proficiency.

10 So for example there was another study of
11 Asians, Latinos and other racial and ethnic groups in
12 California that found about 44.9 percent of
13 respondents with limited English proficiency reported
14 low health literacy versus about 14 percent of English
15 speakers. So we're seeing that there's some
16 disparities in terms of who's able to achieve health
17 literacy and what that really means for their health
18 outcomes.

19 But ultimately we cannot expect people to
20 adopt healthy behavior and be able to take actions that
21 we want to champion if we are not able to have clear
22 communication, also support that clearer communication

1 with supportive activities to help build their skills
2 and then also having an organizational change that
3 will help reduce the demand that we are putting forth
4 onto consumers.

5 So let's talk a little bit about some of the
6 efforts that we have going on in our office. It's
7 definitely a strategic priority. So we want to make
8 sure that we are helping and, you know, working across
9 the agency to make sure that we're helping the
10 consumers make better informed decisions about FDA-
11 regulated products.

12 We know from previous research that sometimes
13 FDA's communications may not reach diverse audiences
14 and that may be due to language and health literacy
15 barriers. So some of the things that we've done in
16 our office, among others, is making sure that we focus
17 in on clear communication, that we are producing
18 health education materials and resources that, you
19 know, focus in on one topic, one key message so we're
20 not overwhelming people.

21 You know, we're avoiding the use of jargon
22 and a lot of complicated medical terminology, making

1 sure that we're breaking those barriers so things are
2 easy to read and easy to understand.

3 We also make sure that we are translating
4 materials. We can't expect people who don't speak
5 English as their primary language to be able to
6 understand this health information. So it's important
7 that we are translating it into their language so they
8 can understand it and make better informed decisions.

9 Also we focus a lot of our efforts on
10 testing, making sure that the consumers that are going
11 to use the products are included in the process. So
12 we want to make sure that, you know, they understand
13 the materials, that it resonates with them, that
14 images that we're using are culturally appropriate,
15 we're using the right language, et cetera.

16 And then also we have several, you know,
17 ongoing initiatives that we're using to promote health
18 literacy and to make sure that the consumers have the
19 information that they need.

20 So as I mentioned, we do produce quite a few
21 health education materials and resources. And most
22 recently we put together a package of materials that

1 includes a brochure, a fact sheet and an infographic.

2 And this is just one of the ways that we are
3 championing health literacy efforts and reinforcing
4 how we're using plain language, using graphics to
5 reinforce information and making sure that we have
6 content available in different formats based on how
7 people want to get their information.

8 We do use various modes of communication to
9 get our messages across with a particular focus on the
10 needs of racial and ethnic minorities. And again,
11 that makes sure that, you know, we're dealing with
12 very complicated scientific and technical information.

13 But it's our job to break down those barriers
14 into making information into plain language to make
15 sure that people can better understand the
16 information.

17 And when possible, we definitely make sure we
18 are using methods testing to assess not only the
19 readability but also the usability of our health
20 education materials. And as I mentioned earlier, we
21 do support research projects on health literacy.

22 And we just had a project that was on methods

1 testing with consumer panels. And we were able to use
2 that information in real time to actually adjust and
3 adapt some of the materials that we had in production.
4 So we're using the information. And so that
5 information is not just sitting on a shelf.

6 One of the initiatives we do have in our
7 office is that we do lead the language access plan.
8 And this is something that was required of all federal
9 agencies to make sure that we are providing timely,
10 quality and language assistance services to people
11 with limited English proficiency.

12 And one of the unique things that we have
13 done is that we've created this volunteers program.
14 So FDA staff who speak a native language, they
15 actually help us review our health education materials
16 and resources before they go out into the public to
17 make sure that the translations were done accurately,
18 make sure that we adhere to any cultural nuances that
19 may have gotten lost in the translation and making
20 sure that we have a quality product before we are
21 releasing it.

22 So we know that there are format and content

1 requirements for the OTC drug labeling. But, you
2 know, as we continue to have these discussions about
3 how to improve the Drug Facts label, we have to keep
4 health equity considerations in mind.

5 So achieving equity requires that we are
6 creating conditions necessary for people to achieve
7 their optimal health potential and making sure that we
8 are using a health equity lens will help ensure that
9 the needs of consumers that have limited health
10 literacy are being considered when planning to improve
11 the Drug Facts label.

12 So I can't stress the importance enough about
13 making sure that consumers who are using the DFL are
14 at the table and helping to make these decisions,
15 helping to test out the different ideas and
16 innovations that, you know, may come about, you know,
17 as we continue these types of conversations.

18 So with that, when we're thinking about, you
19 know, what needs to be done, here are a few questions
20 for consideration. So, you know, what do we need to
21 be asking about the potential changes to the DFL using
22 a health equity lens? So the first people that comes

1 to mind is, you know, what are some of the
2 unintentional consequences that could come about from
3 the changes?

4 So we all want to do good work, right? But
5 we need to ensure that, you know, any proposed changes
6 don't have a negative impact on some of these
7 populations and communities. And if there are going
8 to be some type of negative impact, how can those
9 inequitable impacts be mitigated to reduce the burden
10 on different populations?

11 You know, we also want to make sure that, you
12 know, how do we appropriately consider the needs of
13 consumers who have limited health literacy? What
14 exactly are their needs and how are we going to best
15 move forward to address them? And how are those
16 planned changes going to address these issues?

17 So we want to make sure that we're adequately
18 identifying what the issues are, making sure that we
19 have, you know, a multisector approach with, you know,
20 all hands on deck to make sure that, you know, we're
21 considering the issue from all possible angles and
22 making sure that, you know, we keep our health equity

1 lens bright and that we are able to make sure that
2 we're making the best changes that are going to have
3 the best impact for consumers.

4 So some possible strategies that come to mind
5 when we're talking about, you know, making some
6 changes, here are some things that could be considered
7 using this type of perspective.

8 So one, I can't stress it enough, engaging
9 consumers. Those with health literacy, we want to
10 engage them early in the design process. We really
11 want to learn about the understanding and the
12 acceptability of proposed changes and how is this
13 going to impact how they're interacting with the DFL.
14 Another way to address low health literacy is really
15 about making the task that we're asking less
16 demanding.

17 So we need people to understand the DFL so
18 they don't, you know, have a mistake and they're
19 having medication errors or dose themselves
20 inappropriately and cause some type of adverse
21 reaction. So in this case, you know, this could mean
22 developing secondary materials that go along with the

1 DFL that are obviously written in plain language,
2 using visuals that help convey the information that's
3 needed to help make a decision.

4 So again, that goes back to writing in plain
5 language, using visuals to help reinforce the key
6 messages, taking away anything that's not critical,
7 not important to make a decision at that point in
8 time. But also keep in mind if someone is using a
9 medication, it's usually to treat something.

10 So they may be in distress, you know, if
11 they're getting a pain medication, for example. They
12 may be in pain. Their judgment may be clouded. So
13 we've got to think about how do we make this as easy
14 as possible for them to be able to make this decision.

15 And then another thing that we found in our
16 research is that we know that members of racial and
17 ethnic minorities and other diverse communities are
18 very early adopters and very enthusiastic about
19 adopting digital technology.

20 So infusing digital communications into the
21 process to help people make a decision, so considering
22 those digital outlets as another potential channel for

1 helping to disseminate information, helping to educate
2 consumers about the DFL, how to read it, understand
3 it, interpret it, use it, for example.

4 So those are a few strategies that come to
5 mind when we're talking about how do we continue to
6 advance the conversation around adjusting or adopting
7 the DFL and how do we make it more consumer friendly
8 and how do we keep an equity lens on the conversation
9 and making sure we're adequately addressing the health
10 needs of those with low health literacy.

11 So I'll stop there, and thank you for your
12 time and attention and I look forward to questions in
13 the Q&A period. Thank you.

14 DR. DELLIBOVI-RAGHEB: Thank you very much,
15 Dr. Spinner, for your talk. It is my great pleasure
16 to introduce our next moderator, Dr. Terry Davis, from
17 Louisiana State University, who will be moderating our
18 second panel discussion. Welcome, Dr. Davis.

19 Our panelists will be Cindy Brach, Michael
20 Wolf, Shonna Yin and Jovonni Spinner. Our panel
21 discussion will last for about 25 minutes and will
22 conclude at 2:10 p.m.

1 PANEL 2: HEALTH LITERACY AND INDIVIDUAL LEVEL FACTORS
2 IN DRUG FACTS LABEL COMPREHENSION

3 DR. DAVIS: Great. Can you guys hear me?
4 Can you hear me?

5 DR. DELLIBOVI-RAGHEB: Yes, we can.

6 DR. WOLF: Yeah.

7 DR. DELLIBOVI-RAGHEB: Yes. Go ahead, Terry.

8 DR. DAVIS: Okay. Thanks, panel. And I just
9 want to give a shout-out to the FDA for convening all
10 the experts. Like Ruth, I'm learning a lot. It's
11 exciting that we're going to do -- FDA apparently is
12 ready to do something. The world has changed so much
13 since a lot of this research came out, particularly in
14 the last year.

15 I do want to give one brief comment about
16 health literacy. One of the things that changed is so
17 many kids were not in school last year or disengaged.
18 So the younger ones may never catch up and the older
19 ones may drop out. So health literacy is going to
20 continue to be a problem that we've got to address.

21 There are several things that I'm still not
22 certain on. And I want to drill down. And these

1 include active ingredients first. So Shonna pointed
2 out that it's smaller font. Mike pointed out that
3 people -- with his studies, people don't really look
4 at it. And Cindy pointed out that what's clear to you
5 may be clear to you and not clear to the consumer.

6 Full disclosure, I rarely look at the active
7 ingredient. The words are long. I don't know what to
8 do with that information. How do we make this
9 important if that's essential? If that's essential to
10 safety, how can it be meaningful? How do you think we
11 can make it meaningful to the consumer? So Cindy, you
12 want to start with that?

13 MS. BRACH: Well, I'll offer some fairly
14 prosaic comments here, not research-based. But, I
15 mean, from a consumer perspective, the question is
16 what's in this. And so I think some kind of labeling
17 that indicates what's in this is going to speak more
18 and grab their attention.

19 I suspect that there has been a lot of
20 research on the terminology of active ingredients in
21 an active ingredient. And the only thing we probably
22 agree on is these do not resonate with the public.

1 But as I said, the humbling task is figuring out what
2 will communicate the information. And I'm afraid I
3 don't have a silver bullet for that.

4 DR. DAVIS: Shonna, do you have any idea
5 about notice and, you know, having parents listen or
6 pay attention to the active ingredient?

7 DR. YIN: You know, one of the things that we
8 saw in that FDA-funded study with the OTC cough and
9 cold labels was when you included like explicit
10 warning, so if you say, you know, near the active
11 ingredient list, you give them some information, like
12 do not give your child other medicines that also have
13 these ingredients or there's some context that's
14 provided, that can help people to recognize that this
15 is something important to pay attention to.

16 I know with some of our studies around active
17 ingredients, parents are not thinking about active
18 ingredients at all when they decide which medicine to
19 give. They're thinking about, oh, what the brand name
20 -- you know, they're influenced by the brand name.
21 they're influenced by -- they look at the purpose list
22 and they say, oh, well that's for the same -- you

1 know, that's for the symptom I want. And that's how
2 they make those kinds of decisions and they don't
3 really pay a lot of attention to active ingredients.

4 So trying to -- families that that is
5 something we should be paying attention. And I think
6 it probably has to go beyond the label. I mean, the
7 label might help a little bit.

8 But there needs to be maybe an educational
9 campaign or more -- I don't know, some sort of a
10 support for building those health literacy skills even
11 in elementary school and above so people, you know,
12 understand the concept of active ingredients as well.

13 DR. DAVIS: Mike, do you have any comments,
14 like old people like me, who don't pay attention to
15 it?

16 DR. WOLF: Well, you know, I do think that,
17 you know, there's being able to call it out more, the
18 active ingredient. I think it's a whole new, you know
19 -- it is an educational experience.

20 We need to start focusing on that a bit more,
21 putting it not just on the -- you know, making it very
22 prominent on the DFL but also on the principal display

1 panel. And I think we need to also find ways -- I
2 mean, so just in terms of what this meeting is about,
3 I think, yes, whether it be through -- I don't think
4 the -- I don't -- I think it doesn't need to be an
5 icon like the ones that we had published that were at
6 work around acetaminophen that Shonna showed before
7 that was trying to create a whole set of -- like a
8 whole new dictionary of icons.

9 I think just using any kind of symbol to, you
10 know, direct people's attention that this is an
11 important section of the label would be a start.

12 But I think that, to Shonna's point, I agree.
13 I think it has to be tied to ways to get, you know,
14 healthcare providers to start to, you know, help
15 prioritize it and to talk about it and to also find
16 out what patients are taking and what is their go-to
17 medications and especially for older adults as part of
18 the reconciliation process, even if it's not something
19 done routinely, so they know.

20 So it's going to be a multifaceted strategy.
21 But I think as a starting point, finding ways to
22 whatever helps phonetically break down a term, make it

1 a minimal size font size and that it's -- and also --
2 even not -- maybe not even calling it active
3 ingredient. What's -- you know finding some other
4 more lay subject, but not calling it an active
5 ingredient.

6 MS. BRACH: Right. The question is why
7 should we care. Why do I even care what's in here?
8 And what Shonna just said was I should care if it's
9 going to interact with something else I'm taking or
10 I'm allergic to it or that otherwise, you know, as a
11 consumer, this is supposed to help my headache.

12 So I think that it has to be -- you have to
13 be giving them information that they have a reason to
14 want to know and frame it in that way.

15 DR. DAVIS: Right. Active ingredient to me
16 means yeast or something. So, you know, it's not a
17 helpful term. Jovonni, do you have any comments about
18 --

19 DR. SPINNER: No. I just want to echo what's
20 already been said and I think, you know, reinforcing
21 these concepts through like health education campaigns
22 and really given the opportunity to open up the

1 dialogue, particularly between providers and
2 consumers, right, you know, making sure that we are
3 enforcing why this is important and really why does
4 this even matter. I think Cindy just said it.

5 Like, you know, you don't want to take
6 multiple medications that have the same active
7 ingredient. That's why it's important because you
8 could be overdosing or you could be allergic to that
9 active ingredient in the medication.

10 So, you know, bringing attention to these
11 through educational initiatives or activities as to
12 why we should be paying attention to this information
13 so when you see it you can have a better conversation
14 of, you know, what should I do with this information.

15 You know, I think someone else said, you
16 know, if I'm getting this OTC for pain, I just want to
17 know is it going to alleviate the pain. I don't know
18 as a consumer that, oh, me taking this plus this could
19 equal, you know, a bad reaction.

20 So we need to make those concepts a lot
21 clearer and making sure that we have those
22 communication channels at multiple points and that

1 we're opening up the dialogue so patients can better
2 understand and also report out to their doctors that
3 they're taking all this, you know, other OTC
4 medication and what it could mean for their health.

5 DR. DAVIS: So this is great. This brings me
6 to another question. It dawned on me that if you go
7 to the drug store or a convenience store to buy an
8 OTC, you've gone to buy something to address a problem
9 or a condition you or your child has. So you want to
10 buy something. You are ready to pay for it.

11 So, you know, when you pick it up, y'all are
12 all clear that they look at the front. So would an
13 icon or how do -- it's a very small space.

14 What do y'all -- what do y'all say about
15 highlighting, icons and font size in a really tiny
16 space to really -- if you've gone to buy something,
17 what is the safe use, what is the contraindication,
18 the buy-in and buy-out, as they said. How do you flag
19 that for people who've gone to buy something?

20 MS. BRACH: Okay. Well, I hear at least
21 three different questions in there, Terry. So --

22 DR. DAVIS: Okay.

1 MS. BRACH: -- maybe I'll just take -- a few
2 of them. One was about icons and whether they're
3 worth it.

4 And I want to cite your work that you did
5 showing various auxiliary labels and asking people
6 what they mean, what they thought it meant. And there
7 was one picture of a stomach. And you said I had one
8 patient who told me this looks like Casper the Ghost.
9 And I bet you remember that because --

10 DR. DAVIS: Yes.

11 MS. BRACH: Icons, I believe, are things that
12 we've been taught to understand as having certain
13 meaning. The little men and women sign for restrooms,
14 the little elevator signs, you know, international
15 symbols. I would not think just looking at it that a
16 little box with arrows, you know, necessarily is
17 talking about an elevator. But I've been trained to
18 learn that. So I think icons are dangerous.

19 But what -- but pictograms are something
20 else. And Shonna, I believe you've done some research
21 where, you know, we talk in health literacy about
22 demonstrating how to take medicine and that that could

1 be very powerful and using pictures to do that.

2 Shonna, do you want to talk about your work in that
3 area?

4 DR. YIN: Sure. Yeah. I think -- I think
5 it's especially helpful around the dosing instructions
6 and having a pictogram that shows exactly how much
7 medicine to give in, you know, a specific dosing tool
8 that you want the parent to use. I think that is so
9 helpful to have that.

10 And we've shown in numerous studies that that
11 really does help reduce dosing errors. I think the
12 problem with it is that it takes space. And so if we
13 -- and we've tried to do that in some of these studies
14 that I showed you today as, you know, create these
15 dosing charts with the pictograms in them and, you
16 know, then what's the -- what's the cost in terms of
17 the other things that might not be able to fit onto
18 that Drug Facts label.

19 So I think it's a balance. But I think it's
20 definitely -- I think pictograms are definitely a good
21 thing in terms of, you know, helping people understand
22 dosing especially.

1 DR. DAVIS: Yeah. I think pictograms are
2 more explicit and clear. And as Cindy said, sometimes
3 the icons -- I remember another confusion was the
4 illustration of a pregnant person. Some people
5 thought it was an alien. And so, you know, you never
6 know the interpretation.

7 But a pictogram is a clearer -- a clearer
8 deal. Mike, what about older people? What icons do
9 you think they pay attention to or what about the
10 space? That's huge.

11 DR. WOLF: I think that -- so two things.
12 So, I mean, I do agree that pictograms can be very,
13 very helpful for conveying an action, like the dosage
14 for instance. And we did -- there are cultural
15 considerations to take into account though.

16 So in our Universal Medication Schedule study
17 where we tried to convey, you know, across the
18 morning, noon, evening, bedtime, you know, the times
19 per day, we did actually have a patient that was, you
20 know, a foreign-born patient that interpreted it
21 differently.

22 And also, just as an aside on that, on the

1 pictograms, a study by Elizabeth Wilson and our
2 colleagues in Canada, Rajiv Vallencourt at the
3 University of Ottawa, or I'm sorry, the Ottawa
4 Children's Hospital, worked with the FIP, the
5 International Federation of Pharmacy, and did a survey
6 looking at basically showing icons that they -- you
7 know, asking people to choose between five icons that
8 conveyed a variety of pharmacy, you know, pictogram
9 kind of messaging, like take in the morning or take
10 with food.

11 And so the message of that publication and
12 general health communication years ago really found
13 that, you know, people -- you know, culturally diverse
14 people do not agree on, you know, what icons best
15 convey -- or I'm sorry, pictograms best convey a
16 single picture. So I think that has to be conveyed.

17 Denise Parks, one of our colleagues, has done
18 some work previously in this space, you know, in the
19 pre-health literacy space and shows that some older
20 adults may be more challenged, you know, in terms of
21 the ready interpretation of certain pictograms and
22 icons. So I think that is a consideration, as well as

1 the use of color can be problematic in older adults,
2 especially like the --

3 DR. DAVIS: So what -- just while you're
4 talking, what font size would you like to see if it's
5 feasible?

6 DR. WOLF: Eighteen. I mean, obviously, you
7 know, if you want your pill bottles to be the size of
8 your Coke cans, you have no problem with that. But it
9 all -- it's all relative. So as large as it can be
10 feasible.

11 Or I think requiring people to -- or, you
12 know, to expect that people will go to added efforts
13 to, you know, use a -- you know, again, like a -- you
14 know, a magnifying glass to look at something is only
15 in case if it's a motivated individual, a very
16 activated patient or consumer.

17 It's going to be problematic for those who
18 think that they used this product for 20 years and
19 it's probably the same thing and they don't need to
20 read it, like you said, Terry.

21 DR. DAVIS: So Jovonni, do you have any
22 comments on cultural diversity and icons?

1 DR. SPINNER: I think with the icons, you
2 know, the testing piece is going to be really
3 important because different things mean different
4 things in different cultures.

5 So, you know, it's going to be very hard to
6 find like one-size-fits-all, kind of universal,
7 general icon that would -- you know, everyone is going
8 to understand. I think Cindy mentioned like the
9 elevator icons with the up and down arrows. So, you
10 know, is that universal, you know, across all
11 cultures? I don't know the answer to that.

12 But those are some of the things that you
13 would definitely need to consider. I think in
14 addition to considering the font size, also
15 considering the white space. So making sure you have
16 space between the information so it's not so crowded
17 or looks so overwhelming because I can imagine a lot
18 of consumers can -- you know, they see a bunch of
19 information. They don't know what to do with it. So
20 they decide to do nothing with it.

21 You know, so not even, you know, go into it
22 and try to figure out what it is. So thinking about,

1 you know, the white space as well. But I would just
2 say, you know, making sure that testing is done to
3 make sure that, you know, whatever icons are going to
4 be -- are going to be, you know, as culturally
5 relevant as possible across multiple groups.

6 DR. DAVIS: Right, because --

7 MS. BRACH: Well, I want -- I want to try and
8 nail a -- you know, put a nail in that coffin about
9 the icons because I really want to just distinguish
10 between icons and pictograms, with the pictograms are
11 conveying an action or a specific picture of
12 something. I mean, we have seen repeatedly the
13 difficulty of developing cross-cultural icons.

14 There was a project funded by Robert Wood
15 Johnson Foundation called Hablamos Juntos that tried
16 to develop signage for hospitals that could be used.
17 And what they came up for like radiology and, you
18 know, basically there were very few symbols that you
19 could come up that people would across the board
20 recognize.

21 And I also remember that in that USP advisory
22 group that continued after we developed Chapter 17,

1 and icons were one of the things that they were
2 reexamining because there are a set of sort of USP-
3 sanctioned icons. We kind of were throwing up our
4 hands saying, you know, all our -- there are very few
5 that we could actually agree, you know, promoted
6 understanding.

7 I wanted to also go back to sort of the
8 question that you were throwing at us about font size
9 and space. And Mike, I'm going to turn this on you in
10 a second. So watch out. That I know that there's a
11 lot of talk about using technology.

12 So you could have a barcode that you could
13 scan and that it would -- you know, you could make it
14 whatever font size you want or it could translate into
15 another language or, you know, we get all excited
16 about thinking about these opportunities. But then
17 I'm thinking about the elderly and, you know, I
18 certainly know my 89-year-old mother is not going to
19 be able to do that. And I'm not even sure I know --
20 would feel confident.

21 So Mike, what are your thoughts in terms of,
22 you know, the possibilities of the techno solution

1 here for the limited real estate?

2 DR. WOLF: So, you know, I'll just -- a quick
3 comment on that because obviously the question that
4 that gets into, you know, the technology literacy
5 issues with older adults. And I had an NIH grant
6 reviewed once that was involving technology for older
7 adults.

8 And one of the reviewers said, oh, is this a
9 project for the future elderly, which I thought was
10 the funniest term because I think we're all future
11 elderly. You know, to that point, I think that you
12 are showing the current, you know, generation of older
13 adults are much -- are very -- are becoming more --
14 their baseline technology literacy is much more facile
15 than maybe what we have always assumed that someone
16 over 65 couldn't do that or wouldn't want to do a QR
17 code reading.

18 And I think that's just outright wrong. I
19 think there's a lot of opportunity and interest in
20 that. But it does -- it does -- again, I think the
21 bigger problem is not so much like would that work.
22 It's I think that's a solution that's being used for a

1 lot of things, that just, you know, send it off to
2 this QR code and then it's like a microfiche. Then
3 you can expand it as you want. I'm dating myself
4 there.

5 But it really -- it gets back to someone
6 activated. And around OTC use specifically, it's
7 something that I don't think people put a lot of
8 thought to. So I think that you can do that. I would
9 be very curious, and I don't know if there's any
10 evidence to support, that if made available, how often
11 would it be used or, you know, it seems like a
12 seemingly simple task that people can do.

13 It's the unintentional errors that people
14 make with OTCs, the ones that they don't know that
15 they're even making because people -- I think it's a
16 minority of patients -- or consumers, excuse me, for
17 this context, that are going to go the distance to
18 really feel properly informed about an OTC product.

19 DR. DAVIS: Right. So this -- I want to
20 Google -- toggle to Google. I'm doing a study now
21 with Medicaid patients all over Louisiana. These are
22 low income people. Many of them will have low

1 literacy. And they're a wide age range. I was
2 shocked at how much they use Google and how much they
3 use their smartphones to do everything, a lot more
4 than I do.

5 And I just -- but like Mike said, it's
6 another step that somebody would have to be motivated
7 to take. Do you -- y'all have any envision of
8 technology helping OTCs or is that just a reach too
9 far, another step?

10 DR. WOLF: Well, you know, given that we have
11 just equipped -- just to jump in because I know we're
12 kind of coming to it. But I'm a very big fan of Laura
13 Bix who is coming up next in the third panel who has
14 done some amazing things in this space.

15 So I don't want to -- I don't want to offset
16 it to the next panel. But I think she's done some
17 incredible work with regards to leveraging technology
18 and thinking about the label. But anyway, I'll pause
19 and let anyone else respond.

20 MS. BRACH: Jovonni, did you have something
21 on the technology score?

22 DR. DAVIS: Who are you asking? Jovonni?

1 MS. BRACH: Yeah.

2 DR. DAVIS: Cindy was -- yeah. Jovonni, do
3 you have a comment about -- since you said minorities
4 were, you know, uptaking on technology fast, do you
5 have any comment on using technology?

6 DR. SPINNER: Yes. I think technology is
7 good. So, you know, you can always have apps. You
8 can always have like a QR code where they could scan
9 it, you know, get additional information that, you
10 know, could then -- I think it was already mentioned
11 for it to be translated and larger fonts and things of
12 that nature.

13 But again, that will have to take a more
14 motivated consumer to go the extra step. But at least
15 we have some sort of tool or strategy that is viable
16 that's going to meet different people at their place
17 and need.

18 So I don't think the digital strategies are
19 going to take the place of everything else because
20 obviously, you know, there are some additional
21 barriers there. So you do have to have a smartphone.
22 You do have to have, you know, connectivity, you know,

1 to Google, to the internet, to what have you.

2 So there are still going to be some barriers.
3 But I do think having those additional tools are, you
4 know, very important to making sure that people can
5 have access to the information.

6 DR. DAVIS: So in the last two minutes, what
7 is the one thing you hope the FDA will do to improve
8 this or one or two things?

9 Also somebody is trying to ask a question,
10 and I can't see the whole question. But while the FDA
11 is finding that question, can y'all say, Cindy,
12 starting with you, what is it that you hope really
13 comes out of this meeting?

14 MS. BRACH: Well, I'm pretty excited because
15 I think that there are some simple steps that you can
16 take. So some of the points that I made about
17 streamlining information and language, where you're
18 putting the emphasis, making sure there isn't
19 conflicting or ambiguous instructions.

20 Those are -- you know, within the constraints
21 of everything they put on that label, are very doable.
22 So I think that there are some, you know, ways of

1 having some immediate improvements before we get into
2 rocket science.

3 DR. DAVIS: Gotcha. Shonna, you have a non-
4 rocket science, feasible next step?

5 DR. YIN: Well, I mean, I agree -- I agree
6 with Cindy. You know, I think that there are some
7 just basic things that can be done that are very
8 concrete that's doable with the static label. And
9 then we can think, you know, like big picture and
10 crazy, you know, all the other potential technologies
11 and things like that.

12 But there are some I think easier sort of
13 fixes. And I'm really excited that FDA wants to work
14 on this. I think -- and to really engage consumers in
15 that process.

16 DR. DAVIS: Jovonni? Jovonni or Mike, in the
17 last 20 seconds, do y'all have --

18 DR. SPINNER: So I was going to say my last
19 comment would be just to keep the health equity lens,
20 making sure that the strategies that are moving
21 forward are equitable and are going to meet diverse
22 consumers' needs.

1 DR. DAVIS: Right. And they include diverse
2 consumers in pilot testing.

3 DR. WOLF: Yeah. Yeah. I think that --

4 DR. SPINNER: Absolutely.

5 DR. WOLF: Yeah. And to Jovonni's point, I
6 would -- I mean, they need to be co-designers in this.
7 So that means an iterative engagement with a diverse
8 set of consumers and making sure that again, my last
9 thing is just -- again, we're all in agreement I
10 think, just also if there was a way, you know, getting
11 back to rethinking how you're classifying each of the
12 buckets of information and how you explain to what --
13 you know, what they are, what the information is and
14 why it's important as well as even reconsidering the
15 sequencing of the content coming from the lens of the
16 consumer would be great.

17 DR. DAVIS: Thanks, panel --

18 MS. BRACH: And I want to pile on --

19 DR. DAVIS: Go ahead.

20 MS. BRACH: Well, I just -- you know, I think
21 we all doubled-down on what Jovonni said which is that
22 consumer testing piece that doesn't marginalize

1 certain populations but actually, you know,
2 oversamples if you're talking about actual testing or
3 having those who are most at risk have the biggest
4 voice.

5 DR. DAVIS: Thanks, panel. Thanks, FDA. Now
6 we'll toggle back to you guys.

7 DR. DELLIBOVI-RAGHEB: Thank you, all. That
8 was a very interesting and thought-provoking panel
9 discussion. We will now take a short break and resume
10 at 2:20.

11 (Off the record)

12 SESSION 3: THE FUTURE OF THE DRUG FACTS LABEL

13 DR. DELLIBOVI-RAGHEB: Welcome back from
14 break. We will now start session three, "The Future
15 of the Drug Facts Label." To begin our third session,
16 I'd like to introduce you to our first speaker, Dr.
17 Barbara Kochanowski from Consumer Healthcare Products
18 Association. The title of her presentation is, "The
19 Drug Facts Label - Looking to the Future with the
20 Consumer in Mind."

21 THE DRUG FACTS LABEL - LOOKING TO THE FUTURE WITH THE
22 CONSUMER IN MIND

1 DR. KOCHANOWSKI: Good afternoon, everyone.
2 And thank you for inviting us to be part of this
3 workshop. The future of the Drug Facts label is a
4 very important topic to CHPA, our members and
5 consumers.

6 CHPA is an organization that represents the
7 leading manufacturers and marketers of over-the-
8 counter medicines, an industry focused on consumers.
9 And today I want to begin my comments with a quote
10 that I think is applicable to what we're trying to
11 achieve here.

12 When Steve Jobs was brought back to
13 reorganize Apple in the late '90s, he had a clear
14 vision. He said, "You have to start with the customer
15 experience and work back to the technology." He went
16 on to say that, "You can't start with a technology and
17 figure out where you're going to try and sell it."

18 And we've heard a lot of comments related to
19 this today. We at CHPA believe, as I'm sure all of
20 you do, that it's essential to keep the consumer needs
21 front and center as we consider how to optimize the
22 Drug Facts label so we can ensure that any changes we

1 do make will have a meaningful impact.

2 Today I'd like to emphasize that CHPA and our
3 industry members believe that the DFL has been and
4 remains an important tool in helping consumers get the
5 information they need to safely and effectively use
6 our over-the-counter medicines. Our members hear from
7 consumers regularly. We know that changes in the
8 consumer self-care environment have been profound.
9 And that presents us with challenges and opportunities
10 to ensure that the DFL keeps pace with those changes.

11 As we've heard in earlier panels today and as
12 we hear from consumers, we have opportunities to
13 optimize the label, including improving on small and
14 hard-to-read font, pullouts that go on for pages,
15 making it hard to find the information they need, an
16 overwhelming amount of information that's not
17 prioritized and just seems to run on forever.

18 And while the industry has been able to make
19 some improvements to the DFL within FDA's existing
20 regulations and framework, these regulations also
21 present us with practical limitations in what we can
22 do to optimize the label. And we heard about this

1 this morning from FDA, this very specific language
2 that must be used on the label in all areas from
3 dosing directions to uses to warnings, just to name a
4 few. There is a specific order the information need
5 to be in, and the font has to be a precise size.

6 So when we have to add information to a
7 label, we're not allowed to take anything out. The
8 result is that consumers just get longer and more
9 crowded labels that are hard to read, especially for
10 seniors where the most important information may not
11 be clearly visible.

12 We believe the best way to consider future
13 improvements to the DFL is to take a strategic and
14 scientific approach, a very holistic approach versus a
15 piecemeal one. And when we say a holistic approach,
16 we mean for each product we need to look at the
17 packaging, the principal display panel, the dosing
18 device and the Drug Facts label.

19 Any research on labeling really needs to
20 consider all of these components and how the consumer
21 uses them. That way we can understand what
22 improvements would have the greatest impact and ensure

1 the highest level of safe and effective use for
2 consumers.

3 As we undertake this, the consumer voice
4 needs to be heard and prioritized in the process. And
5 there are many ways we can capture consumer input,
6 including publicizing the existing open docket that
7 FDA has referenced, holding open forums that include
8 consumer groups and hold comment and listening
9 sessions. And we know it works.

10 Over the last 15 years, we've made progress
11 when the FDA, industry and other stakeholders come
12 together to the table. If you look at acetaminophen,
13 for example, we've made the safety information
14 clearer, highlighting in bright yellow in the active
15 ingredient section that the product contains
16 acetaminophen, making ingredients more prominent on
17 the principal display panel and strengthening the
18 liver warning. These changes were initiated by
19 industry in 2002 and were finalized by FDA in 2009.

20 And as Shonna referenced in her talk, we've
21 already made strides in simplifying the information to
22 help consumers properly dose. Specifically we worked

1 with many stakeholders to standardize how information
2 for dosing is presented on all OTC liquid medicines,
3 matching the label to the dosing device on each
4 product and moving to the metric system. We also got
5 rid of the wide variety of spoons and their
6 descriptions that were causing confusion among
7 consumers.

8 And our members took an active role in the
9 Protect program, which Shonna also mentioned, a highly
10 productive partnership that's been in place since
11 2008, showing why some actions of greater than 30
12 percent reduction in the number of young children
13 brought to the emergency department because of
14 accidental medication overdoses. That's 20,000 fewer
15 ED visits per year.

16 This partnership is a great example of the
17 right stakeholders coming to the table to ensure that
18 products which, by design, enable people to promote
19 health and self-care, do not inadvertently harm
20 others, especially young children. We're proud of
21 these steps that industry has taken along with other
22 partners, and we know we should and can do more

1 because our world has changed.

2 After 20 years since the Drug Facts label was
3 first implemented, we've had major shifts in our
4 demographics, our societal expectations and in
5 technological advances. And all of these factors
6 impact the DFL, providing both challenges and
7 opportunities.

8 The demographics in our population have
9 changed significantly since the beginning of the DFL.
10 We are older, and increasingly multilingual. Our
11 society is demanding us to be more environmentally
12 friendly in our process and packaging. The world is
13 more plugged in, offering us the prospect of
14 rethinking the DFL in a way that makes it much more
15 consumer-friendly.

16 And COVID has sped up consumer comfort with
17 many of the technologies that we utilize. For
18 example, QR codes, which have become much more
19 prevalent during COVID, may be a consumer-friendly
20 option in label optimization.

21 Now that people can immediately access a
22 website for additional information by taking a picture

1 of a QR code with their smartphone at the point of
2 sale or access a website, we can move some of the
3 additional information off the label. This would
4 serve two purposes. It would allow consumers to get a
5 simplified label on their product with easier to read
6 information and they would also get expanded
7 information in their language, in larger font, on the
8 product's website.

9 Another important shift we've seen is that
10 the overwhelming majority of Americans have access to
11 both smartphones and the internet. According to a
12 2021 Pew survey, 85 percent of Americans now have
13 smartphones and 93 percent of adults use the internet.
14 And that percentage has been consistently growing over
15 the last decade.

16 As we keep top of mind what will work for the
17 consumer, we also need to consider the environmental
18 impact of what we were doing. Sustainability is an
19 important factor in our decisions. So we must
20 consider how to keep our use of paper and packaging to
21 a minimum when adding more content to a label.

22 These considerations are complex and often at

1 odds with each other, such as the request for larger
2 and larger font size and the request for more
3 sustainable packaging or less paper.

4 On the positive side, technology is advancing
5 so quickly that we believe there are many
6 opportunities to identify practical and effective
7 tools to help consumers access the information they
8 need when they need it. And that speaks to how
9 important it is to have a diverse group of experts and
10 stakeholders at the table to help advance the DFL.

11 In addition to the traditional approach of
12 the healthcare industry representatives getting
13 together with regulators and some stakeholders and
14 determining label changes, we believe we would benefit
15 from also drawing on technology and environmental
16 experts and of course, above all, consumers to
17 understand what would be beneficial to them and
18 society and what is possible in executing it.

19 This holistic approach to stakeholder input
20 and a holistic approach to looking at all aspects of
21 the label is what will get us to changes that are
22 positive and long-lasting.

1 I mentioned the Protect project, and you
2 heard about this from Shonna. Many of us at this
3 meeting today have participated in this initiative
4 ever since it started in 2008. This model of a
5 public-private partnership is driven by stakeholder
6 voluntary collaboration and many of the changes made
7 to product labels, packages and dosing devices came
8 about through dialogue at these meetings and have had
9 meaningful impact. The question now is can we find a
10 similar vehicle to consider opportunities to improve
11 the DFL.

12 From the industry perspective, we bring
13 longstanding expertise in packaging, in graphic design
14 and consumer testing and welcome the opportunity to
15 bring our skills to bear. As an industry, CHPA and
16 its members want to continue to use the DFL as a
17 mechanism to help consumers take our products safely
18 and effectively and move forward in a way that is
19 consumer-friendly.

20 So I thank you for calling this important
21 workshop and for involving us in it.

22 DR. DELLIBOVI-RAGHEB: Thank you very much,

1 Dr. Kochanowski, for your talk. I'd now like to
2 introduce our next speaker, Jason DiMuzio, from Health
3 Canada. His presentation will be on, "Plain Language
4 Labeling of Nonprescription Drugs in Canada."

5 PLAIN LANGUAGE LABELING OF NONPRESCRIPTION DRUGS IN
6 CANADA

7 MR. DIMUZIO: Good afternoon, everyone. My
8 name is Jason DiMuzio, and I am the manager of label
9 review in the Nonprescription Drugs Evaluation
10 Division of Health Canada. I would like to thank the
11 U.S. FDA for inviting me to speak at today's workshop,
12 and I also am very happy to be speaking alongside my
13 fellow panelists and very much look forward to the
14 discussion at the end of the session.

15 Improving drug labeling has been a focus of
16 many health agencies for some time now. And in
17 Canada, we've looked at the application of Drug Facts
18 labeling in the U.S. as a model for presenting drug
19 information to Canadian consumers in a clear and
20 consistent manner.

21 In fact, through the course of this
22 presentation, it will become widely evident the great

1 impact and influence that Drug Facts labeling has had
2 on Canada's regulatory and policy initiatives which we
3 at Health Canada have collectively termed as plain
4 language labeling.

5 Today's presentation aims to offer a review
6 of Health Canada's application of Drug Facts labeling
7 like regulations and policies, and how Canada has
8 found success in transitioning the labeling of OTC
9 drugs.

10 Today I'll situate us with a brief touch on
11 Health Canada and the plain language labeling
12 initiatives. I will then introduce the Canadian drug
13 facts table, along with some of the labeling policies
14 that we've implemented in order to support industry in
15 complying with the requirements.

16 I'll pay close attention to the electronic
17 CDFT, which I think will be of value to today's
18 discussion, and how it's applied for OTCs in Canada.
19 I will then provide a status update on our
20 implementation and look at our next steps.

21 As a quick intro, Health Canada is the
22 federal department responsible for the health of

1 Canadians. It's comprised of several branches,
2 including the Health Products and Food Branch, whose
3 mandate is to manage the risks and benefits of health
4 products and foods. The Food and Drugs Act is the
5 major legislation framework in Canada, and under this
6 act a number of regulations appear for specific
7 product lines. The focus of my discussion today is
8 limited to the food and drug regulations.

9 I'll take a brief moment now to set the stage
10 for how Canada has applied DFL principles under the
11 plain language labeling initiatives. Health Canada
12 considers that easy-to-read information about the
13 potential risks and safe use of a health product is
14 one of the most valuable safety tools we can provide
15 Canadians of all ages.

16 The objective of the PLL regulatory
17 amendments, stemming back to 2014 for prescription
18 drugs and 2017 for nonprescription drugs, was to
19 improve the safe use of drugs by making product labels
20 and packages easier to read and understand. The main
21 idea is that clear labels reduce the risk for
22 confusion, harmful errors and adverse events.

1 Our plain language labeling initiative goes
2 beyond simplifying words. There are provisions to
3 assess drug product brand names as well as the
4 requirements for the submission of label mockups for
5 all drug submissions, recalling that in Canada,
6 although we have a monograph framework in place, drug
7 sponsors need to file and have a product reviewed
8 before it's authorized for sale.

9 We also introduced a regulatory requirement
10 for drug sponsors to provide their contact information
11 in an easy-to-read format, with the aim of simplifying
12 and encouraging the reporting of adverse events
13 associated with drugs.

14 And finally, Health Canada added provisions
15 for a Canadian drug facts table, or commonly known by
16 its abbreviation, the CDFT, which is the Canadian
17 equivalent of the Drug Facts labeling. This provision
18 is exclusive to OTC drugs. The CDFT is to appear on
19 the outermost label of an OTC and since Canada has two
20 recognized languages, information must appear in both
21 English and French, which is a unique challenge.

22 To give you all a sense of what this means in

1 practice, lets focus on a few examples I've listed in
2 the next couple of slides. Before PLL, some important
3 information could be overlooked by the average
4 consumer due to a lack of adequate contrast. Now
5 there are specific requirements for information that
6 is required by the regulations to be prominently
7 displayed, such as the example on the right with the
8 checkmarks.

9 Further, my team of label reviewers regularly
10 works with clients to increase the contrast of
11 information on drug labels so that they can be more
12 easily read.

13 Here is another example demonstrating the new
14 regulatory requirement to include a drug sponsor's
15 contact information directly on the package. As I
16 mentioned just a minute ago, the idea here is that
17 consumers would have a clear manner to connect with a
18 company should they have any questions or wish to
19 report adverse events.

20 Under the regulations, both the inner and
21 outer labels of OTCs must carry the contact
22 information. Though a mailing address still meets the

1 requirements, we are promoting email, websites and
2 phone numbers for more rapid and live exchanges.

3 And finally, perhaps the most noticeable of
4 the changes and specific to nonprescription drugs, of
5 course, is the introduction of the Canadian drug facts
6 table. This table, which contains important
7 information for the safe and effective use of the
8 drug, provides a useful resource for Canadian
9 consumers in an easy-to-read format.

10 This graphic provides you with a sense of the
11 look and feel of a CDFT. Obviously there are very
12 strong similarities between this and the Drug Facts
13 labeling box. We see the use of titles and ordered
14 headings to keep info organized, rules and hairlines
15 to separate information and the white background
16 provides contrast.

17 The CDFT title headings and subheadings are
18 all standardized in both English and French. If a
19 section doesn't apply, it's simply dropped from the
20 table. There are a number of approved font styles
21 available for the CDFT, all of which are sans serif,
22 nondecorative fonts. All text has a set font size

1 with the smallest text appearing in the size 6 pt. As
2 you can see, the formatting and presentation
3 requirements for the CDFT are rather numerous. And
4 despite this, very few of the formatting or
5 presentation aspects actually appear in the
6 regulations themselves.

7 In some cases, it was rather difficult to
8 accommodate the CDFT without repackaging the product
9 into a larger carton or using an innovative label such
10 as a peel-back. To ease the challenges of
11 implementation, Health Canada introduced a series of
12 graduated flexibilities which, when applied, reduced
13 the total real estate needed to accommodate a CDFT on
14 any given package.

15 Importantly, Health Canada insisted that
16 these flexibilities be applied gradually so as to
17 ensure that labels align with the standard format
18 whenever possible.

19 Three sets of CDFT flexibilities exist, the
20 first being the set of graduated flexibilities. This
21 is the most standard set of flexibilities common to
22 all OTCs. Next we have flexibilities tailored to

1 lower risk products meeting specific criteria; that
2 is, those aligning with the Health Canada monograph
3 and carrying low-risk health claims. And finally, a
4 set of flexibilities for any OTCs using innovative
5 labels.

6 The details of each flexibility can be found
7 in our guidance instead of regulation which provides
8 us with a nimble mechanism should we identify a need
9 to adjust any of our labeling policies.

10 The first level of flexibility centers around
11 the format of the table itself. Hairlines that
12 separate warnings are removed and changes to make the
13 rules and box frame of the CDFT center can be applied.
14 We also allow the uses of the drug product to be moved
15 to the principal display panel instead of being listed
16 on the table itself, thereby reducing duplication.

17 Flexibilities in levels two and beyond may be
18 applied within specific parameters. These are only
19 permitted when two unilingual branding panels are
20 merged to a single bilingual branding panel. Once
21 again we see the bilingualism being nuanced here.
22 Once applied, the conventional regular font is

1 exchanged for a condensed font style.

2 After applying all level one and level two
3 flexibilities, sponsors can then apply level three
4 flexibilities which moves some of the information from
5 its normal place in the Canadian drug facts table to
6 elsewhere on the package. Space savings are somewhat
7 minimal here.

8 But the idea is that in certain
9 circumstances, moving the text in let's say the other
10 information section to an end panel can result in
11 eliminating that CDFT section altogether. This is
12 when level three is of most value.

13 Also the list of inactive ingredients can be
14 moved to elsewhere on the package. When doing this,
15 the section heading of inactive ingredients must
16 remain in the CDFT with a prompt on where to find the
17 information.

18 And finally, if a drug sponsor applies all
19 the previous flexibilities and still cannot fit the
20 required information on the package, sponsors may
21 access level four, with the aim of moving select point
22 of use information from the CDFT and onto a leaflet or

1 package insert.

2 Health Canada has spent quite a bit of time
3 developing a distinction between point of selection
4 and point of use warnings. Our thinking is that the
5 needs of consumers when purchasing or selecting a drug
6 are different than when they are using or after using
7 the OTC. And as such, the latter can be migrated to
8 the inside of a package by way of a leaflet or a
9 package insert.

10 I think it's somewhat fair to say that not
11 all drugs are the same and nor do they carry the same
12 safety profile. And so I'll introduce this topic of -
13 - or this notion of a low-risk product.

14 As some of you may be already aware, Health
15 Canada is moving towards a new way of regulating self-
16 care products with the aim of more closely harmonizing
17 the regulatory requirements for products that would
18 otherwise sit beside each other on store shelves.

19 To bridge the gaps between the heavier
20 labeling requirements of OTCs with those of cosmetics
21 and NHPs, or natural health products, Health Canada
22 developed a special set of labeling flexibilities that

1 allow the drug product to more closely resemble a
2 cosmetic than a prescription drug. These are reserved
3 for the lowest risk self-care products captured under
4 the current drug framework.

5 In terms of a regulatory requirement on the
6 PDP, these remain. Principles of minimum font size
7 and high contrast are still necessary. But what is
8 noticeably different from the CDFT on a lower risk, or
9 what we call a category one product, is that after
10 applying the flexibilities, it no longer resembles a
11 table per se.

12 And so this is the example on the image on
13 the right here. The lines around and within the table
14 may be removed and sponsors can arrange information as
15 they please, so long as the warnings stay together so
16 as not to orphan any single warning. The text is
17 still required to be left-justified so as to avoid an
18 enormous block of illegible text.

19 And of note, category one products are able
20 to move point of use warnings in the inactive
21 ingredients list to a website, which is something new.

22 The website must be in a standardized

1 electronic Canadian drug facts table format, which
2 I'll expand on in the next slide. Ultimately the
3 introduction of category one flexibilities has helped
4 sponsors fit the necessary information on their
5 existing packages. And the added flexibilities are a
6 reflection of the low-risk nature of these products.

7 To support the use of websites in the use of
8 OTCs, Health Canada developed a number of criteria and
9 guidance to support industry and ultimately ensure
10 that this new way of presenting information would meet
11 the needs of Canadians.

12 Any time a sponsor chooses to move
13 information from a label and into an online space,
14 they should follow the guidance provided by Health
15 Canada. Aligning with the principles of plain
16 language labeling, eCDFTs must be easily read, fact-
17 based, accessible and mobile-friendly, bilingual and
18 of course consistent with what has been approved by
19 Health Canada.

20 To make the eCDFT somewhat easier to adopt
21 for industry, we put forth a set of open standard
22 templates, free to use and access. Our application of

1 the eCDFT policies has not come without its
2 challenges, of course. Early on several companies
3 were flagging that the standards for the eCDFT would
4 not meet the corporate look and feel requirements for
5 their websites.

6 After much discussion, I think we've settled
7 that the eCDFT is not meant to be a promotional tool
8 for a company, but rather an extension of the label of
9 a product. At this stage, three or so years later, we
10 feel that we've struck a balance in this regard.

11 The particular point from the work on the
12 eCDFT that I'd like to emphasize centers around
13 balance. In Canada, we've been treating the digital
14 space as a complement to the conventional label. But
15 with all we've heard from today, innovation in this
16 drug labeling space is quite fascinating.

17 And as much as I play the role of a
18 conventional regulator insisting that every last word
19 be present on a product label, I continue to be
20 impressed by the ever increasing innovation that our
21 industry has shown. I'd be lying if I'd say there
22 aren't moments of unease or trepidation, particularly

1 in cases when we're speaking about replacing
2 information that would otherwise be on a package, just
3 to ensure that we're keeping everyone informed and
4 that health equity lens.

5 But in my perspective, there's a general
6 acceptance that the way consumers are interacting with
7 OTCs is changing and importantly the shopping
8 experience is also changing. So for me, being part of
9 this discussion, is a great gift and that I can
10 witness the leadership that the FDA has placed in this
11 environment and take back some lessons learned to
12 apply in the Canadian context.

13 The last part of my presentation today
14 focuses on the current status of implementation of
15 plain language labeling in Canada. As I've mentioned,
16 the retail level deadline to apply label changes for
17 OTCs takes effect later this month.

18 To date, we've accounted for nearly 90
19 percent of marketed OTCs and are working closely with
20 our partners and post-market compliance bureaus to
21 hold the remaining sponsors accountable. Our work
22 will continue to ramp up through the summer months.

1 In terms of what we've seen on the labels
2 that my team has evaluated, about 80 percent use at
3 least one flexibility shown in the pie chart on the
4 left. On the right, the take-home is simply the
5 profile of this chart.

6 Many products use the format and font-
7 specific flexibilities that I mentioned in levels one
8 and two and few use the levels three and four which
9 center around moving information outside of the CDFT
10 to elsewhere on the package or within the package.

11 We also see that if a product is a lower risk
12 OTC, that they generally take advantage of the special
13 flexibilities that were implemented in advance of the
14 self-care framework, including the use of that
15 electronic CDFT. These are listed as cat four and SCF
16 cat one on the right side of this bar chart.

17 Our success in the labeling initiatives
18 hasn't come without plenty of work, however. This
19 timeline provides you a glimpse of the level of
20 engagement we've had, and recall this is all after the
21 regulations and initial guidance for industry was put
22 in place.

1 In retrospect, my colleagues and I have a
2 greater understanding of the impact that labeling
3 initiatives have on industry and we develop better
4 policies through collaboration with them. Likewise
5 their openness and transparency and trust has allowed
6 us to reach the finish line of this important
7 initiative.

8 I'll close my presentation today by sharing
9 some of Health Canada's next steps regarding OTC
10 labeling. First we will be transitioning toward the
11 closeout phase for implementation of PLL and shifting
12 from promoting compliance to restoring it when
13 noncompliant products are identified.

14 As a personal goal, I see great value in
15 leveraging all of the information presented here today
16 and starting on the early plans on evaluating what
17 went well and perhaps not so well on the
18 implementation of Health Canada's PLL program.

19 Lastly, Health Canada is aiming to table
20 regulatory amendments for the labeling of natural
21 health products or supplements in the short-term, and
22 so applying best practices and lessons learned from

1 the OTC experience will be key toward the successful
2 passage of regulations for improved labeling of NHPs.

3 Lastly, I wish to once again thank the FDA
4 for inviting me to participate in today's session. It
5 is truly an absolute pleasure. I'll now turn it over
6 to the next speaker. Thank you.

7 MR. KONYA: Hello. Okay. Are you ready for
8 me to begin?

9 DR. DELLIBOVI-RAGHEB: Yes, go ahead.

10 SUPPORTING INNOVATION WITH DRUG FACTS LABEL STANDARDS

11 MR. KONYA: Okay. Sorry. I didn't hear you
12 say. Thank you, everyone, for having ONC, the Office
13 of the National Coordinator for Health IT, which is
14 part of the office of the secretary at HHS, be part of
15 today's exciting workshop.

16 My name is Stephen Konya, and I serve as the
17 senior advisor to the deputy national coordinator for
18 health IT, and I also wear another hat as the
19 innovation portfolio lead for our agency.

20 So ONC, if you're not familiar with it, is
21 the principal federal entity that is charged with
22 setting health IT standards and policy for the

1 country. These are our key national strategic
2 priorities for right now. And there are some links in
3 this presentation to some of those supporting
4 documents if you're interested in learning more about
5 that.

6 One thing that you -- that relates to today's
7 event is that ONC has been on a journey over the past
8 15-plus years to try to move healthcare electronic
9 information off of the paper base and into an
10 electronic format and then to make that interoperable
11 using standards and then ultimately to improve the
12 usability of that information for achieving the triple
13 lane and other goals.

14 So we have this journey going from a paper-
15 based environment of data to making it electronic and
16 digital to the next step of once it's digital, to
17 making it interoperable and then the third phase of
18 making it usable, a similar journey that I see your
19 DFLs following.

20 Currently our biggest guiding light is the
21 21st Century Cures Act. And ONC and CMS put out final
22 rules as part of that. Many federal agencies were

1 included in that Cures Act. But our rules were
2 focused again on standards and interoperability and
3 leveraging modern API -- APIs. If you want to learn
4 more information about that, you can go to these links
5 here.

6 But for today's purposes, I want to focus on
7 how can we set the standards for digital innovation
8 and specifically for digital innovation with the use
9 of the Drug Facts labeling.

10 The first step is to think about how you're
11 defining your innovation community. For ONC, this is
12 who we defined our community as when it comes to
13 health IT innovation community. For the Drug Facts
14 labeling innovation community, it may be different.
15 I'm sure that you think of the manufacturers of these
16 products as being one of your key stakeholders, those
17 who were printing the labels and in charge of making
18 sure that they're complying with getting the right
19 information on there.

20 But I think, as we want to broaden that tent,
21 you think about also those who are interacting with
22 the consumer on behalf of those manufacturers, so the

1 retail settings, retail clinics, pharmacies, et
2 cetera. And maybe there are other ones as well.
3 There's a whole new emerging consumer e-health and
4 consumer engagement community that also might be worth
5 figuring out how you can engage them in this process
6 as well. And I'll share some examples later of where
7 that may become relevant.

8 The next thing to think of is after you
9 figure out who are the innovators you want to work
10 with to determine this and reaching outside of those
11 nontraditional stakeholders who you're used to working
12 with, the second thing is to think about where are
13 they in that innovation spectrum.

14 Are they -- are you looking to engage with
15 them at an early ideation stage, are you looking to
16 engage with them more around a development and testing
17 and building and validating and iterating or are you
18 looking to engage with them at the deployment support
19 stage?

20 And that's for commercialization, usability,
21 you know, et cetera. And so ideally you're figuring
22 out how do you engage with innovators at each and

1 every one of these stages to make sure that you're
2 covering them from a full product lifecycle.

3 But for today's purposes, I really wanted to
4 narrow in on two kind of key recommendations or
5 opportunity areas for greater innovation and use of
6 modern technologies and approaches. The first one
7 you've heard a lot about earlier in today's
8 presentations including from our friends in Canada.
9 But the use of embedded QR codes.

10 I know some of the earlier presentations were
11 really focused around using a code to direct you to a
12 website where you can get some more information. But
13 think a little bit broader than that. How can you use
14 it not just for educating the consumer but really
15 engaging the consumer? So for pharmacovigilance, for
16 ensuring proper use, behavior change, et cetera.

17 Translation services and engagement there,
18 you did say that as well before. When you do think
19 about education, not just perhaps a website, which is
20 the first option here, but other types of interactive
21 media including chatbots and other things that can
22 directly engage with the consumers.

1 Links to peer-to-peer community forums to
2 help them make decisions and understand reviews of the
3 product and other things. And then also for those
4 companies to be able to obtain consumer feedback or
5 even for the FDA and other regulators to obtain
6 feedback using surveys, adverse interactions reporting
7 and other types of comments.

8 But the second one is something that I wanted
9 to go a little bit deeper on. It somewhat relates to
10 the last topic that one of our previous presenters did
11 around the electronic standards side of things. And
12 this is being able to realize the full potential of
13 open data opportunities.

14 And so the idea here is that you partner with
15 industry to use the DFL standards in the online
16 digital marketplace. In the case of meeting consumers
17 where they are, so much of the purchasing is now moved
18 to an electronic environment.

19 People are buying with their cell phones, on
20 their websites, on their tablets, et cetera and not so
21 much in the actual physical brick-and-mortar place
22 holding a product in their hand and therefore we want

1 to make sure that those standards that are used on
2 paper-based labeling to assist education and helping
3 people make the decision at those retail environments
4 is happening also in the electronic retail
5 environments.

6 And then to work with civic coders and big
7 tech companies on feedback for future development of -
8 - and that's supposed to be of, not off, future
9 development of standards and releases of API
10 accessible/machine readable open data around Drug
11 Facts labeling and over-the-counter medication.

12 So here's one example I want to give you.
13 Nearly a decade ago -- actually, maybe even more than
14 a decade ago, there was a big push by Yelp, a big tech
15 company providing restaurant reviews and helping
16 consumers make educated decisions about where to go
17 eat their dinner for the evening and then also helping
18 businesses find those consumers, to incorporate public
19 health restaurant inspection scores and violations
20 directly into those pages for those on the yelp app.

21 And so you would see here, this was in the
22 city of San Francisco, one of the earlier

1 municipalities to do this. They were able to put a
2 health score directly in the information in the bottom
3 corner. And you could click on that and even see the
4 latest inspection reports and what were the violations
5 that led to that score.

6 In order to do this, they had to come up with
7 -- sorry, I'm back up here. They had to come up with
8 a standard nationally for how that open data was going
9 to be shared from the government agencies that were
10 doing the restaurant inspections with the general
11 public.

12 This was not protected information. It was
13 information that could be Freedom of Information Act-
14 requested. And the city of San Francisco, their
15 department of public health who did these inspections,
16 worked with Code for America, a civic coder national
17 organization working on open data, and Yelp to develop
18 a standard that ultimately led to the integration into
19 these.

20 If you go to it today, it has now evolved to
21 where there's a whole organization called HD Scores
22 that manages that now for Yelp. And I think they've

1 got close to half of the country geographically
2 covered with this type of information being available
3 in those Yelp reviews.

4 Some other examples that I wanted to share on
5 the electronic marketplace and how consumers are
6 interacting with the Drug Facts labels, if you go to
7 the CVS Mobile app, and this is just the other day I
8 did this, if I was looking for Zyrtec, something that
9 was approved for over-the-counter use not that long
10 ago, it has a number of screenshots of the packaging
11 itself that you can scroll through.

12 And as you can see, the first one, you can't
13 really read it. So if you try to pinch and grab and
14 zoom in on it, you can't read it again. It's very
15 blurred, right? Aside from that, they do have a
16 couple of other -- if you scroll down further, they do
17 have a couple of collapsible windows that you can open
18 up to get to some of that information.

19 In this case, CVS uses details, ingredients,
20 directions, warnings and reviews as their main
21 categories. And each one you click in and out of and
22 go back and forth. But even when you click into

1 those, the information is not necessarily using some
2 of those best practices for the consumer to be able to
3 easily understand and digest the information.

4 A lot of the hard work that went into the
5 font size, to white space, all those things that AHRQ
6 has worked on in the past with helping consumers
7 understand healthcare information doesn't quite
8 translate into those drop-downs. It's more than
9 likely more of a cut-and-paste and can be very arduous
10 for a user to read through that and to go back and
11 forth. But at least it's there, right?

12 For Walgreens, a competitor of CVS, they have
13 a slightly different format, a different user feel.
14 In this case, same style as far as having a number of
15 photos that are of the actual hard packaging. In this
16 case, if you were to zoom in, you can read it a little
17 bit better. They have higher rendering and the
18 ability to -- but that could also depend on your
19 device.

20 But nonetheless, they too, if we scroll down,
21 have it organized a little bit differently. In this
22 case, they have a description at the top and then they

1 have reviews being prioritized as the second category,
2 ingredients, warnings and then information about
3 shipping. And under description is where they merge
4 some of the other information that was separated in
5 the previous -- in the previous example.

6 And again, once you click on it and go into
7 it, you'll notice it's not exactly in the most user-
8 friendly way to digest the information. It's not
9 simple, not a lot of white space. It's just a lot of
10 text. In this case, they do have some bullet points,
11 but again, very hard to understand it compared with
12 all that innovation that's gone on into the paper-
13 based label.

14 Which leads me to the next point of how do
15 you get that improved. Well, one way is like the
16 restaurant example is that through openFDA, which is
17 an open data platform where some of this information
18 is already being made available and accessible through
19 an API, you could consider are there additional
20 standards and metadata standards that you need to work
21 on with industry and especially these retail
22 environments to figure out how is that data going to

1 be the most useful to them and how can they access it
2 in the most user-friendly way to ultimately enable
3 them to provide that information to the consumer
4 through their mobile apps and through their other
5 electronic means.

6 And so one thing to do is to look at some of
7 the existing data sets that are available and think
8 through, working with the community, how it can be
9 better standardized, how it could be more machine-
10 readable and accessible through an API and then reach
11 out to the big tech companies and other civic hackers
12 to figure out how can they incorporate that for
13 ancillary third-party uses to better serve the
14 community and their needs.

15 And that asks -- that begs the question of
16 what types of standards are mandated and required
17 versus what kind of role can the FDA play and the
18 federal government play in doing some convening and
19 coordination of volunteer standardization efforts.

20 The restaurant example I shared with Code for
21 America and the city of San Francisco wasn't something
22 that was mandated or required. It was developed in

1 partnership and encouraged for other health
2 departments to look at throughout the country at a
3 state, county, municipal level, the ones who were
4 doing these restaurant inspections and then ultimately
5 was adopted by a large number of them because of the
6 value it served in meeting consumers where they were.

7 And so I think a similar question could be
8 had here as far as what can the FDA do to not only
9 look at having the flexibility for their regulatory
10 requirements as well as what can they do to help
11 convene and go above and beyond that for greater
12 innovation and use of that type of information.

13 In the case of the regulatory environment, we
14 can look at one example where ONC most recently has
15 established a process for a certification requirement
16 called the standards version advancement process, or
17 SVAP.

18 In this case, ONC looks to set a floor for
19 standards that are required for certain aspects of
20 certification and then ultimately leaves the ceiling
21 open for people to innovate above and beyond that and
22 potentially try to get certified with the use of

1 standards that are not quite called out yet or that
2 are a little bit immature in the industry but are very
3 innovative and still meet the need.

4 In that case companies can -- and
5 organizations who are applying for certification can
6 let ONC know that although we are not looking at using
7 the currently required standard, there is a version of
8 another standard that we feel is more innovative and
9 we want to be one of the early ones to implement that.

10 And this process is streamlined and more
11 efficient than going through a complete overhaul of
12 the certification program or requirements for existing
13 standards. So it allows us to set a floor with that
14 current standard that's required but then let
15 organizations come to us and innovate above and beyond
16 that with a more streamlined process that we are given
17 the ability to put in place.

18 And this is similar to I think some of that
19 flexibility that you saw from our friends in Canada on
20 the earlier presentation. And the second one is again
21 working closely for that volunteer coordinating type
22 effort with the broader community.

1 In ONC's case, we just launched a new
2 opportunity to set a vision for the future of health
3 IT standards. It's called Health Interoperability
4 Outcomes 2030. And it's an open call, open source
5 call for people to tell us what do they want to see be
6 the outcomes ten years from now and what do we need to
7 try to get done in these next ten years when it comes
8 to it.

9 In this way, we can codevelop our goals for
10 future standards in partnership based on those shared
11 visions for the future. And in this case, when you
12 look at those third-party ancillary uses of some of
13 that data when it comes to the Drug Facts labeling,
14 same type of thing is to work with that broader
15 community and figure out what are all of the known
16 potential uses as well as unknown and help surface
17 some of those things that maybe aren't top of mind for
18 some folks but could also provide a great value to the
19 marketplace and to consumers.

20 So with that, thank you very much. And I
21 look forward to our panel discussion a little bit
22 later.

1 DR. DELLIBOVI-RAGHEB: -- Stephen for your
2 talk. I'd now like to introduce our next two
3 speakers, Dr. Laura Bix and Dr. Mark Becker, from
4 Michigan State University. The title of their
5 presentation is, "To See or Not to See? What does
6 Research Say About the Future of the Drug Facts
7 Label?"

8 TO SEE OR NOT TO SEE? WHAT DOES RESEARCH SAY ABOUT THE
9 FUTURE OF THE DRUG FACTS LABEL?

10 DR. BIX: Excellent. Thank you very much.
11 My name is Laura Bix, and I'm from the School of
12 Packaging at Michigan State University. I'll be
13 presenting with my colleague, Mark Becker, who is a
14 cognitive psychologist, works much more in fundamental
15 science than I do. And we've collaborated for a
16 number of years.

17 We'd like to provide some insights from our
18 research about the current approach to packaging and
19 labeling, but then also maybe some ideas about the
20 future as well.

21 So long ago, I learned that you put your
22 acknowledgements up front. And I'd like to recognize

1 our collaborators in the work that's being presented
2 today at K-State and University of Wisconsin, Madison,
3 the current and former students that were involved, as
4 well as our community partners from the Tri County
5 Office on Aging, MSU Extension and of course the FDA
6 for allowing us or inviting us to come and present
7 some of our ideas.

8 In terms of the ideas that we have and the
9 presentation that we're making today, the first
10 section and the majority of the presentation will
11 focus on what our research says about improving the
12 current approach to packaging and labeling; that is,
13 stagnant, printed words, and very briefly at the end
14 we'll talk about some ideas that we have for
15 leveraging technology to shift the paradigm for the
16 DFL.

17 Long ago when we started, about 20 years ago
18 honestly, our review of the literature suggested three
19 gaps that we've concentrated our work on. As we
20 reviewed the literature, we found a tendency to assess
21 comprehension; that is, late-stage understanding of
22 the messages. While this is very, very important,

1 prerequisite to being able to understand is attending
2 or paying attention to the messaging. And in
3 particular, paying attention to information that is
4 critical for the safe and effective use of these OTC
5 products.

6 Additionally we identified the need to
7 objective measure -- that is, to sort of look at the
8 empirical evidence around how people behave as opposed
9 to asking them to self-report because frequently we
10 found that they would self-report things that they
11 didn't actually do.

12 And so the guiding principles of our work
13 over the years have been to use objective measures to
14 determine the attentional prioritization of different
15 design strategies with an emphasis on information that
16 was critical for the safe and effective use of these
17 products.

18 So the methods that we use include eye-
19 tracking, change detection, forced choice assessments
20 and absolute judgments. That comes from Mark's
21 fundamental field of perceptual psychology. And we
22 frequently use objective measures like speed and

1 accuracy in making a safety judgment.

2 So the first study that I want to highlight
3 for you we did about six years ago. And this was
4 Lanqing Lui's master's work. And Mr. Liu was
5 interested in how the formatting of information on the
6 PDF affected people's judgment or assessment of
7 whether or not a drug was appropriate for them to
8 take. This was sponsored by the Consumer Healthcare
9 Products Association.

10 And what we did was we took three drug
11 categories, namely pain reliever, cough and cold and
12 acid reducer, and within each category we had three
13 active ingredients and within each of the active
14 ingredients we had three levels of formatting. So on
15 the left -- or on the right there, you see the pain
16 reliever acetaminophen, one time with the brand name
17 formatted sort of boldly, another with the active
18 ingredient and a third with the purposes.

19 So this three by three by three gave us 27
20 trials where we eye-tracked 82 people that were over
21 the age of 65. And this should be showing you a very
22 fancy video of eye-tracking across these three-

1 dimensional objects as people answered the question is
2 this appropriate for me to take, yes or no.

3 Of the 82 people, 51 of them never turned a
4 single trial to the DFL. So 62 percent of the
5 participants that we tracked across 27 trials never
6 turned beyond the PDP when they assessed the question
7 is this appropriate for you to take, yes or no. By
8 contrast, seven people, or 8.5 percent of our trial
9 population turned all 27 trials in answering that
10 question.

11 Additionally we were very interested in the
12 trials that the pharmacist said, no, this is not
13 appropriate for you to take. And there were a total
14 of 334 of those. So after the eye-tracking was done
15 with the different formatting, we revisited the active
16 ingredients, the non-active ingredients and asked is
17 acetaminophen appropriate for you to take, yes or no.

18 Out of all of those trials, which there
19 should have been 82 times 9 is a total of 738 trials,
20 but ten people or ten trials were left blank. So we
21 had a total of 728 events. Of those 728 events, 334
22 times the pharmacist said no, this is not appropriate

1 for this participant.

2 When we looked at that 334 trials, 127 times
3 participants said yes, this is good for me to take.
4 This is appropriate for me to take when the pharmacist
5 said no or approximately 38 percent of the possible
6 combination. In terms of the 152 trials there, that's
7 the number of people that said maybe this is
8 appropriate for me to take when the pharmacist said
9 no, it's not.

10 So combining those, you end up with a total
11 of 84 percent of the time when we had the pharmacist
12 saying no, this is not appropriate for you to take,
13 people either said, yes, it is appropriate for me or
14 maybe it's appropriate for me. Only 16 percent of the
15 time did they say, no, it is not, agreeing with the
16 pharmacist. And 66 people total out of the 82, or
17 80.5 percent, had a yes/no combination within the
18 products.

19 Additionally interestingly 128 times -- we
20 also asked about familiarity with these active
21 ingredients. Were you familiar with this active
22 ingredient prior to -- prior to this study. Out of

1 the 127 trials, 118 times people indicated they were
2 familiar, which suggests that if you're familiar with
3 a drug, you're more likely to say, yes, it's
4 appropriate for me to take. I guess that's probably
5 intuitive, but also a little bit scary.

6 So the question that we got from all of this
7 is can we increase attention to critical health
8 information, that is information that is critical for
9 the safe and effective use of these products. And we
10 applied to the AHRQ and received a grant with
11 University of Wisconsin to look at this issue.

12 We had previously had an NIH grant that
13 looked at the efficacy of front-of-pack labeling
14 strategies for food. These are strategies where you
15 move specific nutrients to the front of the package
16 and maybe overlay qualitative assessment over the top
17 of those truncated nutrients.

18 And the research was quite clear saying that
19 if you moved information that was affiliated with
20 disease states -- that is, salt, sugar, fat and
21 saturated fat -- to the package's front, people were
22 more likely to attend them. They were better with

1 cross-product comparisons and even made better
2 decisions.

3 And so, with that, Mark's going to share some
4 of our AHRQ data with you related to OTCs.

5 DR. BECKER: Thank you, Laura. So we would
6 like to be able to leverage the work done in nutrition
7 front-of-pack labeling to try to improve OTC labeling.

8 However there's a major barrier in doing so,
9 which as Laura just said, in the nutrition world,
10 there seems to be pretty high consensus about the
11 things that were most important in terms of health
12 that would benefit from moving to the front of pack.

13 When we think about OTC medications, it's far
14 less clear that there's consensus about what aspects
15 of the Drug Facts label would be most important to
16 reducing adverse drug reactions and therefore would be
17 candidates to move to a front-of-pack label.

18 And so the first thing we did was try to
19 assess whether there was such a consensus. And to do
20 that, we surveyed experts. And in this case, we
21 surveyed 318 practicing pharmacists. And to begin
22 with, we asked those pharmacists to rank order the

1 importance of the various sections required in the
2 Drug Facts panel in order to determine whether there
3 was consensus about which sections were most important
4 for reducing drug reactions.

5 And three headings were -- had consensus that
6 they were rated as important: the active ingredients,
7 purposes and warnings. I will mention that in typical
8 packages, the active ingredients and purposes already
9 appear on the front of the pack, suggesting that
10 warnings may be the information that is most important
11 on the Drug Facts label that doesn't already appear on
12 the front of pack.

13 A couple more little things. One problem
14 with that is, as was discussed earlier today, warnings
15 can be really extensive. There are actually 13 kind
16 of subheadings in the regulations about types of
17 warnings that should be considered for inclusion in
18 the DFL.

19 Luckily we also had those experts rate those
20 13 types of warnings in terms of their importance.
21 And there was consensus that two warnings were
22 extremely important to reducing adverse drug

1 reactions. They were the "Do Not Use" warning and
2 "Ask a Doctor or Pharmacist Before Use" warnings. So
3 basically the drug-drug or drug-diagnosis warnings
4 were far and away seen as the most important warnings
5 to include.

6 Now I should as a side note mention that
7 these data I'm showing you are about importance at the
8 time of purchase. We had the -- sort of the
9 pharmacists also rank the importance of things at the
10 time of administration. And the data changed a little
11 bit. For instance, in terms of sections, the
12 directions become more important at time of
13 administration.

14 But using this information, we did find there
15 was consensus about which types of warnings were most
16 important to reducing adverse drug reactions. So we
17 used that information to try to create a front-of-pack
18 label.

19 So we started with a traditional label. This
20 is a flattened kind of mock label. And then we made a
21 front-of-pack warning label by pulling the drug-drug
22 and drug-diagnosis warnings from the DFL into a front-

1 of-pack warning that we placed on the front of pack.

2 And this work was just published in an
3 article by Harben, et al. There's more detail than
4 I'm going to go into today if you're interested in the
5 paper.

6 In addition to looking at front-of-pack
7 warnings, we also looked at whether highlighting that
8 critical information, the active ingredient and those
9 drug-drug, drug-diagnosis warnings would help drive
10 attention and help people make better decisions.

11 So those are the four types of labels that
12 we're going to -- that were used in the experiments
13 that I'm going to be talking about today.

14 So our first experiment was interested in
15 whether these label manipulations impacted attention
16 to that critical information. And to assess that, we
17 had 60 older adults perform a change detection task.
18 Now in a change detection task, what happens is you
19 show people an image and then an almost identical
20 image where only one thing has been changed.

21 In this case, we're changing the relatively
22 large brand name. and the subject's task is to detect

1 what's changing as these two alternate. And they
2 alternate with brief lights between them which keeps a
3 motion signal from drawing attention to the change.

4 And so there are some really nice things
5 about this task. The subject is tasked with just
6 finding a change. And finding a change when presented
7 in this way requires attention. And as a result, the
8 time to first detect the change can be used as an
9 index of when attention first gets to the information
10 that's changing.

11 In addition, since the subjects are simply
12 told find a change, it doesn't require telling
13 participants that warnings or active ingredients are
14 critical to our interest. And so we can evaluate the
15 attention to that information in people who aren't
16 explicitly looking for it. And in fact, across
17 trials, we had many other parts of the display change
18 in filler trials so that participants didn't key into
19 the importance of that information.

20 And that's important because we can evaluate
21 the attentional properties of these labels among
22 people not explicitly looking for that information

1 like many consumers who aren't explicitly looking for
2 that information. Or to put it another way, an ideal
3 label would be one that draws attention to critical
4 information even among those not looking for it.

5 So what did we find? So what I'm showing you
6 here is the data -- reaction time data for the active
7 ingredient trials. And there are a couple of things
8 you should note here. One is that when the change was
9 on the principal display panel rather than in the Drug
10 Facts panel, people were much faster at detecting it,
11 suggesting that there's a bias to attend to
12 information on the principal display panel even though
13 in our displays there were flattened packages where
14 both were visible simultaneously.

15 In addition you'll notice that the yellow
16 bars which represent the highlighted conditions are
17 all lower or faster than their blue counterparts,
18 suggesting that highlighting produced faster change
19 detection or drew attention.

20 If we switch to the data on warnings, the
21 same pattern emerges. When there was a front-of-pack
22 warning label, people were much more rapid at

1 detecting the change than when that same information
2 changed in the Drug Facts panel. In addition, again,
3 the yellow highlighted bars are faster than their blue
4 counterparts; that is, highlighting produced faster
5 change detection.

6 So a summary of experiment one is that
7 highlighting increased attention to critical
8 information and people tend to preferentially attend
9 to information on the principal display panel. And
10 therefore placing warnings on the principal display
11 panel increased attention to them. Well, while that
12 was true for people who aren't explicitly looking for
13 that information, in the next experiment we asked will
14 those same labels allow people to better use critical
15 information.

16 So for this experiment, we changed the task.
17 We had 68 older adults who used -- we presented them
18 with the same four labels. But their task now became
19 that they were given a prompt. So for instance, in
20 this example, the prompt was should this medication be
21 avoided by someone using a prescription for
22 Parkinson's disease. And these prompts required using

1 the warning information to answer them. And people
2 were to make a speeded yes/no response to those
3 prompts.

4 So what did we find? Well, if we look at how
5 well people -- I'm showing you both accuracy and
6 reaction time here. So if we look at how well people
7 were able to use those warnings as a function of the
8 label types, a couple things should become apparent.

9 One is both highlighting, so in terms of
10 accuracy, the yellow bars here, the highlighted are
11 higher than their blue counterparts. So highlighting
12 improved accuracy. And in general, having a front
13 warning improved accuracy.

14 If you switch down to look at the bottom
15 panel of reaction time, the pattern reverses which is
16 good because what that's showing you is that
17 highlighting produced faster accurate responses and in
18 general front-of-pack warnings was a trend towards
19 faster responses. So these are basically ideal data.
20 You're getting more accurate and faster with our
21 manipulations.

22 So in summary, there's consensus that

1 information about drug-drug and drug-diagnosis
2 warnings are important to the reduction of ADRs in
3 older adults. Putting these warnings into a front-of-
4 pack warning increases attention to that information
5 and increases the speed and accuracy of using that
6 information. Highlighting similarly appears to
7 increase attention and allow better use of that
8 information.

9 In a future experiment, we're going to eye-
10 track while participants judge whether an OTC is
11 appropriate for them given their health history. That
12 will allow us to assess how novel labels influence
13 attention and in turn support OTC decision-making.
14 And those will have 3-D displays. So they may produce
15 even larger effects because people would have to turn
16 to the Drug Facts label to use it.

17 So in conclusion, labels could be improved by
18 highlighting critical information and using front-of-
19 pack warnings that have the drug-drug, drug-diagnosis
20 warning. They increase early processing, or
21 attention, and usability of critical information and
22 therefore may reduce ADRs.

1 However even with an ideal label, there are
2 challenges. There are human errors, which I won't go
3 into because I think we've talked about that all day.
4 But there are also even within ideal labeling label
5 issues. And that's because the way a label works, to
6 find an appropriate OTC requires the search for an
7 absence of information.

8 What I mean by that is if I have diabetes,
9 I'm looking for an OTC with no warnings about
10 diabetes, which is the search for the absence of
11 information. And there's a lot of data from visual
12 search tasks that suggests that search for the absence
13 of information are problematic and slow, which brings
14 us to our novel approach. Laura?

15 DR. BIX: Oh, it took me -- sorry. It took
16 me a minute to unmute. So obviously this is a
17 multifactorial problem. Information processing can
18 occur for a myriad of different reasons. It could be
19 the size of the font. It could be the complexity of
20 the decision. It could be just the lackadaisical
21 approach to OTCs.

22 So our idea is basically we scrape existing

1 databases to identify possible combinations of drug-
2 drug or drug-diagnosis. We overlay a risk management
3 theory at three levels of risk; that is, this is good
4 to go, this is caution, see a pharmacist or this is a
5 definite stop for this combination.

6 And we build an app that interfaces to return
7 an actual answer through augmented reality to the
8 participants as they interrogate possible solutions
9 for OTCs. So with that, I think we're out of time.

10 DR. DELLIBOVI-RAGHEB: Thank you very much,
11 Dr. Bix and Dr. Becker, for your talk. We will now
12 take a short five-minute break, and resume at 3:35.

13 (Off the record)

14 DR. DELLIBOVI-RAGHEB: Welcome back from
15 break. It's my pleasure to introduce our final
16 speaker for session three, Dr. Eric Brass, from the
17 University of California, Los Angeles. The title of
18 his presentation is, "The Future of the Drug Facts
19 Label: Thinking Outside of the Box."

20 THE FUTURE OF THE DRUG FACTS LABEL: THINKING OUTSIDE
21 OF THE BOX

22 DR. BRASS: Thank you very much. Let me add

1 my thanks and appreciation to the FDA and the meeting
2 organizers for the opportunity to join you today, as
3 well as to all the previous speakers who have made
4 this a most interesting and worthwhile workshop.

5 Now speaking last on the program always has
6 its challenges. At least I was spared during the
7 break watching everybody grab their roller boards and
8 head to the airport. But nonetheless I'm faced with
9 the challenge of at the end of the day not only
10 keeping you awake but also trying to say something new
11 and different.

12 Knowing the quality of the speakers that were
13 coming before me, I knew that would be quite a
14 challenge. So what I've tried to do is synthesize
15 some of the ideas, put a little bit of spin on what I
16 anticipated people would be saying and try to put them
17 into a framework that I think might have value going
18 forward.

19 You've heard that the Drug Facts label
20 provided enormous improvements and advantages in OTC
21 labeling. But over the years, the limitations of the
22 current regulations have become clear.

1 Now I think this is particularly clear in the
2 area of innovation. As one tries to bring new
3 products into the marketplace that have the
4 opportunity to improve personal and public health, to
5 empower consumers and to further self-care, one finds
6 that the ability to use the Drug Facts label to
7 support those initiatives is often very challenging.

8 In fact, Drug Facts labeling becomes a
9 balancing act. There's the high desire for
10 readability, large font sizes, et cetera, but limited
11 space on the label. We like to include large numbers
12 of messages, warnings, cautions, et cetera, but risk
13 information overload. And we'd like to use icons to
14 help consumers, but there's always the risk that there
15 will be secondary confusion and that education is
16 required to use them properly.

17 Overall I think that it's clear now that
18 tweaking of the Drug Facts label yields only limited
19 benefits. For example, you've heard a lot about
20 information overload from efforts to place too many
21 messages on the Drug Facts label. Thus adding
22 information may actually decrease communication and

1 decrease safety of the product.

2 Well, how do we reduce this text burden?
3 You've heard opinions that not all messages on the
4 Drug Facts label are equally important and raises the
5 question whether some can be omitted. But it's
6 important, while not all messages may be equally
7 important, some individual messages may be uniquely
8 important to individual consumers. Again, this
9 inflexibility or the need for flexibility is
10 highlighted.

11 Some information could be moved to a consumer
12 information leaflet to supplement the Drug Facts label
13 and you've heard information and suggestions around
14 adjunctive communication tools.

15 Well, when it comes to limiting the amount of
16 messages or reducing the text burden, I'd like to
17 suggest one place to start. When one begins
18 constructing a Drug Facts label for a new innovative
19 product, often the starting point is the Rx label, and
20 an effort is made to map the information from the Rx
21 label into the Drug Facts label.

22 But I'd like to suggest quite explicitly that

1 not all information on the Rx label needs to appear on
2 the Drug Facts label. Remember the prescription
3 label's intended for healthcare professional and the
4 healthcare professional is better able to filter
5 information of minimal relevance in a particular
6 situation.

7 There's less risk of information overload or
8 incorrect decision-making if information that is
9 included is only a theoretical concern or rare
10 relevance in the selection process for that
11 medication.

12 Equally important, the prescription label may
13 include outdated information, especially around the
14 warnings. Often post-approval studies and scientific
15 advances may have superseded the label information.
16 Well, you might suggest, well, that's easy then. Just
17 check the prescription -- just change the prescription
18 label.

19 But often there are very limited incentives
20 for formal updating about prescription label and the
21 nonprescription innovator may not even own the
22 prescription product and therefore not have access to

1 the label.

2 And I pose the question to you should the
3 consumer actually bear the burden of irrelevant and/or
4 outdated information on a Drug Facts label simply
5 because it has historically been on the prescription
6 label.

7 In the category of no magic bullets, we've
8 heard a lot about icons and pictograms. They clearly
9 provide an accessible format to provide information to
10 varied consumers, including groups for whom text Drug
11 Facts label is less effective and has been shown to
12 improve communication in a variety of research
13 settings. But the same research efforts have made it
14 clear that the consumer must understand the icon
15 and/or pictogram.

16 Here we have a sign I came across in France
17 with all kinds of important warnings, at least
18 somebody thought they were important, that I was
19 challenged to decipher, including the one in the
20 middle there warning me that there were black holes
21 waiting to suck me up further down the trail. And
22 this was not a very effective communication tool

1 because I didn't understand what these apparently
2 French standard icons went.

3 Many of you have heard about the pictogram of
4 a pregnant woman with a red line through the drawing
5 intended to indicate do not use if pregnant which was
6 actually interpreted by some to mean it prevents
7 pregnancy. Now that may actually be an -- trouble
8 finding the original source for that. But it appears
9 in print on a regular basis.

10 So research supports the need for education
11 around the icon to ensure its proper interpretation.
12 And we need to also recognize that adding an icon or
13 highlighting or color to a complex Drug Facts label
14 may impact the communication of the non-icon messages.
15 Now we may think that the icon or the highlighting or
16 the color is the most important message. But again,
17 to some consumers, this would be distracting
18 information that's critical to them.

19 I think increasingly we need to think about
20 the Drug Facts label as not the complete reference but
21 the starting point for the consumer product interface.
22 As you've heard over the past 20 years, it's clear

1 that there are limits on what the existing Drug Facts
2 can do. But yet it's clear as well that there are
3 untapped opportunities to increase consumer access to
4 safe and effective drugs and improve the efficiency of
5 the healthcare system if product-related message
6 delivery could be optimized.

7 But we mustn't lose sight that the Drug Facts
8 labeling and all drug labeling must meet the
9 consumer's need for safe and effective use.

10 So I'd like to propose a slightly different
11 framework for thinking about the Drug Facts label in
12 the future. While the Drug Facts label must continue
13 to provide the most critical information, and while,
14 if needed, effectively guide the consumer to
15 adjunctive resources that ensure safe and effective
16 use.

17 It is that guiding to the adjunctive sources
18 of information that I think needs to be emphasized
19 going forward where the Drug Facts label is simply the
20 starting point of that consumer journey to use the
21 product in a safe and effective way.

22 Now technology has been talked about as one

1 of those adjuncts to assist in Drug Facts label
2 communication. I think it's useful to reflect that
3 the Drug Facts -- any adjunctive intervention has to
4 be designed to mitigate specific barriers to a
5 specific Drug Facts label's effectiveness. That is
6 this is not one solution fits all. One needs to
7 understand what -- how a specific product is going to
8 be used by consumers and what the barriers to
9 communication are going to be.

10 For example, there might be the need to
11 communicate more messages effectively to consumers.
12 This might be done by presenting discrete messages in
13 an uncluttered and sequential way. Importantly
14 there's the opportunity to use adaptive presentation,
15 so only those messages that are relevant to the
16 individual consumer based on those individual
17 consumer's needs need be seen by that consumer.

18 There are a variety of strategies to
19 implement such strategies. You've heard about
20 smartphone apps, QR codes, point of purchase tablets,
21 et cetera, all of which may be right for individual
22 products depending on the need of the communication

1 objectives.

2 We've also heard about the need to
3 communicate messages effectively to more consumers.
4 We need to personalize the presentation and use other
5 strategies to increase engagement which is going to be
6 different for different consumers. The use of
7 pictures and video may assist in this.

8 We may present alternative syntax for
9 different consumers based on their literacy, heritage
10 or other factors. And there is obviously the
11 potential for language translation capabilities.

12 Technology can also provide post-purchase
13 assistance, reinforcing messages about directions for
14 use, potential criteria for deselection and other
15 important messages.

16 The FDA's NSURE initiative has opened the
17 door to this type of innovation even as detailed
18 regulations are pending. But I feel strongly that
19 this provides an opportunity today for sponsors to
20 leverage the opening of NSURE, to provide evidence-
21 based solutions to mitigate barriers in Drug Facts
22 label effectiveness.

1 I want to just spend a second about this
2 concept of adaptive presentation and prioritizing the
3 important messages and eliminating the irrelevant. It
4 can easily be seen how some early questions can make
5 subsequent messages more or less relevant.

6 Simply asking the sex of the consumer might
7 make breast cancer, oral contraceptive and pregnancy-
8 related messaging relevant to a female but need not be
9 shown to the male who might see instead warnings about
10 prostate cancer or problems with benign prostatic
11 hypertrophy that are relevant for that specific
12 product.

13 This can be further broadened in terms of
14 prioritization. For example, simply by screening on
15 the basis of age, an elderly consumer, and I'm over 50
16 by a lot, so I can call that elderly, might be
17 interested or may be most relevant messages around BPH
18 or heart disease and non-age-dependent warnings may be
19 less important.

20 But for the consumer under 50, some of those
21 non-age-dependent warnings may be most relevant to
22 them, might be presented earlier and the BPH or heart

1 disease messages can appear later or may not even be
2 relevant at all, depending on the specific product.

3 So here you can see the blending of the kind
4 of decision-tree algorithms that you saw earlier with
5 the identification of the prioritization you heard
6 from Laura that can be integrated into an adaptive way
7 of presenting discrete messages in a most relevant
8 context for the consumer. So this type of adaptive
9 presentation may result in an individual consumer
10 seeing actually fewer messages and better
11 communication of those that are actually seen.

12 Now some of this is happening in the
13 healthcare marketplace already. This is the Ellume
14 COVID-19 home test kit which was introduced under an
15 emergency use authorization in December of 2020. Now
16 I understand an EUA under the conditions of a pandemic
17 may not be the most generalizable precedent. But I
18 think it introduces some very useful concepts.

19 The authorized labeling for this product
20 included all of the following. It included the box
21 labeling which included a quick start guide. This
22 guided the consumer to an animated instruction video

1 as well as a home test app. These features were not
2 adjunctive but were actually integral to the product's
3 use. And all this was laid out on the packaging
4 label. But that information was not sufficient to use
5 the product, but was sufficient to guide the consumer
6 on how to access that other information.

7 This opens up a number of other
8 considerations, some of which were alluded to earlier.
9 With the proper technology, the consumer may have the
10 option of sharing the results with, for example, their
11 personal physician, healthcare authorities or their
12 employer in a very seamless manner.

13 It may facilitate access to relevant
14 healthcare educational materials which the consumer
15 can use to better understand their test results and
16 what to do with the results once they have them. But
17 the sophistication of this test and the need for a
18 smartphone means that it will not be usable for all
19 consumers.

20 This leads to another concept that I think
21 should be considered looking forward. Should the
22 inability of some consumers to use the product -- or

1 I'm sorry, specifically the inability of some
2 consumers to use the product should not be a barrier
3 to approval of the product.

4 An innovative product may have a highly
5 favorable benefit-risk for consumers, but only for
6 those who are able to use the product correctly.
7 Well, you might naturally ask what about consumers who
8 can't use the product due to reasons of technology
9 requirements or complexity.

10 I would suggest the relevant questions to ask
11 are whether for those consumers who are unable to use,
12 is there actual harm if they attempt to use or will
13 they simply not select to use the product. And can
14 the consumer determine their ability to use the
15 product prior to purchase?

16 Should some consumers be denied the benefit
17 of a product that other consumers are unable to use?
18 For such products, the potential for both individual
19 and public health benefits may be very substantial.
20 And obviously the industry has incentives to maximize
21 the number of consumers who are able to use,
22 suggesting that there'll be every effort to increase

1 the population that will be able to use the product
2 safely and effectively. But again, as one considers
3 increasing use of technology, universality may not
4 necessarily be the right priority.

5 Just a reminder about another underutilized
6 adjunctive technology, and that's the pharmacist. The
7 challenges here are how to ensure that we provide
8 value-added for all stakeholders, the pharmacist, the
9 consumer, the sponsor and the overall healthcare
10 system.

11 Clearly this means that the pharmacist should
12 not be required to do simple clerical or
13 nonprofessional level tasks and the adjunctive use of
14 a pharmacy should not be a default behind-the-counter
15 classification but only should be used where it truly
16 mitigates a limitation.

17 Clearly the pharmacist has the ability to
18 implement and interpret facile tools designed to
19 ascertain information critical to the selection
20 decision or the deselection decision with repurchase.
21 And certainly the role of pharmacist in vaccine
22 administration provide an example of their ability to

1 serve in an expanded role as well as integrate other
2 healthcare information with the selection to choose
3 the vaccine.

4 Now I want to emphasize that unambiguously
5 there is a need to ensure that any future improvements
6 on the Drug Facts label are truly evidence-based. And
7 the obligation is on the sponsor to provide regulators
8 that evidence. And that evidence needs to be clear
9 and convincing of the substantive benefit-risk
10 associated with any improvement.

11 But at the same time, I think we are missing
12 opportunities for research in a variety of marketplace
13 experiments that are occurring all around us that I
14 think are important in better understanding the
15 environment in which these further improvements are
16 going to be introduced.

17 Evolutions in the worldwide marketplace allow
18 for research to inform future regulatory decisions.
19 For example, what is the impact of pharmacists in the
20 markets that have a behind-the-counter class? Now you
21 ask anybody, and they will give you an opinion. Many
22 feel that the pharmacists actually don't provide

1 value-added, they are a rubber stamp and that they are
2 actually a barrier. Others feel that pharmacists play
3 an important role.

4 But you'd be hard-pressed to find evidence in
5 the literature as to which of this is true and how to
6 maximize the value of the pharmacist as an adjunctive
7 information source.

8 When we talk about reclassification of
9 products, we have the opportunity to study how
10 consumers respond in a market when a product is down-
11 classified. For an example, diclofenac was down-
12 classified in the UK. So it would no longer be
13 available without a prescription. Well, people who
14 were using diclofenac non-prescription, what did they
15 actually elect to do when it was down-classified?

16 And were there unintended consequences so
17 that they actual used alternatives that increased
18 their individual health risk? How do consumers use
19 other healthcare products that have adjunctive tools
20 such as the COVID test kit I just shared with you?
21 Are consumers able to do this? What features do they
22 find user-friendly? How to make it more value-added?

1 Do consumer-healthcare provider interactions change
2 after an Rx-to-OTC switch?

3 Again, a very important issue and concern
4 around consumers being diverted from other healthcare
5 provider services by accessing products exclusively in
6 the OTC environment. Is there a harm from a decrease
7 in other healthcare services?

8 So in summary, going forward the Drug Facts
9 label I feel should be viewed as the starting point
10 for consumer communications. It is okay if
11 information on the Drug Facts label is necessary but
12 not sufficient.

13 Adjunctive tools can be used to enhance
14 decision-making, including the purchase decision, the
15 use decision, ensuring proper use as well as the
16 deselection decision. Decisions on messaging
17 strategies should be evidence-based with focus on
18 product-specific, clinically important outcomes that
19 improving behaviors that are not clinically relevant
20 should not be the focus of ongoing efforts.

21 So I thank you for your attention. I
22 appreciate your staying with me through what has been

1 after a long day, and I very much look forward to the
2 panel discussion.

3 DR. DELLIBOVI-RAGHEB: Thank you very much,
4 Dr. Brass, for your talk. It is my great pleasure to
5 introduce our moderator, Dr. Elisabeth Walther, from
6 FDA's Office of Nonprescription Drugs, who will be
7 moderating our last panel discussion. Welcome, Dr.
8 Walther.

9 Our panelists will be Barbara Kochanowski,
10 Jason DiMuzio, Stephen Konya, Laura Bix, Mark Becker
11 and Eric Brass. Our panel discussion will last for
12 about 30 minutes, and will conclude at 4:25 p.m.

13 PANEL 3: THE FUTURE OF THE DRUG FACTS LABEL

14 DR. WALTHER: All right. I think we are
15 almost all here. So we'll get started. We'd like to
16 thank you all, especially for all those that came to
17 present for us.

18 With this third panel, we're going to really
19 take time to focus on everything that we've heard
20 today and really brainstorm about the future of the
21 DFL and how we can take where we've been and really
22 move it into the future.

1 The good thing is, is because we're talking
2 about tomorrow and the future, there are no wrong
3 answers. So we will take your best brainstorming. We
4 will take your best ideas and really take the time now
5 to discuss them.

6 So again, thank you all. And we'll get
7 started with the first question. So, you know, we've
8 got -- we're almost out of this pandemic. But we've
9 been surrounded by and maybe overwhelmed by technology
10 this year.

11 We walk around with our heads down. We are
12 trying to get out of Zoom calls every day. There's
13 too much information. There's misinformation.
14 There's not enough information. It's hard really,
15 especially this year, to find a balance.

16 But really how do we take this and harness
17 this technology to increase public health to really
18 help the consumers. So I guess the big question is
19 how do we use this digital technology that we have at
20 our fingertips to really make the DFL both accessible,
21 but most importantly, usable to the consumers so as to
22 make sure they have the information but not to

1 overwhelm them? Eric, do you want to start? Dr.
2 Brass?

3 DR. BRASS: Sure. I think when thinking
4 about those challenges, and they're very real, I think
5 it's helpful to remember a couple of things. First of
6 all, the technology should be developed and applied to
7 solve a specific problem.

8 A Drug Facts label works well in a number of
9 settings. It works less well in others. What that
10 less well actually -- how it manifests itself is very
11 different for different products and different
12 consumers. So you first have to identify what problem
13 it is you're trying to solve. And I'm speaking
14 specifically around innovative products. What is it
15 you're trying to solve?

16 Second, you should select the technology and
17 the format of that technology in a way that is
18 specific to that problem and is most effective in
19 solving your problem. As you've alluded to, we have
20 technology all around us. And we use different types
21 of technologies to do different things. I'm talking
22 to you not on my phone right now because the images

1 would be too small. I've selected an alternative
2 platform. I wish it wasn't Adobe, but maybe that's a
3 separate problem. But I've selected how I want to
4 engage in this.

5 And I think it's the same type of flexibility
6 and the opportunities around flexibility that we need
7 to keep in mind. And that's why I emphasize that the
8 opportunities are there for the sponsors to bring
9 forward innovative ideas in an evidence-based way, in
10 formats that the regulators can evaluate to make a
11 case for how this can be applied in a positive,
12 benefit-risk health perspective.

13 DR. WALTHER: Does anybody have anything to
14 add? Are there standards that we could put in place
15 to enhance this? Stephen? I think -- is he back on?
16 There he is.

17 MR. KONYA: Apologies. I've been having some
18 technical difficulties for the last couple of days.
19 Yeah. I think it's continuing to take a look at
20 having standards for -- and we're still on question
21 one, correct? I got disconnected for a second there.

22 DR. WALTHER: Yes.

1 MR. KONYA: Yeah. Again, when you think of
2 the SVAP process that we have, and there are some
3 other examples, whether you look at our USCDI, U.S.
4 Core Data for Interoperability, there are areas where
5 we set a floor for that and say, at a minimum, this is
6 the type of data that needs to be shared, but then try
7 to leave that ceiling open by having an option for
8 industry to go beyond that, above and beyond that and
9 look at developing their own standards or sometimes
10 helping them develop those standards to say, you know,
11 for early adopters, those who want to be on the
12 cutting edge, here is the standardized approach you
13 can do.

14 While it's not mandated or required yet, it
15 could potentially be in the future. So it can serve
16 as kind of an on-ramp ultimately for something that is
17 reinforced in regulations down the road. It gives you
18 a chance to kind of test out some of the value of
19 having those standards in use. And again, it allows
20 the industry to move ahead of being mandated and
21 required to do it which can take, you know, a long
22 time --

1 DR. WALTHER: A long time.

2 MR. KONYA: -- to get into place through
3 rules and regulations and whatnot. You know, there's
4 a cycle for that.

5 When we look at ONC under the 21st Century
6 Cures rule act, you know, you had the time that the
7 act took to get passed in Congress with broad
8 bipartisan support and then the ONC and CMS
9 interoperability rules that were written to actually
10 have the devil in the details of how, what was going
11 to be mandated and required, that took another, you
12 know, year to two years to develop in an open process.

13 And then there's a two- to three-year horizon
14 on the implementation where we hold people accountable
15 to that, right?

16 So you're looking at a five- to eight-year
17 horizon, and technology certainly moves much faster
18 than that. So it's really critical and important that
19 as we use the regulatory process and the rulemaking
20 process and all of that and certification process to
21 catch those laggards and those who are straggling
22 behind and bring them along for the ride and make sure

1 that, you know, everybody's in a more innovative,
2 industry-driven, consensus approach and having a way
3 for the government to help kind of surface and bring
4 visibility to that certainly always provides value --

5 DR. BRASS: I think --

6 MR. KONYA: -- because it allows you to do it
7 on a much faster horizon.

8 DR. BRASS: I was going to say I think
9 there's a spectrum across what you're referring to.
10 Clearly if a consumer wants to communicate to the
11 healthcare provider or the healthcare system that
12 they've taken a drug and their app is going to do
13 that. It'd be very helpful to have a standard for how
14 that communication of healthcare information is
15 standardized.

16 On the other extreme, how the consumer is
17 interfacing with the drug information, I think the
18 more flexibility you provide for how that actually
19 accomplishes the more consumers you're going to be
20 able to service effectively.

21 MR. KONYA: Yeah. I'd agree with that. And
22 that's where I think that the open data push -- again,

1 I may be misinterpreting you, but I think that when I
2 was mentioning that, it's one way of the FDA opening
3 up information that has to be reported to them in a
4 user-friendly way to let third parties and others make
5 good use of that data to meet the consumers' needs in
6 a number of different ways, right?

7 So it's not just on the paper label in the
8 back. If somebody's buying something online and they
9 don't have access to that, how are you going to help
10 them make that decision?

11 And there's a lot of other digital tools and
12 consumer engagement practices through mobile health
13 apps, through other means that could be empowered and
14 enabled if they have that same minimum data that's
15 being reported and could provide it in an updated way.

16 If you look on the CVS and the Walgreens
17 apps, when I shared that example, they had disclaimers
18 out the wazoo about, you know, this may not, you know,
19 have the most up-to-date information or whatever.
20 Basically it's a snapshot in time.

21 And the same thing on the open FDA website
22 when they talk about their datasets, that they only

1 have currently what was last reported to them. There
2 may be new information that hasn't quite been reported
3 to them yet and hasn't been made available into that
4 database yet.

5 Well, if you provide an open data format that
6 helps people subscribe to it, like CVS and Walgreens
7 subscribe to a data list through an API, then as that
8 data gets updated, Walgreens and CVS don't have to go
9 back and manually update that information.

10 The API when it's refreshed, you know, if
11 they've subscribing to it, you know, every so often,
12 as it's refreshed, that new information is
13 automatically updated from the FDA database to those
14 apps in real time without any human intervention.

15 So it just streamlines all of that updating
16 in the marketplace as well. So those were some of my
17 thoughts. And again, it could be used for any --

18 DR. WALTHER: Yeah, I was going to say
19 there's --

20 MR. KONYA: -- any number of consumer
21 engagements.

22 DR. WALTHER: Yeah. I was going to say, you

1 know, again, it's all that information and trying to
2 get the right information.

3 But, you know, over-the-counter drugs are
4 used by such a large percentage proportion of
5 Americans. And, you know, we've talked throughout the
6 day about how different we are as Americans.

7 We have different languages. We have
8 different health literacy, different reading literacy.
9 And so there isn't a one-size approach for all the
10 different consumers of over-the-counter products.

11 And so as we contemplate all these further
12 things that we can do digitally, how do we also make
13 sure that we can innovate paper as well so that the
14 paper doesn't kind of get left behind as we continue
15 to move digitally.

16 How do we move them both forward, and can we
17 do both? And I think, Barbara, you talked a little
18 bit about that in your presentation.

19 DR. KOCHANOWSKI: Sure. I think from anyone
20 who makes a product prospective, there will have to be
21 a label on it. There will have to be core
22 information. But today we heard a lot of great ideas

1 about how to go beyond the label. That's sort of the
2 NSURE concept as well.

3 But is there a way to then connect people
4 that want to sort information differently or filter
5 information or do, you know, different things with the
6 label information and then get expanded information
7 too in another language or, you know, in a different
8 font size.

9 All of that can be done digitally as long as
10 we start with the core regulated text, that would be
11 the base Drug Facts labeling.

12 So I would love to see us be able to try some
13 of these experiments and start getting feedback
14 because any of us with products know that consumers
15 are not afraid to give us feedback.

16 They see something they don't like, they call
17 that 800-number. They send a comment on the website.
18 There's a constant loop of feedback and suggestions.
19 So I think if we open that door, we would get a lot of
20 help in improving things.

21 DR. WALTHER: Yeah. I think so. And just as
22 a follow-up to that, how do we know what works? You

1 know, I use a lot of technology in my life, whether
2 it's personally, professionally.

3 But then at the same time, more than
4 anything, I love my paper copies of the Code of
5 Federal Regulations. I love my paper copy of the
6 Food, Drug and Cosmetic Act. You know, I love to just
7 feel it and read it and I know how to find information
8 there.

9 So, you know, how do we assess what really
10 does work with consumers and what version is both
11 accessed and used by the consumers?

12 DR. KOCHANOWSKI: Well, we've talked about
13 metrics, you know, social media websites, anything
14 that's accessed electronically. I'm sure Stephen can
15 speak to this too. There are ways to measure every
16 time a consumer hits something. I see Jason nodding
17 his head as well. So I think we can definitely set up
18 ways to measure things.

19 And then, I think as Eric said, what works
20 for someone might not work for someone else. If I'm
21 looking for a French version or a Spanish version of a
22 label, you know, that's what I'm going to go look for.

1 But that doesn't mean that we make bilingual labels in
2 the U.S. yet. And so we can step our way there.

3 DR. WALTHER: And how is -- how is Canada
4 looking to evaluate some of the success with the
5 usability of some of your labels?

6 MR. DIMUZIO: So that's a really great
7 question, and I think, you know, in reflecting on the
8 question, that's something that Health Canada I think
9 continuously struggles with is to think about, okay,
10 acknowledging we have this paper-based, you know,
11 product carton in front of us.

12 We don't really know how to evaluate how
13 often it's used beyond, you know, the common metrics
14 of focus groups, surveys, that type of thing. And
15 then when we compare that to the digital space, you
16 know, like Barb was mentioning, we have all these
17 opportunities to run analytics to say, okay, you know,
18 that got that many social media clicks and people
19 spent x number of minutes on this webpage, that type
20 of thing.

21 Those are all readily available for us and
22 I'm thinking in the context of in an electronic Drug

1 Facts table, right, where we already have websites
2 available, those are metrics I'm sure can be pulled
3 rather simply.

4 The one thing that, you know, is difficult
5 though, and from my perspective, you know, perhaps the
6 Canadian context is a little bit different. We heard
7 that, you know, most folks have a smartphone. I
8 imagine it's the same, you know, in the U.S.

9 But for Canadians, cell phone service and
10 data packages are quite expensive still. And so there
11 is that kind of economic disparity and, you know,
12 earlier in the presentations we spoke about health
13 equity and applying an equity lens to it.

14 And Eric, completely, 100 percent agree with
15 the notion of, like, okay, driving innovation has to
16 come at a cost, right? And we're not going to be able
17 to take everyone along with us at the same time. But
18 perhaps we can't simply stop innovating and stop
19 benefiting from these types of technologies because we
20 can't capture everyone, right?

21 So we have to keep moving forward. But
22 that's one of the things that, you know, Health Canada

1 continues to look at. How can we leverage some of
2 those capabilities in the e-labeling space and, I
3 mean, not only -- we're looking not only at the Drug
4 Facts label but also in terms of, you know, some of
5 the promotional materials for some of our prescription
6 drugs. You know, there's work underway there.

7 So really trying to identify what role will
8 electronic labeling play over the next, you know, 10,
9 15, 20 years, right?

10 Can it start to be viewed less so as a
11 complement to the conventional carton or the pill
12 bottle that you receive from your pharmacist and start
13 moving more to where I think a lot of our industry
14 colleagues and the researchers are suggesting, to, you
15 know, become more of the pivotal point of information
16 for consumers.

17 DR. WALTHER: Dr. Brass, do you have anything
18 else to add to that?

19 DR. BRASS: Yeah. I was just going to say
20 two things quickly. One is to remind everybody where
21 we are now. We don't know -- or what we do know is
22 not very encouraging about how people actually engage

1 with the Drug Facts label. So when you ask how are we
2 going to know how effective or how people use the new
3 technologies, I think we'll actually have better tools
4 to do that assessment.

5 And just to quibble a little bit with Barb, I
6 would again push for being even more innovative around
7 the concept of the Drug Facts label, that I think the
8 existing regs may need -- would benefit from
9 narrowing, to have less information, allow less
10 information on the Drug Facts label, as long as the
11 Drug Facts label was effective in guiding consumers to
12 the relevant information and ensuring safe and
13 effective use.

14 DR. WALTHER: Laura or Mark, do you have
15 anything to add based on your research and what you've
16 seen?

17 DR. BECKER: Well, I think the point that
18 Eric just made is really important, which is one of
19 the problems that we kind of seem to be glossing over
20 at some level is that people don't -- they don't use
21 the Drug Facts. You know --

22 DR. WALTHER: Right.

1 DR. BECKER: -- in some of the data Laura
2 presented, they don't turn to it. And so we could
3 build -- what I fear is we could build the best system
4 in the world. But if nobody wants to use it, it's not
5 going to be beneficial.

6 So I think there's a part here that people's
7 attitudes are generally that over-the-counter
8 medications are safe. And so they're not very
9 motivated to do any of the things that we could
10 create. And so I think part of this has to be some
11 way of educating people that there really are risks
12 associated with OTCs. And I think that has to be part
13 of any real solution.

14 DR. BIX: I think to add to that, you know,
15 I've done 20 years of eye-tracking studies now, many
16 of which were focused on OTCs. And one day I was
17 sitting with my 18-year-old, who's now older, but he
18 went to take something. And he didn't turn to the
19 DFL. And I was like, oh my gosh, he's one of those
20 people that don't look at it.

21 Well, then it occurred to me, he takes
22 nothing. He has no allergies. He knows the dosage.

1 He doesn't need to turn to the DFL. And that gave me
2 a slightly different paradigm to all those eye-
3 tracking studies that I'd done over the years. And it
4 started to occur to me that really what information is
5 important is contextual and it's personal.

6 And I think the beauty of the next wave is
7 that we can start to address at almost the individual
8 level getting you the information that you need. And
9 we know that people get overwhelmed by the one-size-
10 fits-all. They get -- they can't read the text
11 because of the one-size-fits-all. And so they just
12 take two sometimes.

13 DR. WALTHER: Two.

14 DR. BIX: So I think there's a lot of promise
15 in the future in being able to deliver something
16 that's personalized, which unfortunately my beautiful
17 graphics didn't work in my presentation.

18 But we've been able to superimpose, using
19 augmented reality, a floating icon over the drug. Now
20 we don't have all the brains behind it yet to see
21 which of those floating icons do you get based on your
22 information that's loaded into your phone.

1 DR. WALTHER: That is fascinating. And I
2 think --

3 MR. KONYA: I was going to just add something
4 onto the end of that as well. First of all, AHRQ,
5 love the work that they've done on eye-tracking.
6 They've done it -- they've even put out a guide for if
7 you're developing like a user interface with health IT
8 products and, you know, they've tracked eyes and
9 looked at making recommendations in the same vein.

10 And we use that at ONC to engage a patient
11 engagement playbook for providers to talk about how
12 they can engage with patients in healthcare settings
13 and in other ways. And we designed the playbook with
14 that same type of guidance that came out of AHRQ using
15 their eye-tracking.

16 Just in general, I wanted to react to a
17 couple of the comments here because I think when it
18 comes to the use of technology, and you're always
19 looking to leverage more innovative approaches for
20 engaging with the users of those technologies, there's
21 always going to be this challenge of not everybody's
22 going to engage with every aspect and every

1 functionality of every, you know, piece of technology.

2 However the people who really need it, you
3 want it to be as intuitive, user-friendly, easy to
4 digest as possible, right? And so while the average
5 consumer going through the Walmart, you know, aisles
6 may not use that label as much as we'd like and for
7 the purposes that it's there, there are a lot of
8 people who really heavily depend on that.

9 I can tell you for new parents who have kids
10 and they're buying their first medication over-the-
11 counter for their kids for an earache or something
12 like that or allergies, they absolutely are reading
13 through every single aspect there and trying to think
14 of how is this going to impact my child, right? At
15 least you would hope they are. And I know as a
16 parent, that I certainly have done that.

17 So there's certain use cases where they
18 definitely are more focused. But it's also one of
19 those things where if we look at the example of EHR
20 adoption, and we were looking to get more and more
21 health systems adopting electronic health records, we
22 had an issue of providers not wanting to use it at

1 first. Part of that was is it wasn't very user-
2 friendly, right?

3 The second thing is, you know, you get this
4 friction and resistance to using the technology when
5 it's not user-friendly. And the same thing when it
6 comes to patient portals.

7 As we started requiring EHR vendors to make
8 patient portals available to their patients to provide
9 that information to them, very low level of adoption
10 and very low level of engagement in those portals
11 partially because of how they were designed and
12 because they weren't that user-friendly.

13 Since then, you are seeing an explosion of
14 consumer engagement, hence the reason we had the
15 playbook for providers on consumer engagement. And it
16 is based on a more informed consumer around an active,
17 healthy lifestyle.

18 It is because of this wearables market and
19 other things that are integrating some of this data
20 and people want to take a little bit greater ownership
21 and be more empowered with their healthcare. And
22 they're looking to technology to help that.

1 We're seeing it when it come to patient-
2 generated health data use cases and them wanting to be
3 able to not only get data but contribute their own
4 data to the healthcare system. Ten years ago, that
5 was unheard of and the answer was nobody's going to
6 want to do that. Nobody's going to use it.

7 Times have changed. People are becoming more
8 and more comfortable using technology, certainly when
9 it makes their life easier and they can get benefit
10 out of it. We've just got to make sure that it is as
11 intuitive when it comes to it as possible so that it
12 doesn't push them away.

13 DR. WALTHER: So I think we only have a few
14 minutes left. And so I think maybe we can go around
15 to each of the panelists and maybe each of you could
16 say something about what you really think is next for
17 the DFL or what is the thing that you would improve in
18 the DFL.

19 I think it's the same question as kind of how
20 the last panel ended. What would you say to FDA as we
21 move forward? What do we do better? Jason, we'll
22 start with you in Health Canada. What do you have for

1 us?

2 MR. DIMUZIO: Oh, boy.

3 DR. WALTHER: What is the best thing that you
4 think you did that you want to tell the U.S.?

5 MR. DIMUZIO: That's a great question.
6 That's a great question. I think, you know, if I put
7 my regulator hat on, obviously there's a ton of
8 challenges with this, right? I think from my
9 perspective, as a regulator, we need to be really good
10 and clear on what the bar is going to be for industry,
11 right?

12 Stephen mentioned earlier about, you know,
13 setting the threshold. What is that minimum kind of
14 bar that we expect as a regulator? And then, from
15 there, establishing whatever boundaries are necessary
16 to, you know, allow the innovation to occur, allow
17 these different types of technologies to be, for lack
18 of better words, trialed, okay, applied, right,
19 presented even to the regulator, you know, to build
20 the comfort and to build the trust, right?

21 I think as regulatory agencies, we tend to
22 be, you know, sort of boxed in, in our view of, well,

1 this has worked or we think this works or we have
2 guidance that says this, so let's stick with that.

3 And so, you know, I think in this modern age,
4 it's important for us to really, as a regulator, turn
5 the lens back around and see, well, you know, drug
6 sponsors are really great at doing a lot of really
7 neat innovations. How can we leverage this to improve
8 the lives of, you know, our people?

9 DR. WALTER: Thank you. Dr. Brass, what
10 would you tell us at FDA? What does the future look
11 like?

12 DR. BRASS: So I'll say a couple of quick
13 things. One, ten years ago, we couldn't imagine what
14 technology would look like today. And I think the
15 same's going to be true ten years from now. And
16 therefore that the agency must maintain great
17 flexibility, keeping as its primary standard ensuring
18 that any product is safe and effective in the
19 marketplace in which it's introduced.

20 And then sponsors have the responsibility and
21 the opportunity to bring forth innovation in a
22 properly evidence-based way that could convince the

1 regulators that it's meeting that benefit-risk
2 standard, whatever technology they choose to use to
3 mitigate the limitations of the label.

4 DR. WALTHER: And Dr. Becker?

5 DR. BECKER: I guess I would suggest kind of
6 a three-pronged approach. I think there needs to be
7 the ability to try to improve existing OTC labeling
8 with the understanding that regardless of what happens
9 with technology, it's going to be phased in and there
10 are going to be some people who, for various reasons,
11 still have to rely on what's on the package.

12 So one phase I think would be looking at ways
13 to increase the signal-to-noise in the traditional
14 label. A second is I do think some education of the
15 public, so people who have a serious health concern
16 are probably not the people we need to meet, reach.

17 They are making -- you know, if they know
18 they've got something going on, they tend to be
19 careful and know where to find the information they
20 need for their particular thing.

21 But I think we need to expand the
22 understanding that there may be dangers involved with

1 this. And then ultimately, I think leveraging
2 technology for personalized, personalized and
3 directive augmented technologies. So as I was saying,
4 it's hard to search for lack of information, which is
5 what the current label does.

6 What you really want from kind of a human
7 factors standpoint is something that tells you, yes,
8 take this, it's fine. And right now, we don't have
9 anything like that.

10 But that's got to be -- to do that, it has to
11 be completely individualized to the individual, not
12 the product. So all products have to be part of
13 something that can be individualized to the
14 individual.

15 DR. WALTHER: Yeah. So Barb, I hope that
16 you've heard all this too. I'm sure we'll be working
17 together on this. Do you have any words before we
18 have Dr. Michele come and give her closing remarks?

19 DR. KOCHANOWSKI: Well, I think from the
20 regulated industry perspective, we are always up for
21 the challenges of trying to turn these ideas into
22 real-life products' labels examples and would love to

1 continue to be part of how to optimize and improve
2 DFL.

3 And then secondly, I think everyone was
4 thrilled to hear so much mention about NSURE to FDA,
5 we can't wait to see the proposed regulations.

6 DR. WALTHER: All right. Well, thank you all
7 very much.

8 DR. DELLIBOVI-RAGHEB: Terri, I think you're
9 muted.

10 AV SUPPORT: Dr. Michele, this is AV support.
11 I think you're muted from your telephone.

12 CLOSING REMARKS AND NEXT STEPS

13 DR. MICHELE: Thank you, AV support, as
14 usual. Defeated by technology. So it's a little bit
15 counterintuitive. But that's what I'm here to talk
16 about.

17 But again, thank you, everyone. This was
18 just such an impressive conference. I was hoping that
19 we would get a few things that we could take back and
20 think about. But we've gotten so much rich
21 information from all of the speakers.

22 So thank you all for that. And we're looking

1 forward to getting some additional information from
2 the public with our open docket. So I'd encourage you
3 to submit comments to that as well.

4 This is a great opportunity for us. I think
5 we're on the cusp of a lot of really neat things in
6 the OTC marketplace. And there are so many good ideas
7 here for us to think about, everything from some low-
8 hanging fruit that we can perhaps do some tweaks to
9 the Drug Facts labels to help it a bit, to some more
10 forward-looking things related to personalized
11 medicine. And that's a really cool concept to think
12 about what we can do in the OTC marketplace.

13 I think personalized medicine is just
14 starting to come in the prescription world. And now
15 here we're talking about it for over-the-counter. So
16 lots and lots going on here.

17 And again, I wanted to thank everyone who has
18 participated and all of you who have been on the -- on
19 the webinar for all day. Thank you all. And we'll
20 look forward to further discussion on this.

21 DR. DELLIBOVI-RAGHEB: Thank you, Dr.
22 Michele. Before we wrap up the workshop, I'd like to

1 acknowledge and thank all the speakers and panel
2 moderators for the wonderful talks and discussions.

3 I also want to thank the workshop organizing
4 team, the CDER public meetings team, the technical
5 team and all those who provided support and assistance
6 in coordinating today's event. It is with their
7 collaborative efforts and contributions that this
8 workshop has come to fruition. Lastly I'd like to
9 thank the audience for your participation.

10 Thank you all, and this concludes today's
11 public workshop.

12 (Whereupon, the foregoing was concluded.)

1 CERTIFICATE OF NOTARY PUBLIC

2 I, CARL HELLANDSJO, the officer before whom
3 the foregoing proceeding was taken, do hereby certify
4 that the proceedings were recorded by me and
5 thereafter reduced to typewriting under my direction;
6 that said proceedings are a true and accurate record
7 to the best of my knowledge, skills, and ability; that
8 I am neither counsel for, related to, nor employed by
9 any of the parties to the action in which this was
10 taken; and, further, that I am not a relative or
11 employee of any counsel or attorney employed by the
12 parties hereto, nor financially or otherwise
13 interested in the outcome of this action.

14 
15

CARL HELLANDSJO

16 Notary Public in and for the

17 STATE OF MARYLAND
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CERTIFICATE OF TRANSCRIBER

I, SONYA LEDANSKI HYDE, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

A handwritten signature in blue ink, appearing to read 'Sonya Ledanski Hyde', is written over a horizontal line.

SONYA LEDANSKI HYDE

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