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U.S. FOOD AND DRUG ADMINISTRATION

Public Meeting on Over-The-Counter Monograph
Drug User Fee Program (OMUFA) Reauthorization

Hybrid Meeting

Thursday, September 28, 2023

9:04 a.m. to 11:41 a.m.

1 **Meeting Roster**

2 **Nana Adjeiwaa-Manu**

3 Center for Drug Evaluation and Research, FDA

4

5 **James Baumberger**

6 American Academy of Pediatrics

7

8 **Heather Boyd**

9 American Pharmacists Association

10

11 **Eric P. Brass**

12 University of California, Los Angeles

13

14 **Patrizia Cavazzoni**

15 Center for Drug Evaluation and Research, FDA

16

17 **Maria Coyle**

18 The Ohio State University College of Pharmacy

19

20 **Theresa Michele**

21 Center for Drug Evaluation and Research, FDA

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Karen Murry

Center for Drug Evaluation and Research, FDA

Tom Myers

Personal Care Products Council

Ruth Parker

Emory University

Lisa Parks

Consumer Healthcare Products Association

Meredith Petillo

Independent Beauty Association

Jessica Satterfield

National Community Pharmacists Association

Dan Selechnik

Fragrance Creators Association

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Douglas Troutman

American Cleaning Institute

Cornell Stamoran

Pharma & Biopharma Outsourcing Association

Diana Zuckerman

National Center for Health Research

1	C O N T E N T S	
2	AGENDA ITEM	PAGE
3	Welcome and Introduction	
4	Nana Adjeiwaa-Manu	7
5	Opening Remarks	
6	Patrizia Cavazzoni	11
7	OMUFA Background and Reauthorization Process	
8	Karen Murry	16
9	Panel 1 - Health Care Professional	
10	Perspectives	38
11	James Baumberger	39
12	Heather Boyd	45
13	Jessica Satterfield	49
14	Panel 2 - Consumer/Patient Perspectives	53
15	Diana Zuckerman	54
16		
17		
18		
19		
20		
21		
22		

1	C O N T E N T S (continued)	
2	AGENDA ITEM	PAGE
3	Panel 3 - Regulated Industry Perspectives	62
4	Lisa Parks	63
5	Dan Selechnik	71
6	Douglas Troutman	77
7	Meredith Petillo	85
8	Tom Myers	94
9	Cornell Stamoran	97
10	Panel 4 - Scientific and Academic	
11	Perspectives	101
12	Eric Brass	102
13	Ruth Parker	111
14	Maria Coyle	118
15	Closing Remarks	
16	Theresa Michele	127
17	Adjournment	130
18		
19		
20		
21		
22		

P R O C E E D I N G S

(9:04 a.m.)

Welcome and Introduction

Nana Adjeiwaa-Manu

[Slide 3.]

DR. ADJEIWAA-MANU: Good morning, everyone, and welcome to this public meeting on the Reauthorization of the Over-The-Counter Monograph Drug User Fee Program or OMUFA. My name is Nana Adjeiwaa-Manu, and I'm with the Program Evaluation and Implementation staff in the Center for Drug Evaluation and Research or CDER. I will be your moderator today.

OMUFA authorizes FDA to collect user fees to support over-the-counter monograph drug activities. The current legislative authority for OMUFA expires on September 30, 2025. Preparations are therefore underway to begin the process to reauthorize the program for fiscal years 2026 through 2030. The purpose of today's hybrid public meeting is to gather input and recommendations from the public in advance of discussions that will occur with the

1 regulated industry.

2 [Slide 4.]

3 Today's meeting is an important step in
4 engaging with public stakeholders on features of
5 the OMUFA program.

6 We have a full agenda for our meeting today.
7 We will begin with Patrizia Cavazzoni, Center
8 Director of CDER, who will provide opening remarks.
9 Next, Karen Murry, who is the Deputy Director of
10 the Office of Nonprescription Drugs in CDER, will
11 follow with a presentation that will provide
12 background on OMUFA and the reauthorization
13 process.

14 We will then have panels, which will provide
15 perspectives from the following types of groups:
16 healthcare professionals; consumer and patient
17 advocates; regulated industry; and scientific and
18 academic experts. Following the panels, Theresa
19 Michele, the Director of the Office of
20 Nonprescription Drugs, will give brief closing
21 comments. I will then close the meeting around
22 12:30 p.m.

1 The stakeholder panels will include a series
2 of speaker presentations. Each speaker will have
3 10 minutes to present their perspective on OMUFA.
4 As we do have a full agenda, we will need to adhere
5 to that time frame. It will be my job to let
6 speakers know as they approach their time limit.

7 In the Federal Register notice announcing
8 this meeting, FDA provided two questions to help
9 panelists frame their comments. The first question
10 is, what new elements should FDA consider
11 recommending be added to the program to enhance the
12 efficiency and effectiveness of the agency's
13 over-the-counter monograph drug activities?

14 And the second question is, what current
15 elements of OMUFA should be modified to ensure the
16 continued efficiency and effectiveness of the
17 agency's over-the-counter monograph drug
18 activities? Policy issues are beyond the scope of
19 the OMUFA reauthorization process, therefore, the
20 presentations should focus on process enhancements
21 and funding issues, and not on issues of policy.

22 This meeting is an opportunity for FDA to

1 listen to public perspectives. FDA will not ask
2 questions, nor answer questions raised at the
3 meeting. Please keep in mind that you can submit
4 comments to a public docket that will be open until
5 October 27, 2023. We encourage everyone to submit
6 their perspectives to the public docket for FDA
7 review.

8 [Slide 5.]

9 As you can see on the screen in the next
10 slide, you can submit formal comments to the public
11 docket by clicking on the green button at the top
12 of the Federal Register notice.

13 A few housekeeping items. Since this public
14 meeting is being conducted in a hybrid format, some
15 speakers will be participating virtually. We thank
16 all of the speakers for their efforts to prepare
17 for this meeting, and we thank participants viewing
18 remotely for your patients.

19 If your audio or visual connection
20 diminishes, we recommend trying to reconnect
21 through the system. If you experience other
22 technical issues during the webcast, please e-mail

1 Grace Carmouze at grace.carmouze@fda.hhs.gov.

2 We will have a 20-minute break at about
3 10:30. If schedule modifications are needed due to
4 technical issues, we will communicate those
5 verbally and show them on the screen. For those of
6 you attending the meeting in person, please note
7 that restroom facilities are located down the hall
8 to the right of the conference room.

9 For press inquiries, please contact Cherie
10 Duvall-Jones, Office of Media Affairs at
11 cherie.duvalljones@fda.hhs.gov, or by phone at
12 301-357-0607. A video recording and transcription
13 of today's meeting, as well as the slides
14 presented, will be published on the FDA website
15 after this meeting.

16 I'll now turn it over to Dr. Cavazzoni for
17 some opening remarks.

18 [Slide 6.]

19 **Opening Remarks - Patrizia Cavazzoni**

20 DR. CAVAZZONI: Good morning. On behalf of
21 CDER, I also want to welcome you to the public
22 kickoff meeting that starts the negotiations for

1 the reauthorization of the OMUFA program.

2 Two hundred and forty million Americans use
3 over-the-counter drugs every year. OTC drugs have
4 long provided an efficient, low-cost way for
5 Americans to manage everyday health needs, and they
6 play an increasingly vital role in our healthcare
7 system.

8 Although manufacturers can bring
9 nonprescription drugs to market through a new drug
10 application, a large portion of the OTC drugs
11 marketed in the U.S. are regulated under the OTC
12 monograph system, which could be thought of as a
13 series of rule books for given therapeutic areas,
14 and these rule books specify conditions such as
15 active ingredients; uses or indications; doses;
16 routes of administration; labeling and testing,
17 under which an OTC drug is generally recognized as
18 safe and effective.

19 The beginning of an exciting new chapter in
20 OTC drug history began in March of 2020, in the
21 early days of the pandemic, when the president
22 signed into law the Coronavirus Aid, Relief, and

1 Economic Security Act or the CARES Act. This
2 included important reforms that modernized the way
3 OTC monograph drugs are regulated in the United
4 States, including the establishment of a user fee
5 program or OMUFA.

6 Over the first three years of the OMUFA
7 program, FDA made huge strides in setting up the
8 infrastructure that is needed to implement this
9 major change in how we regulate OTC monograph
10 drugs. During the first year of its
11 implementation, the FDA was able to meet the
12 following goals.

13 We posted all 33 OTC monographs deemed final
14 orders, established by operation of law, under
15 Section 505G of the Food, Drug, and Cosmetic Act.
16 We published a proposed order to amend the
17 sunscreen monograph, which has been long awaited.
18 We met performance goals for formal meetings
19 between FDA and OTC monograph drug industry.

20 We expanded the portal that enables certain
21 electronic OTC monograph submissions, which we
22 refer to this portal as the CDER NextGen Portal,

1 and we issued five draft guidances, one on formal
2 dispute resolution and administrative hearings; one
3 on the format and content of over-the-counter
4 monograph order requests, or OMORs; one on
5 assessing user fees under the OMUFA program; and
6 another one on how to provide over-the-counter
7 monograph submissions in electronic format; and
8 then one on formal meetings between FDA and
9 sponsors.

10 And last but not least, we developed and
11 made available an online portal to have regulatory
12 and policy documents pertaining to OTC monograph
13 drug activities at OTC monograph at FDA, and user
14 fee documentation at the OMUFA website.

15 The FDA has historically been underresourced
16 for activities related to OTC monograph drugs. The
17 resources provided by OMUFA, which have allowed us
18 to hire many more staff, among other things, are
19 critical for ongoing implementation of the OTC
20 monograph drug reform and to keep up with evolving
21 science and the fast pace of drug development.

22 The FDA is holding a public meeting to

1 obtain input on development of reauthorization
2 recommendations for the second iteration of the
3 OMUFA program, or what will be referred to as
4 OMUFA II. The FDA is required by law to negotiate,
5 with industry, recommendations for reauthorizing
6 the OMUFA User Fee Program as part of the OMUFA
7 reauthorization process. These negotiations can
8 also help the agency improve the efficiency of
9 these OTC monograph programs, including through
10 agreed-upon timelines for FDA's action on certain
11 regulatory matters.

12 Now that we have much of the infrastructure
13 in place for the OTC monograph reform program, we
14 hope to begin realizing the true promise of the
15 program, to meaningfully advance our efforts to
16 modernize the OTC monograph drug development, as
17 well as the review process, by improving
18 efficiency, timeliness, and predictability.

19 FDA is committed to using these new tools to
20 promote innovation in the OTC marketplace and
21 continue to ensure the safety and effectiveness of
22 OTC monograph drugs. We look forward to working

1 with industry and other stakeholders to continue
2 this transition to modernize the OTC monograph
3 process.

4 We especially look forward to receiving
5 input on the development of reauthorization
6 recommendations, and thank all of those who are
7 speaking today and also are in attendance here in
8 the Great Room, as well as online, and we also
9 thank those who will submit, or have submitted,
10 comments to the public docket. Thank you.

11 DR. ADJEIWAA-MANU: Thank you,
12 Dr. Cavazzoni.

13 I would now like to introduce Karen Murry,
14 the Deputy Director of the Office of
15 Nonprescription Drugs in CDER, to provide
16 background on OMUFA and the reauthorization
17 process.

18 [Slide 7.]

19 **FDA Presentation - Karen Murry**

20 DR. MURRY: Good morning. Next slide,
21 please.

22 [Slide 9.]

1 I'll be giving an introductory overview of a
2 few important topics. I'll briefly review why OTC
3 monograph reform and user fees were needed prior to
4 passage of the CARES Act with its OTC monograph
5 provisions. The monograph user free portions of
6 the CARES Act are often referred to as OMUFA, and
7 that abbreviation will be used throughout this talk
8 and through much of the overall meeting today.

9 I'll talk about what FDA has accomplished
10 since the CARES Act was passed. FDA is meeting all
11 its commitments, and I'll go into a bit of detail.
12 I'll then give some highlights of OMUFA's financial
13 information, review the reauthorization
14 requirements, and finally present some questions we
15 hope stakeholders will address.

16 Next slide, please.

17 [Slide 10.]

18 I'll start with why OTC monograph reform was
19 needed. The prior OTC monograph system, while a
20 good idea initially, became increasingly burdensome
21 over the years and was no longer fit for purpose.
22 It relied on complex multistep rulemaking, it was

1 very hard for industry to innovate, and FDA was
2 underresourced to ensure the effectiveness and
3 safety of the enormous OTC monograph program, which
4 includes more drug products, by far, than any other
5 FDA drug program.

6 Discussions between FDA and industry led to
7 proposed solutions. Together, they proposed a much
8 more nimble system. Most monograph rulemaking
9 would be replaced by administrative orders. These
10 orders can usually be signed off at the division
11 level, a huge streamlining of the process.

12 Industry would have a clear path for innovation;
13 industry and FDA could act on safety concerns more
14 quickly; regulatory uncertainty would be reduced by
15 a finalization process for proposed monographs; and
16 monograph user fees would add people and IT systems
17 to handle the new workload and commitments.

18 The HHS secretary transmitted a goals
19 document, which had been jointly written by FDA and
20 an industry team, to Congress in 2017, and FDA
21 provided extensive technical assistance to Congress
22 as it wrote a statute covering OTC monograph

1 reform.

2 Next slide, please.

3 [Slide 11.]

4 Then on March 27, 2020, CARES was enacted.

5 This was the Coronavirus Aid, Relief, and Economic
6 Security Act, and it included important statutory
7 provisions that reformed and modernized the way OTC
8 monograph drugs are regulated in the U.S. In most
9 cases, rulemaking for the OTC monograph is now
10 replaced by an administrative order process, which
11 is much more streamlined. The system now more
12 easily accommodates innovation by industry. The
13 CARES Act also authorized monograph user fees.

14 Of note is that date of enactment,
15 March 2020, right as the Office of Nonprescription
16 Drugs was plunged into the pandemic. It was an
17 extremely challenging time to implement a highly
18 complex new monograph program. The Office of
19 Nonprescription Drugs, or ONPD, was inundated with
20 pandemic work.

21 You recall the critical hand sanitizer
22 shortage, and ONPD's work made it possible for over

1 3,000 nontraditional facilities to manufacture hand
2 sanitizer to meet that need. What many do not
3 realize is that ONDP also handled more emergency
4 use authorization requests than any other FDA
5 entity because it was all hands on deck, and ONPD
6 handled all topical EUA requests, both prescription
7 and nonprescription. And as you all know, the
8 pandemic is not over. In spite of the pandemic's
9 absolute demands and the heavy IND-NDA workload,
10 ONPD has still been accomplishing all of its OMFUA
11 workload.

12 Another important thing to note is that the
13 legislation passed in 2020. While the goals
14 document was transmitted to Congress much earlier,
15 in 2017, there are substantive differences between
16 what was written in the CARES Act statute and what
17 was proposed in the goals document much earlier.
18 When these differ, FDA must follow the statute.

19 Next slide, please.

20 [Slide 12.]

21 The program began in October 2020, so we are
22 in year 3 now. This table shows the monograph

1 activities agreed upon in the goals document for
2 the first three years of the program. FDA is on
3 track for all of them, and you don't need to read
4 every part of this slide because I'll be going into
5 a bit more detail in future slides.

6 Next slide, please.

7 [Slide 13.]

8 This slide lists individual accomplishments.
9 Again, you don't need to read this slide in detail
10 because I'll talk about how FDA is doing on each of
11 these items in subsequent slides.

12 Next slide, please.

13 [Slide 14.]

14 First, hiring. In order to lay the
15 foundation and to handle the expected increased
16 workload from our commitments, FDA needed to ramp
17 up its monograph staff. The left column of this
18 table lists the fiscal years of OMFUA I, the middle
19 column lists the hiring goals from the goals
20 document for each of these years, the right column
21 lists the actual on board.

22 Hiring has been challenging due to a variety

1 of factors, including the huge competing priority
2 of the pandemic and its effects on HR systems.
3 Looking at that right-hand column in year 1, which
4 was fiscal year '21, you can see that in that
5 actual fiscal year, FDA was only able to onboard
6 13 new hires, but in the next year, FDA onboarded
7 the additional 17 hires needed to meet that goal of
8 30 you see in the middle column. In year 2, hiring
9 came closer, onboarding 19 in that fiscal year, and
10 then the additional 5 in the next fiscal year, to
11 add up to the goal of 24 in the middle column.

12 For the current fiscal year, FDA has
13 onboarded 11 people. ONPD has identified
14 candidates for all its open monograph positions for
15 this fiscal year. FDA will continue to work until
16 the agreed-upon positions are all filled.

17 Next slide, please.

18 [Slide 15.]

19 FDA has met its commitment each year
20 regarding the annual forecast. FDA agreed to
21 publish an annual nonbinding forecast of its
22 planned activities over the ensuing 3 years. FDA

1 publishes it each year by October 1st. FDA
2 generally decides what to place on the forecast by
3 public health priority. The forecast can include
4 any type of planned monograph activity such as
5 safety orders, finalization of the status of
6 general recognition of safety and effectiveness, or
7 others.

8 Next slide, please.

9 [Slide 16.]

10 Resources for IT systems were a significant
11 need for the monograph. Prior to monograph reform,
12 FDA had no monograph tech system at all. FDA has
13 met its goals for progress on this. There are two
14 types of systems. One is a public facing system
15 called OTCMonographs@FDA. There you can find many
16 useful links and important information.

17 There is also a portal where industry can
18 submit meeting requests, and in the near future
19 will be able to submit over-the-counter monograph
20 order requests or OMORs. In addition to this live
21 external system, FDA is also meeting its goals for
22 development of an internal system for archiving,

1 workflow, reporting, search, and tracking. This
2 will have great benefit for efficiency of monograph
3 review systems.

4 Next slide, please.

5 [Slide 17.]

6 As I just noted, prior to monograph reform,
7 no IT systems existed for the monograph. A large
8 number of paper documents existed that had never
9 been catalogued and could not be searched. Some of
10 these documents are not in a docket or anywhere
11 else that is publicly accessible. FDA agreed to
12 catalog these documents and make the catalog index
13 available. Once complete, sponsors, or requestors,
14 will be able to obtain these documents and perhaps
15 use them to support OMORs. The cataloging contract
16 has been issued and work is underway.

17 Next slide, please.

18 [Slide 18.]

19 FDA committed to writing several guidances.
20 Included among these is the guidance regarding
21 formal meetings between FDA and monograph sponsors
22 or requestors. Among the topics of these meetings

1 may be discussion of studies needed to support a
2 submission, matters relevant to the regulation of
3 monograph drugs, or discussion of development of
4 new monograph drugs. The processes in the guidance
5 will be quite familiar to sponsors who have met
6 with FDA regarding PDUFA products, as the
7 procedures parallel PDUFA meeting procedures in
8 many ways.

9 Because changes to the monograph often
10 affect multiple makers of monograph drugs, the
11 guidance includes information on procedures needed
12 to facilitate efficient participation by multiple
13 sponsors or requestors, or by organizations
14 nominated to represent their interests.

15 Next slide, please.

16 [Slide 19.]

17 Performance goals for formal meetings have
18 begun. For the current fiscal year, FDA committed
19 to meet 50 percent of total meeting management
20 goals for the first 12 meetings. These goals
21 include timelines for responding to meeting
22 requests, scheduling meetings, issuing preliminary

1 responses, and issuing final minutes. Currently,
2 FDA is exceeding those goals.

3 Next slide.

4 [Slide 20.]

5 FDA also committed to issuing a guidance on
6 the format and content of OMORs and a guidance on
7 submissions in electronic format. The content and
8 format guidance includes FDA's recommendations on
9 what content should be in OMORs and the format,
10 which generally follows the common technical
11 document. When requestors begin to submit OMORs,
12 they will need to be in electronic format. The
13 electronic format draft guidance includes
14 recommendations on how to manage the electronic
15 submissions.

16 Next slide.

17 [Slide 21.]

18 Another commitment FDA has fulfilled is for
19 issuance of a draft guidance on formal dispute
20 resolution and administrative hearings. It
21 describes the formal dispute resolution process,
22 which is quite similar to that for PDUFA. It also

1 describes an administrative hearing process that is
2 somewhat unique to the OTC monograph. FDA also
3 wrapped in guidance on consolidated proceedings for
4 formal dispute resolution for when more than one
5 party wishes to participate.

6 Next slide.

7 [Slide 22.]

8 Among the most labor-intensive activities of
9 OMUFA I was completion of the deemed final order or
10 DFO process, which is foundational for future
11 amendments and innovations to the OTC monograph.
12 When the CARES Act was passed, it established these
13 DFOs for 32 different monograph categories. The
14 DFOs were effective on the date of enactment, which
15 was March 27, 2020, but FDA had to do a tremendous
16 amount of research, writing, date checking, and
17 technical work to create a consolidated document
18 for each monograph category.

19 Each of these DFOs combines the most
20 recently promulgated regulations for a given
21 monograph into a single document. The process
22 required a great deal of cross-checking for

1 references and some technical amendments to make
2 sure that each order was appropriately harmonized;
3 however, FDA could not change the actual content of
4 any of the monographs. The statute required FDA to
5 determine what the most recent version is and to
6 post that version. Each DFO includes the relevant
7 references so that the reader can know which
8 documents FDA identified. These DFOs are all
9 posted on OTC monographs at FDA. Requestors and
10 FDA now have the baseline to be used for future
11 amendments.

12 Next slide.

13 [Slide 23.]

14 That DFO process was complex. First, FDA
15 had to review all final monographs published in the
16 Code of Federal Regulations and the rulemaking
17 histories for each therapeutic category. FDA
18 identified the DFOs that had been created by
19 section 505(b)(8). FDA staff then created a
20 document that included the most recently issued
21 version of the conditions of use and any technical
22 amendments that were necessary; however, as

1 mentioned earlier, no actual content was changed.
2 Each DFO was assigned a number and consequent order
3 ID, and was posted at OTCmonographs@FDA.

4 Next slide.

5 [Slide 24.]

6 FDA published 33 DFOs. The last five issued
7 here were posted May 2nd. Thirty-two of the DFOs
8 are for individual therapeutic areas and one
9 concerns non-monograph conditions. These DFOs are
10 very important because they had to be posted before
11 FDA could initiate safety orders and before
12 industry could submit OMORs to amend the DFOs. As
13 a next step, FDA will be issuing a Federal Register
14 notice to withdraw the corresponding regulations.

15 Next slide.

16 [Slide 25.]

17 FDA has been doing a great deal of training
18 on monograph reform issues, both for FDA staff and
19 for the public. Among that training have been
20 9 webinars listed here that FDA has given on a
21 variety of topics. We recommend watching these
22 webinars to get a good foundation on where

1 monograph reform is now and on how one can
2 accomplish important tasks such as meeting requests
3 and OMOR submissions.

4 Next slide.

5 [Slide 26.]

6 So that was a brief overview of what FDA has
7 accomplished so far, and FDA is meeting its
8 commitments. There's more to come in years 3 to 5.
9 FDA will continue hiring and training, and putting
10 out the annual forecasts. FDA will be finalizing
11 multiple guidances. Meeting management performance
12 goals will advance. FDA is working on an order
13 guidance pair to outline what changes to solid oral
14 dosage forms might be able to be made without
15 submission of an OMOR. Timelines and performance
16 goals for OMORs will begin, and FDA looks forward
17 to receiving those OMORs. FDA will continue
18 meeting with industry as sponsors and requestors
19 continue to advance their development programs.

20 Next slide.

21 [Slide 27.]

22 The portal for submission of OMORs will be

1 live soon. As I mentioned earlier, FDA will be
2 withdrawing regulations from the Code of Federal
3 Regulations for the monographs that have been
4 supplanted by deemed final orders, and again, FDA
5 will have timelines and performance goals for
6 OMORs.

7 Next slide, please.

8 [Slide 28.]

9 Next, I'll give a brief overview of some
10 financial information about OMUFA. This is a very
11 lean program with a target revenue of \$25.4 million
12 for fiscal year 2023. There are two types of fees,
13 facility fees and OMOR fees. There are two types
14 of facilities, monograph drug facilities,
15 abbreviated MDF, and contract manufacturing
16 organizations, abbreviated CMO.

17 Each has a very specific legal definition,
18 but basically, a CMO manufactures drugs for others
19 but does not itself sell the drug. Most facilities
20 fall under the category of MDF and pay a full
21 annual fee, which for fiscal year 23 is just over
22 \$26,000. CMOs pay a two-thirds fee or about

1 \$17,500. Facility fees provide the main source of
2 OMUFA revenue.

3 The second type of fee is an OMOR fee for
4 submissions of over-the-counter monograph order
5 requests. Most OMORs are expected to be tier 1
6 OMORs and have a full fee, which for fiscal year 23
7 is set at just over \$517,000. A defined set of
8 OMORs are tier 2. These are generally requests for
9 minor changes to a monograph, for example, certain
10 minor labeling changes. The fiscal year 23 tier 2
11 OMOR fee is just over \$103,000. OMORs for certain
12 proposed safety changes have no fee.

13 Next slide, please.

14 [Slide 29.]

15 As I mentioned, OMUFA is a very lean program
16 in terms of total revenue target. For a concept of
17 the relative size of the program, this slide shows
18 the fiscal year 23 target revenue for OMUFA in this
19 very small and perhaps hard-to-see blue column on
20 the left, and the fiscal year 23 target revenue for
21 the Prescription Drug User Fee Act on the right in
22 red, \$25 million for OMUFA versus \$1.3 billion for

1 PDUFA.

2 Next slide.

3 [Slide 30.]

4 This slide contrasts the amount for the
5 types of fees for OMUFA and PDUFA. For each of
6 these three pairs of columns, OMUFA is in blue and
7 PDUFA is in red. In the first pair of columns on
8 the left, you see the full fee for a monograph drug
9 facility is \$26,000 compared to \$416,000 for a
10 program fee for PDUFA. A PDUFA program fee is not
11 a facility fee, but instead is the fee assessed for
12 each prescription drug product under a specified
13 definition; however, for each of the programs,
14 these fees are the major source of user fee
15 revenue.

16 The middle and right-hand pairs of columns
17 contrast submission fees under OMUFA and PDUFA. In
18 the middle pair of columns, the blue column shows
19 the tier 1 OMOR fee of \$537,000 compared to the
20 \$4 million fee for a PDUFA new drug application
21 with clinical data, shown in red. The right set of
22 columns shows the fee for a tier 2 OMOR in blue of

1 \$107,000 compared to \$2 million for a PDUFA NDA
2 without clinical data, shown in red.

3 Next slide, please.

4 [Slide 31.]

5 So we have seen that OMUFA fees are much
6 lower than PDUFA fees; however, there are far, far
7 more listed monograph drug products than listed
8 PDUFA products. These data from the Electronic
9 Drug Registration and Listing System show in the
10 red column on the right that there are about 7,000
11 listed PDUFA products, while the blue column on the
12 left shows that there are about 41,000 listed OMUFA
13 products, far more. On a per-product basis, the
14 revenue for OMUFA is very, very low. OMUFA is a
15 good value. Relatively speaking, industry
16 contributes relatively little per product to
17 support FDA's work to ensure the safety and
18 effectiveness of these 41,000 listed monograph
19 products.

20 Next slide, please.

21 [Slide 32.]

22 So we've talked so far about FDA's

1 accomplishments to date under OMUFA I and about
2 financial aspects of OMUFA. As an overall message,
3 I'd like to circle back to some points about the
4 benefits of the reforms of the monograph system
5 supported by these user fees. Regulatory burden is
6 significantly reduced. Innovation is easier now,
7 with the potential for new markets and for
8 expansion of the breadth and depth of product
9 lines. Enhanced self-care is beneficial and can
10 reduce the need for more costly forms of care, such
11 as emergency room visits and doctor visits.

12 The reforms and FDA's commitments increase
13 efficiency, timeliness, and predictability of the
14 review process, and safety updates can now be
15 streamlined and more timely. These reforms were
16 guided by input from industry, consumer, patient,
17 and professional groups, and reauthorization will
18 also be guided by these stakeholders. FDA is
19 meeting its commitments, and OMUFA I has been
20 successful.

21 Next slide, please.

22 [Slide 33.]

1 Next, I'll give a brief overview of the
2 reauthorization process. This is spelled out very
3 specifically in the statute, but briefly, it begins
4 with a consultation process, including today's
5 meeting, where FDA seeks input from scientific and
6 academic experts, healthcare professionals,
7 representatives of patient and consumer advocacy
8 groups, and regulated industry. Congressional
9 committees are also involved in the consultative
10 process.

11 There will then be negotiations between FDA
12 and industry, beginning in the coming months and
13 resulting in a draft commitment letter. After
14 that, public review of the recommendations will
15 begin. The draft commitment letter will be sent to
16 the congressional committees. There will be a
17 Federal Register notice regarding the commitment
18 letter, followed by a 30-day comment period and
19 another public meeting. The final recommendations
20 are to be transmitted to Congress no later than
21 January 15, 2025.

22 Next slide, please.

1 [Slide 34.]

2 The previous slide provided a brief overview
3 of the reauthorization process. This slide
4 provides the details of the actual statutory
5 language for those who want to read it.

6 Next slide, please.

7 [Slide 35.]

8 So this brings us to why we are here today,
9 to listen to input from those stakeholder groups
10 mentioned. Here are some questions FDA has for
11 your input.

12 What new elements should FDA consider
13 recommending to be added to the program to enhance
14 the efficiency and effectiveness of the agency's
15 OTC monograph drug activities? And what current
16 elements of OMUFA should be modified to ensure the
17 continued efficiency and effectiveness of the
18 agency's OTC monograph drug activities?

19 Next slide.

20 [Slide 36.]

21 This final slide lists some other useful
22 references. One is for an overall explanation of

1 OTC monograph reform in the CARES Act, the link for
2 OTCmonographs@FDA is also here, and we've conserved
3 the historical status of rulemaking. Thank you.

4 [Slide 38.]

5 **Panel 1**

6 DR. ADJEIWAA-MANU: Thank you, Karen.

7 We will now move into the stakeholder panel
8 session. To keep moving forward on time, I will
9 announce when there is one minute left. At the
10 10-minute mark, I will ask you to conclude, and
11 then introduce the next speaker.

12 Our first panel provides healthcare
13 professionals' perspectives on OMUFA. Our three
14 speakers in this panel are James Baumberger from
15 the American Academy of Pediatrics; Heather Boyd
16 from the American Pharmacists Association; and
17 Jessica Satterfield from the National Community
18 Pharmacists Association.

19 James, you're first on the agenda. We
20 welcome your comments now.

21 [Slide 39.]

22 **Presentation - James Baumberger**

1 MR. BAUMBERGER: Thank you very much.

2 Good morning, everybody. It's a pleasure to
3 be here. My name is James Baumberger. I'm the
4 Senior Director for Federal Advocacy at the
5 American Academy of Pediatrics. The AAP is a
6 nonprofit professional medical organization of
7 67,000 primary care pediatricians, pediatric
8 medical specialists, and pediatric surgical
9 specialists dedicated to the health and well-being
10 of children.

11 AAP believes that it is important for the
12 health of America's children to ensure that FDA's
13 modernized over-the-counter drug regulation efforts
14 are well resourced, efficient, and productive. We
15 therefore strongly support the continuation of the
16 Over-The-Counter Monograph User Fee Program, and
17 urge sufficient resources for FDA to accomplish
18 public health priorities related to OTC products.

19 Every day in the United States,
20 pediatricians get urgent calls from anxious
21 parents, often in the middle of the night, asking
22 about the best way to treat their sick child.

1 Sometimes the answer is a prescription drug,
2 sometimes it's a non-drug supportive treatment, and
3 sometimes the answer is an OTC medicine that they
4 can access at their local drugstore. Because the
5 parents often rely on OTC drugs to treat their
6 children, it is essential that they can feel
7 confident in knowing that those products are safe
8 and effective. Pediatricians want to know that the
9 products they recommend have been tested in
10 children and labeled appropriately for their use.

11 Because we know that children are not just
12 little adults, the AAP believes that drugs used in
13 children should be appropriately studied
14 specifically for them. While we have made great
15 strides in improving new prescription drug
16 therapies for children through the Best
17 Pharmaceuticals for Children Act and the Pediatric
18 Research Equity Act, we have a long way to go to
19 bring this record of success to OTC monograph
20 drugs.

21 The AAP strongly supported OTC monograph
22 reform because FDA needed a modern process to

1 regulate these drugs that was responsive to the
2 best and most recent medical science. Many of the
3 OTC monographs are antiquated and have not been
4 adapted to emerging evidence and to changes in how
5 pediatricians practice medicine. They were, in
6 large part, developed based on the state of
7 evidence from over 50 years ago.

8 Some monograph drugs continue to be
9 mainstays of pediatric practice, but others provide
10 little or no benefit to children. Much of the
11 pediatric drug labeling included in the OTC
12 monograph was based on evidence that no longer
13 meets today's rigorous standards for safety and
14 efficacy or was based on incorrect assumptions
15 about how adult data should inform the labeling of
16 drugs in children.

17 While it was clear that the monograph must
18 be modernized, the previous process did not allow
19 for this modernization. Revising the OTC monograph
20 was cumbersome and slow, and therefore, the FDA
21 could not act quickly to respond to developments in
22 the science, public health and safety concerns, or

1 to product innovation. AAP supported reforms to
2 the system to speed needed changes in drug
3 labeling.

4 While fixing the process was a necessary
5 step, resources are also crucial. Even the new
6 streamline process for updating OTC drug
7 requirements is resource-intensive. The only way
8 to ensure that customers will be afforded reliable,
9 safe, and quality medicines over the counter is to
10 provide sufficient resources for this important
11 regulatory work. The AAP supports the continuation
12 and strengthening of the user fee program to fund
13 these activities.

14 We know that since the passage of OMFDA
15 three years ago, the FDA has been largely focused
16 on building infrastructure, including staffing up
17 for the work that it will be doing; however, we are
18 eager to see FDA begin to move from capacity
19 building to forward progress. In particular, we
20 urge forward progress on revising the monograph for
21 cough and cold medicines for children.

22 The data that led FDA to label cough and

1 cold medicines for children does not come close to
2 meeting today's standards for pediatric data. Not
3 only that, but additional data gathered since that
4 time has clearly shown certain cough and cold
5 products to be completely ineffective in the
6 pediatric population. Nevertheless, these products
7 are still commonly marketed to children and often
8 in combination with other products that can
9 increase safety risks.

10 In 2007, an FDA advisory committee, in
11 response to a citizen petition, voted unanimously
12 that it was no longer appropriate for adult data on
13 cough and cold products to be extrapolated to
14 establish efficacy of the drugs in children under
15 12. The committee also voted to recommend that
16 cough and cold drugs not be used in children under
17 6 years of age. After this meeting, FDA embarked
18 on a process to revise the cough and cold monograph
19 to better reflect the current state of the
20 evidence, but 15 years later, this process is no
21 further along.

22 There is significant need for FDA to make

1 progress on OTC cough and cold drugs. The recent
2 advisory committee decision on phenylephrine
3 underscores this point, but in order for FDA to do
4 this, we must reauthorize OMUFA and ensure that the
5 agency has significant resources, not just to fund
6 industry-initiated label changes, but to fund
7 agency-initiated projects that are public health
8 imperatives.

9 Another issue we are hopeful FDA will make
10 progress on is acetaminophen dosing instructions
11 for children under the age of 2. Even though there
12 are well-accepted guidelines for acetaminophen
13 dosing for children aged 6 to 24 months, the label
14 of infant and children's acetaminophen still asks
15 parents of children under 2 to ask a doctor for
16 dosing instructions. Parents unable to quickly
17 reach a physician may be tempted to make a guess of
18 an appropriate dose, putting their infant at risk.
19 This issue also requires prompt attention from FDA,
20 and the continuation of OMUFA should help
21 facilitate these important needed changes.

22 Thank you for the opportunity to speak

1 today. Thanks so much.

2 DR. ADJEIWAA-MANU: Thank you, James.

3 Heather, you are next. We welcome your
4 comments now.

5 [Slide 40.]

6 **Presentation - Heather Boyd**

7 MS. BOYD: Good morning. My name is Heather
8 Boyd, Director of Health Policy for the American
9 Pharmacists Association. APhA is the only
10 organization advancing the entire pharmacy
11 profession. I would like to thank FDA for holding
12 this public meeting today to solicit stakeholder
13 input and discuss recommendations for the
14 reauthorization of the Over-The-Counter Monograph
15 Drug User Fee Program. APhA supports FDA's timely
16 and efficient review of the efficacy and safety of
17 all over-the-counter products and ingredients.

18 Millions of patients and other healthcare
19 professionals, especially pharmacists, rely on the
20 FDA's review of over-the-counter products, their
21 ingredients, and the accuracy of the products'
22 labeling to make recommendations regarding these

1 over-the-counter products to patients. This
2 significance is amplified by the number of
3 over-the-counter products on the market and the
4 risks of these medications interacting with other
5 over-the-counter products and prescription
6 medications.

7 As you know, pharmacists are the medication
8 experts on the patient care team and the most
9 accessible healthcare professionals, with almost
10 90 percent of Americans living within 5 miles of
11 the pharmacy. Pharmacists play an important role
12 in ensuring the safe and effective use of
13 over-the-counter medications. The inappropriate
14 use of over-the-counter medications could lead to
15 unanticipated and potentially harmful side effects.

16 Pharmacists provide patients with the
17 necessary information to make an informed decision
18 on which over-the-counter products to choose.
19 Pharmacists also liaise with other healthcare
20 professionals and providers in the management of
21 their self-care practices by patients. Pharmacists
22 also advise patients on the best over-the-counter

1 medications and give advice for the patients to
2 receive their over-the-counter medications. When
3 pharmacists take the time to counsel patients about
4 over-the-counter products, the results are
5 significant.

6 In one study following pharmacists'
7 consultations, 42.6 percent of patients changed
8 their over-the-counter choice, 8 percent made no
9 purchase, 4.3 percent were referred to a physician,
10 and 7.1 percent avoided a potential adverse drug
11 event. Surveys have also shown that over
12 41 percent of pharmacists make recommendations for
13 6-to-10 OTC products per day.

14 FDA is also in the process of finalizing the
15 nonprescription drug product with an additional
16 condition for nonprescription use, also known as
17 ACNU. This ACNU proposed rule does not fully
18 recognize the essential role a pharmacist plays in
19 assessing the appropriate use and dispensing of
20 medications, and the significant, and operational,
21 and logistical issues associated with
22 implementation of this proposed rule.

1 Safety concerns must be mitigated, and there
2 is currently no established pathway for this in the
3 United States. FDA must ensure pharmacists play
4 their essential role in assisting patients to
5 determine whether a particular ACNU or
6 over-the-counter product is appropriate for each
7 individual patient's healthcare needs.

8 Given the large number of over-the-counter
9 medications on the market accessible to millions of
10 consumers, OMuFA provides an opportunity to develop
11 a pathway that provides greater access to
12 prescription drugs that may have some condition for
13 use, and capitalize on the knowledge, expertise,
14 trust, and access of the pharmacist.

15 Thank you again for the opportunity to
16 provide APhA's perspective at today's meeting.
17 AphA looks forward to continuing to support FDA's
18 efforts to broaden access to safe medications under
19 OMuFA that maximizes the expertise of our nation's
20 pharmacists. Thank you again.

21 DR. ADJEIWAA-MANU: Thank you, Heather.

22 Jessica, we welcome your comments now.

1 [Slide 41.]

2 **Presentation - Jessica Satterfield**

3 DR. SATTERFIELD: Good morning. My name is
4 Jessica Satterfield, and I'm a pharmacist and work
5 as Associate Director of Policy and Pharmacy
6 Affairs for the National Community Pharmacists
7 Association. I would like to thank FDA for hosting
8 this meeting and their efforts to modernize OMUFA.
9 Today, I'll address the importance of pharmacists
10 advising patients on self-care with OTC products
11 and how OMUFA is helping to ensure that patients
12 have safe and effective over-the-counter
13 medications.

14 NCPA members include independent pharmacy
15 owners at more than 19,400 independent pharmacies,
16 serving communities across all demographics in all
17 parts of the U.S. Pharmacists are highly trained
18 healthcare professionals who play a vital role in
19 patient care. We're experts in medications and can
20 help patients understand and use their medications
21 safely and effectively. Pharmacists also provide
22 patients with counseling on a variety of health

1 topics, including disease prevention, chronic
2 disease management, and nutrition.

3 OTC medications can be safe and effective
4 and treat common health problems; however, it's
5 important to use OTC medications correctly in order
6 to avoid any adverse effects or drug interaction.
7 Pharmacists help patients choose the right OTC
8 medication for their needs and provide them with
9 instructions on how to use it safely, and when to
10 seek medical care.

11 I'll take a couple minutes to just list some
12 specific examples of how pharmacists are helping
13 patients with OTC medications. The pharmacists
14 help patients choose the right OTC medication for
15 their needs, based on their symptoms, age, and
16 other medical conditions. They also explain how to
17 use an OTC medication safely and effectively, and
18 can answer any questions that the patient might
19 have. Another important role of the pharmacist in
20 OTC medications and self-care is counseling
21 patients about potential side effects and drug
22 interactions with their prescription medication.

1 Pharmacists also take the time to monitor
2 patients who are taking OTC medications for chronic
3 conditions to ensure that they're using the
4 medications safely and effectively, and despite the
5 important role that pharmacists play in self-care,
6 they are not reimbursed by federal commercial
7 payers for evaluation, counseling, or OTC patient
8 consultations. This means that pharmacists are
9 providing these services to patients for free.

10 Lack of reimbursement can make it difficult
11 for pharmacists to provide patients with the
12 counseling and support that they need; however,
13 many pharmacists continue to provide counseling and
14 OTC patient consultations because they believe it's
15 an important part of their job and an important
16 part of patient care as a whole. They know that
17 these services help patients use OTC medications
18 safely and effectively, and can also help patients
19 improve their overall health and well-being.

20 OMUFA has been very successful in helping
21 the FDA to review and improve OTC monograph drugs
22 in a timely manner. This is important for

1 patients, as it ensures that they have access to
2 safe and effective medication. And while NCPA
3 doesn't have an official policy regarding user fees
4 or development of these programs, we appreciate
5 FDA's efforts on this issue. OMUFA is an important
6 program that helps to ensure that patients have
7 access to safe and effective OTC medications.

8 Pharmacists are a part of the OMUFA process
9 of providing feedback to the FDA on OCC monograph
10 drug applications and by helping patients to
11 understand and use those medications safely and
12 effectively. That concludes my comments, and we
13 thank you for your time.

14 DR. ADJEIWAA-MANU: Thank you, Jessica.

15 That concludes our session from the
16 healthcare professional perspectives. We will now
17 move on to a session on consumer and patient
18 perspectives. Our speaker in this session is Diana
19 Zuckerman from the National Center for Health
20 Research. We will take a break following this
21 session.

22 Diana, as our only speaker in this session,

1 you may begin.

2 (Pause.)

3 AV TECH: Diana, if you're speaking, you're
4 muted.

5 (No response.)

6 MS. CARMOUZE: Diana Zuckerman, if you're
7 online, we're ready for you. Please unmute.

8 (Pause.)

9 MS. CARMOUZE: She is online. Perhaps she's
10 having some issues. Since this was the only
11 presenter for this particular perspective, we can
12 go ahead and have our break now, and we'll try to
13 reconnect with her afterwards.

14 We're going to break for 20 minutes. The
15 time is -- we'll reconvene at 10:15. Thank you
16 all.

17 (Whereupon, at 9:56 a.m., a recess was
18 taken, and the meeting resumed at 10:15 a.m.)

19 [Slide 42.]

20 **Panel 2**

21 DR. ADJEIWAA-MANU: Welcome back to our
22 OMUFA public meeting. As a reminder, if you

1 experience technical issues during the webcast,
2 please e-mail Grace Carmouze at
3 grace.carmouze@fda.hhs.gov. Also, please keep in
4 mind that you can submit comments to a public
5 docket that will be open until October 27th. We
6 encourage everyone to submit their perspectives to
7 the public docket for FDA review. You can submit
8 formal comments to the public docket by clicking on
9 the green button at the top of the Federal Register
10 notice.

11 We're going to give Diana a chance to speak
12 for her presentation regarding consumer and patient
13 perspectives. And as a reminder, Diana is coming
14 to us from the National Center for Health Research.

15 Diana, as our speaker in this session, you
16 may begin.

17 [Slide 43.]

18 **Presentation - Diana Zuckerman**

19 DR. ZUCKERMAN: Thank you so much, and I'm
20 sorry for the delay, and thanks for putting my
21 slides up. I should just say, yes, we're still in
22 part of the pandemic. I'm recovering from COVID,

1 so if my voice gives out at some point, I will do
2 my very best.

3 [Slide 44.]

4 I'm Dr. Diana Zuckerman, President of the
5 National Center for Health Research, and my
6 training has been epidemiology and public health,
7 and I've been working with patients and consumers
8 for more than 30 years, both in terms of working in
9 the House of Representatives and U.S. Senate, and
10 for nonprofit organizations, including the National
11 Center for Health Research.

12 Next slide, please.

13 [Slide 45.]

14 Our center is a nonprofit public health
15 think tank that focuses on the safety and
16 effectiveness of medical and consumer products, and
17 we do not accept funding from companies that make
18 those products. I personally inherited and own
19 stock in Johnson & Johnson, and that's my
20 disclosure.

21 Next slide, please.

22 [Slide 46.]

1 Before I start with this slide, I just want
2 to say we have strongly supported OMUFA, and we
3 think it was very important because of the resource
4 issues and the need to improve the whole process,
5 but we are concerned that it's modeled a little too
6 closely on PDUFA, and PDUFA has some problems for
7 consumers, and patients, and health professionals,
8 and I think pharmacists as well. So we want to
9 make sure that because OTC products obviously are
10 even more entwined with the needs of consumers, and
11 health professionals, and pharmacists, we need a
12 stronger voice in this process.

13 Now, I'll start with this slide. The
14 Generally Recognized as Safe and Effective standard
15 is one of the standards being used in these
16 monographs, and it does have problems compared to
17 actual scientific evidence. When you depend on
18 these generally recognized as safe and effective
19 standards, it can result in products that aren't
20 really that safe and aren't that effective, and
21 that can delay care.

22 It creates missed opportunities for use of

1 more effective treatments, including a doctor's
2 visit when that's needed. It also has a problem
3 because you want to avoid the risks of potential
4 allergic reactions or other side effects for
5 products that you don't know that much about, and
6 the last thing is to avoid the inherent risks that
7 are in any product. All products have risks, and
8 especially combination therapy -- we've heard a
9 little bit about that this morning -- where
10 patients take too many medications in order to seek
11 some benefit when the one medication isn't actually
12 working, so they just keep taking more.

13 Next slide, please.

14 [Slide 47.]

15 On the other hand, the benefits of evidence
16 compared to this assumption of generally recognized
17 as safe and effective is that when you have
18 evidence, you can avoid unnecessary costs, and you
19 can restore consumers' trust that the FDA approval
20 means that a product has benefits that outweigh the
21 risks compared to placebo. The recent example of
22 Sudafed P/E, which was previously mentioned this

1 morning, and the related cold products, is really
2 the poster child for consumers spending enormous
3 amounts of money on products that experts now agree
4 do not work, and actually have known for years do
5 not work.

6 Next slide, please.

7 [Slide 48.]

8 So when we think about enhancements from
9 OMUFA, I would have to say I don't feel like I have
10 enough evidence yet to know how best to improve
11 OMUFA, but there are a few issues. Based on what I
12 know about PDUFA and MDUFA, we know that consumers
13 deserve a stronger voice. Negotiations are being
14 held behind closed doors, and that should not be.
15 Consumers should be at the table, and I think we've
16 heard this morning why health professionals and
17 pharmacists -- well, I should say physicians and
18 pharmacists -- should also be at the table. And
19 perhaps most important, performance goals should
20 benefit consumers. The goal of too many
21 performance goals is on speed, and they should
22 benefit consumers in terms of safety and

1 effectiveness.

2 Next slide, please.

3 [Slide 49.]

4 Speed of review is important, but it's just
5 not as important as proving that there is a
6 meaningful benefit to consumers, and that is safety
7 and effectiveness; and effectiveness should be as
8 important as safety because all medications have
9 costs and risks, even when those are quite modest.

10 Next slide, please.

11 [Slide 50.]

12 Just a few metrics that I think are very
13 important in a commitment letter, and it's just not
14 clear to me to what extent this can be changed. I
15 will say that the information in the first
16 slideshow this morning was really very helpful, but
17 it's clear that most of this information has been
18 made available to industry and consumers, and
19 health professionals have not had as much of a
20 role. This is a public health issue.
21 Over-the-counter medication is a public health
22 issue, and we need to be at the table.

1 So first of all, metrics that should be part
2 of performance goals should be label changes, how
3 many label changes were made over the period of the
4 authorization, and those label changes should be
5 geared towards enhancing safety, information,
6 whether it's warnings and contraindications, and so
7 on. What about responses to citizen petitions to
8 determine whether and when a medication was
9 withdrawn from the market because of safety or
10 effectiveness? That's the kind of transparency and
11 important information that should be part of
12 performance goals.

13 Another one is the percentage of facility
14 reinspections that are carried out within 6 months
15 after the letter to the facility, indicating FDA's
16 intent to reinspect. And I understand that
17 reinspections can be foreign or domestic and maybe
18 need to have different numbers of months, but
19 again, that's the kind of metric that has an
20 important implication for the safety and
21 effectiveness for consumers.

22 Next slide, please.

1 [Slide 51.]

2 Pertaining to adding and strengthening
3 warnings, this is something that is part of OMUFA
4 as I understand it. We agree that there should not
5 be extra fees for changes that are intended to
6 enhance safety; for example, if the FDA finds that
7 the OMOR seeks to change the drugs facts labeling
8 of an OTC monograph drug in a way that would add or
9 strengthen a contraindication; a warning or a
10 precaution; a statement about risks, or misuse, or
11 abuse; or to revise dosage information to increase
12 the safe use.

13 So those are things that should be added,
14 and we don't think that there should be extra fees
15 for that, but we do think it should be a very
16 important part of metrics to see how well this
17 system is working and how well these user fees are
18 benefiting patients and consumers.

19 Last slide, please.

20 [Slide 52.]

21 This is just my contact information. I
22 appreciate the opportunity to speak today and

1 apologize for being late because of my problem with
2 the sound system on my computer, and I look forward
3 to working with all of you as we continue to
4 improve this whole system, because over-the-counter
5 medications are ones we all depend on, and believe
6 me, in the last few days, that's been really
7 important to me. You can't just live on hot tea.
8 Thank you very much.

9 [Slide 54.]

10 **Panel 3**

11 DR. ADJEIWAA-MANU: Thank you for your
12 comments, Diana.

13 That concludes our session on consumer and
14 patient perspectives. Our next session is on
15 regulated industry perspectives. We have
16 6 speakers in this session: Lisa Parks from the
17 Consumer Healthcare Products Association; Dan
18 Selechnik from the Fragrance Creators Association;
19 Douglas Troutman from the American Cleaning
20 Institute; Meredith Petillo from the Independent
21 Beauty Association; Tom Myers from the Personal
22 Care Products Council; and Cornell Stamoran from

1 the Pharma & Biopharma Outsourcing Association.

2 Lisa, as our first speaker in this session,
3 you may begin.

4 [Slide 55.]

5 **Presentation - Lisa Parks**

6 MS. PARKS: Good morning. My name is Lisa
7 Parks, and I am the Senior Vice President of
8 Regulatory and Scientific Affairs at the Consumer
9 Healthcare Products Association, CHPA. On behalf
10 of CHPA, I would like to extend our appreciation
11 for this opportunity to address you today.

12 CHPA represents manufacturers and marketers
13 of OTC medicines. Our mission is to empower
14 self-care by preserving and expanding choice and
15 availability of trusted consumer healthcare
16 products. One way we achieve this mission is by
17 working closely with the FDA for the efficient and
18 effective implementation of monograph reform.

19 OMUFA stands at the core of our collective
20 success in implementing monograph reform. A
21 well-structured OMUFA program provides the FDA with
22 resources for efficient monograph review, while

1 guiding and supporting industry and stakeholders
2 via guidance and feedback. We commend the FDA for
3 the steps already undertaken in the pursuit of
4 monograph reform and the fulfillment of its OMUFA I
5 commitments. Specifically, we appreciate the
6 issuance of draft guidance on vital topics. These
7 guidance documents serve as an invaluable resource
8 for industry.

9 CHPA appreciates that FDA has fulfilled this
10 obligation to issue deemed final orders for drugs
11 that were previously classified as Category 1 drugs
12 under final and tentative final monograph. This is
13 an important first step that will allow FDA to
14 focus on label changes and review of new OMOR
15 submissions in the coming years. We also applaud
16 the FDA's efforts in establishing new IT
17 infrastructure and meeting its hiring goals.

18 As we approach the reauthorization of
19 OMUFA II, CHPA would like to underscore five
20 critical points that we believe are pivotal in
21 building upon these achievements and ensuring
22 success of the program. First, maintaining GRASE

1 standard. The existing regulations dictate that
2 GRASE determination should primarily rely on
3 published studies potentially supplemented by
4 unpublished research, data, and significant market
5 experience. The monograph reform law was very
6 intentional in leaving the substantive standard for
7 GRAS/GRASE determinations in place. This
8 legislative intent is underscored by statements
9 from the primary sponsor of the bill in the House
10 of Representatives on the very day the new law was
11 enacted.

12 The FDA itself acknowledged this in its
13 June 2023 draft guidance on formal dispute
14 resolution and administrative hearing, where it
15 confirmed that general recognition of safety and
16 effectiveness requires, among other things, the
17 information demonstrating that a drug is safe and
18 effective for its intended use to be published so
19 that such information is generally available to
20 qualified experts.

21 It is imperative for the FDA to base its
22 review and guidance on the standard, with the

1 emphasis on affirming that GRASE determination
2 should principally rely on reported reports from
3 relevant studies and published literature.
4 Moreover, it is crucial for the FDA to recognize
5 the valuable role that real-world evidence can play
6 in supporting GRASE conclusions, including evidence
7 indicating the absence of safety concerns for drugs
8 with a long-standing market presence. This
9 standard must remain intact and be adhered to by
10 FDA to ensure the viability and sustainability of
11 the overall program for the American public.

12 Second, GRAS/GRASE determination distinct
13 from NDA style submissions. GRAS/GRASE
14 determination should not be dependent on NDA style
15 submissions and review. The focus should be on
16 assessing the safety and efficacy of active
17 ingredients for conditions specified in the
18 applicable monograph. This evaluation does not
19 involve a review of inactive ingredients, which may
20 vary among products authorized under a single
21 monograph, as long as those inactive ingredients
22 meet the applicable regulatory standards for safety

1 and suitability.

2 Similarly, while monograph drugs must be
3 produced in compliance with CGMPs, GRASE
4 determinations do not involve a review of the
5 manufacturing process for each drug marketed under
6 a monograph. Thus, sponsors are not required to
7 submit the same CMT data to support an OTC GRASE
8 determination that would be expected to be
9 submitted under an NDA.

10 In the assessment of OMOR submissions for a
11 drug previously examined by an advisory panel, such
12 as a Category 3 under a TFM, the FDA should not aim
13 to reevaluate all of the data already considered by
14 the panel. Instead, the law specifies that the FDA
15 should outline the general types of data it
16 believes are necessary to establish general
17 recognition. The FDA should identify gaps that
18 need to be addressed, based on prior agency
19 findings, rather than initiating a new review.
20 This approach maintains robust review standards
21 while allowing for efficiencies in either the OMOR
22 process or FDA-initiated GRASE determination for

1 Category 3 ingredient uses.

2 Third, encouraging FDA to initiate orders.

3 Both the FDA and the industry have pathways to
4 initiate the administrative order process. We
5 encourage the FDA to initiate orders where it
6 possesses sufficient data to support GRASE
7 determinations or changes to the monograph. This
8 will streamline the OTC monograph process and
9 allocate industry resources effectively.

10 Fourth, enhancing OMUFA meeting
11 efficiencies. Timely and comprehensive advice
12 during OMUFA meetings is essential. Industry
13 stakeholders require clear and concise guidance
14 from the FDA, particularly concerning the data
15 needed to submit OMORs since this is a new and less
16 familiar process. CHPA has some concerns about how
17 the FDA has been handling OMUFA meetings.

18 For instance, some stakeholders have
19 experienced delays in scheduling meetings and
20 scheduling in-person meetings, although it is
21 understandable that FDA would have been less
22 inclined for in-person meetings and delayed in

1 responding to meeting requests during the pandemic
2 and during the staffing-up phase of implementation,
3 but response delays and hesitation towards
4 scheduling in-person meetings persist. The FDA
5 should work to streamline meeting processes,
6 ensuring timely responses, maximizing in-person
7 engagement, offering comprehensive advice based on
8 legal principles, and considering the full record,
9 including any relevant OTC panel reviews.

10 Fifth, prioritizing administrative orders
11 and guidance for minor changes. The new law
12 establishes a pathway for sponsors to make minor
13 changes in dosage forms without submitting an OMOR.
14 They must maintain specific records supporting the
15 change, and on request, sponsors must provide these
16 records to the FDA.

17 This pathway enables the industry to
18 introduce important innovations into the OTC drug
19 market more efficiently, addressing a significant
20 hurdle in the previous monograph system.

21 Ultimately, this aims to offer consumers easier
22 access to improved and convenient dosage forms of

1 safe and effective products.

2 We know that the first of these order
3 guidance pairs on solid oral dosage forms has a
4 goal of next year. We look forward to working with
5 the agency. Going forward, we request the FDA to
6 prioritize the development of administrative orders
7 and companion guidances that permit minor changes
8 in dosage form without the submission and approval
9 of an OMOR.

10 In closing, CHPA would like to express our
11 appreciation to the FDA for convening this meeting
12 and providing us this opportunity to share these
13 insights. We anticipate collaborating closely with
14 the FDA and other stakeholders throughout the OMUFA
15 reauthorization process as we jointly strive to
16 ensure the continued success of the program. Thank
17 you.

18 [Slide 56.]

19 DR. ADJEIWAA-MANU: Thank you, Lisa.

20 Dan, you may begin.

21 [Slide 57.]

22 **Presentation - Dan Selechnik**

1 DR. SELECHNIK: Hi, everyone. I am Dan
2 Selechnik, the Director of Regulatory Science with
3 the Fragrance Creators Association. I appreciate
4 the opportunity to be here today and to speak, so
5 thank you to the FDA for putting this meeting
6 together.

7 Next slide, please.

8 [Slide 58.]

9 So a little bit about Fragrance Creators, we
10 are the trade association representing the majority
11 of fragrance manufacturing in North America. Our
12 membership is diverse, consisting of about
13 60 companies from large to small, and representing
14 the full value chain, everything from raw materials
15 to fully finished formulations.

16 We proactively and reactively manage matters
17 related to legislative, regulatory, retailer,
18 consumer, and other stakeholders like NGOs, and our
19 membership also relies upon the Research Institute
20 for Fragrance Materials, or RIFM, for fragrance
21 safety information, and I'll go a little bit more
22 into RIFM later in my comments.

1 Next slide, please.

2 [Slide 59.]

3 First, why we're here today. Fragrances
4 serve an important role as excipient ingredients in
5 OTC drugs for the purposes of enhancing the smell
6 or masking a malodor, all to increase the
7 palatability and appeal to consumers.

8 Slide, please.

9 [Slide 60.]

10 The fragrance industry values the safety and
11 innovation that OMFUA affords and appreciates
12 OMFUA's flexibility. We also support the
13 collection of fees for OTC monograph activities but
14 believe in discretion as to where these funds
15 should be allocated.

16 Slide?

17 [Slide 61.]

18 To be the most efficient possible, we
19 believe that FDA should identify industries that
20 already have a strong safety record and take
21 advantage of existing safety information and
22 expertise available from those industries. That

1 way, the resources that are afforded by OMUFA
2 funding can be used only where the funds are needed
3 to address existing gaps.

4 [Slide 62.]

5 So going into the fragrance industry
6 specifically and our history with safety, this all
7 comes down to the Research Institute for Fragrance
8 Materials or RIFM. Established in 1966, this is a
9 member-funded, nonprofit research institute with
10 the similar memberships of fragrance creators being
11 about 60, large to small, and representing the full
12 value chain, and they are staffed by experts in the
13 human health and environmental toxicological
14 endpoints, as well as a full database team and a
15 communications team.

16 [Slide 63.]

17 The database team is essential at RIFM for
18 maintaining a continuously updated database of
19 safety studies on all of the fragrance materials in
20 their inventory. They also generate exposure data
21 using the Creme-RIFM Aggregate Exposure Model based
22 on survey data collected from across the industry.

1 They conduct detailed safety assessments that are
2 peer reviewed and published, addressing human
3 health endpoints, from systemic, like repeated dose
4 toxicity, all the way to local, like skin
5 sensitization, and all of the publications are open
6 access and available on the Fragrance Material
7 Resource Center linked on the slide here.

8 The Research Institute also conducts
9 research on innovative new approach methodologies,
10 or NAMs, always looking for ways to replace animal
11 testing with in silico or in vitro methods that can
12 evaluate the safety of fragrance ingredients
13 without compromising the accuracy of the results.

14 [Slide 64.]

15 In addition to RIFM, there's also the Expert
16 Panel for Fragrance Safety. This is an independent
17 team of experts, such as academics and physicians,
18 with no affiliation to industry. Their role is to
19 critically review RIFM safety assessments and
20 research projects, and determine the safe use of
21 fragrances based on available information, and also
22 making determinations as to when additional new

1 data has to be generated.

2 [Slide 65.]

3 In terms of how these safety studies are
4 conducted, luckily for our industry, there is an
5 abundance of guidelines for RIFM and whoever among
6 the manufacturers wishes to properly test their
7 ingredients. These include the Good Laboratory
8 Practice, or GLP; the Organization for Economic
9 Cooperation and Development, or OECP; and the
10 National Toxicology Program or NTP. There are
11 clear guidelines to standardize the methodology for
12 safety studies in the industry.

13 [Slide 66.]

14 I also want to highlight that the industry
15 has served as a resource for the FDA Office of
16 Cosmetics and Colors in developing the
17 Modernization of Cosmetics Regulations Act or
18 MoCRA. I feel like this is important to highlight
19 to encourage communication between different
20 offices of FDA and to encourage leveraging
21 information that the organization, the agency, has
22 already gathered in order to minimize data gaps

1 that remain.

2 Thank you.

3 [Slide 67.]

4 In conclusion, the fragrance industry
5 happily supports OMUFA but believes that the
6 program can be most efficient if the FDA does not
7 have to duplicate work, so Fragrance Creators and
8 RIFM are both here to help. Fragrance Creators is
9 the expert source on all things fragrance, from
10 legislative, to regulatory, to consumer, to retail,
11 and RIFM is the expert source and scientific
12 authority on all fragrance safety information.
13 Both organizations are here at your disposal.

14 Next slide.

15 [Slide 68.]

16 Thank you, and I appreciate the opportunity
17 to be here today.

18 [Slide 69.]

19 DR. ADJEIWAA-MANU: Thank you, Dan.

20 Douglas, please begin.

21 [Slide 70.]

22 **Presentation - Douglas Troutman**

1 MR. TROUTMAN: Good morning. My name is
2 Douglas Troutman. On behalf of the American
3 Cleaning Institute, I appreciate the opportunity to
4 provide recommendations on OMUFA reauthorization,
5 so good morning to those online and in the room,
6 and I appreciate the meeting here today at FDA to
7 make these remarks.

8 Next slide.

9 [Slide 71.]

10 ACI is the home of the \$60 billion U.S.
11 cleaning product industry, and our members include
12 suppliers and formulators of soap, detergents, and
13 general cleaning products, and healthcare topical
14 antiseptic drug products sold in the U.S. This
15 includes manufacturers and suppliers of five
16 topical antiseptic ingredients you see on the
17 screen there, and FDA also deferred these actives
18 from final rulemaking, as my notes here reflect,
19 and also on the screen. ACI members are diligently
20 working and leading the industry on the FDA
21 requested studies to establish GRASE status, and
22 these topical antiseptics with these ingredients

1 are lawfully marketed under the law.

2 Next slide, please.

3 [Slide 72.]

4 First, I'd like to address what we call the
5 free rider problem. Today, ACI has submitted
6 multiple reports to the agency demonstrating
7 ongoing progress generating safety and
8 effectiveness data to satisfy FDA's request;
9 however, filling those data gaps are costly and
10 resource-intensive over time. The production of
11 robust safety and effectiveness data requires
12 significant financial investment. I cannot stress
13 enough the importance of the ACI member company
14 contributions supporting our data collection
15 efforts.

16 There are disincentives inherited in the
17 monograph system. This is seen in the collection
18 of data to establish GRASE for products that are
19 already lawfully marketed. The ACI member
20 companies funding agency requested studies are a
21 fraction of the antiseptic ingredient in product
22 manufacturers that will ultimately benefit from the

1 ACI member-generated data. Under the current
2 system, ACI member companies are shouldering all of
3 the data costs, but the benefits derived from that
4 data will support the continued marketing by all
5 antiseptic manufacturers, including
6 non-participating companies.

7 A simple image may help. Think of a
8 railroad. ACI members were told to follow the FDA
9 policy railroad tracks. ACI member companies built
10 and paid for the locomotive and passenger cars, and
11 now no one must help pay for the vehicle's
12 investment. Also, anyone can ride. The valuable
13 benefit conferred on non-members discourages
14 participation in the data collection effort at a
15 time when that very participation is critical to
16 finalizing the regulatory status of topical
17 antiseptics.

18 Next slide.

19 [Slide 73.]

20 The recommendations. ACI encourages FDA to
21 think critically about potential solutions to
22 address the free rider problem. FDA should

1 incentivize industry buy-in for finalizing GRASE
2 determinations. Two options to consider. One,
3 include a waiver or reduction in facility or user
4 fees for sponsors that actively participate in the
5 data generation process. Also develop a cost
6 sharing or compensation system for free riders to
7 pay those who generate the data in exchange for the
8 ability to market product in the U.S.

9 Second, extending or, at the very least,
10 maintaining the exclusivity period. It is
11 important for FDA to take enforcement action
12 against products that unlawfully compete against
13 products with exclusivity. Compared to the new
14 drug application process, the current exclusivity
15 period is short. The protection of confidential
16 commercial information and trade secrets is also
17 more limited.

18 Next slide.

19 [Slide 74.]

20 Data confidentiality. To help protect the
21 interests of ACI member companies who are
22 developing the requested safety and efficacy data,

1 we also urge FDA to broadly interpret the statutory
2 provisions that protect the confidentiality of data
3 and others submitted information. A more
4 productive confidentiality policy is supported by
5 the CARES Act, which requires public disclosure
6 with limited exceptions of information submitted in
7 support of an OMOR. Our written comments in the
8 future will confirm this point, that FDA should
9 narrowly define what information is needed in
10 support of an OMOR.

11 Next slide, please.

12 [Slide 75.]

13 On enhanced transparency, it is imperative
14 that FDA provide industry with clear and
15 transparent guidance and maintain ongoing dialogue
16 through regular feedback and communication. ACI
17 appreciates recent guidance from the agency on
18 formal meetings, as well as guidance on formal
19 dispute resolution and administrative hearings of
20 final administrative orders. These developments
21 help to ensure the FDA requested studies can be
22 completed, but there are three categories I wish to

1 address.

2 First is routine and flexible communication.
3 While formal meetings and public hearings are
4 helpful to gain insight into the agency's thinking,
5 more routine communications -- like e-mail
6 responses, letters, and phone conversations,
7 regular communications -- are important and
8 imperative to make progress aligned with FDA's
9 viewpoints. ACI encourages ongoing dialogue and
10 further flexibility to obtain the meaningful
11 feedback from FDA on the status of the deferred
12 antiseptic ingredients I've noted.

13 FDA should prioritize resource allocation to
14 provide additional opportunities to obtain informal
15 FDA feedback in order to provide collaboration and
16 progress. Such engagements will spur solutions for
17 establishing efficient and transparent channels for
18 formal and informal dispute resolution, such as by
19 limiting the number of appeals required before an
20 administrative hearing. Comprehensive and
21 iterative feedback, as well as timely dispute
22 resolution, will help requestors prepare OMORs that

1 meet the agency expectations for format and
2 content. Second, ACI requests that FDA set forth
3 clear and detailed expectations for the substantive
4 content of OMORs, including the specific success
5 criteria standards under which FDA will review OMOR
6 submissions.

7 Next slide, please

8 [Slide 76.]

9 This content criteria, FDA must also present
10 ample evidence and advance notice before FDA issues
11 any proposed order regarding GRASE status for
12 conditions of certain ingredients based on data it
13 has or is expecting from companies working on
14 generating data FDA has requested.

15 [Slide 77.]

16 My final slide here is with regard to data
17 type and quantity. With this significant data
18 burden needed to establish GRASE, the short
19 exclusivity period, and the free riders, additional
20 guidance is needed to explain the potential
21 benefits of submitting an OMOR as opposed to a new
22 drug application. FDA should provide additional

1 guidance on whether there are certain circumstances
2 under which the agency may accept reduced
3 quantities or different types of data. This may be
4 real-world evidence or foreign marketing experience
5 in the demonstration of safety and efficacy.
6 Similarly, FDA should provide greater clarity on
7 the pros and cons of using the monograph pathway
8 versus the new drug application pathway.
9 Clarification should also be given as to whom and
10 what FDA entity will be responsible for issuing
11 final administrative orders.

12 These recommendations, including clear
13 guidance and transparent and timely agency
14 feedback, will alleviate burdens demonstrating the
15 GRASE status of topical and antiseptic ingredients.
16 ACI is committed to collaborating with FDA to
17 achieve these objectives and believes that the
18 recommendations made today will further our common
19 goals. ACI will provide written comments for the
20 record, and I thank you for your attention the time
21 today.

22 DR. ADJEIWAA-MANU: Thank you, Douglas.

1 Meredith, we welcome your comments now.

2 [Slide 78.]

3 **Presentation - Meredith Petillo**

4 MS. PETILLO: Good morning. Thank you,
5 Dr. Michele and the entire FDA team, for putting
6 this meeting together and for the opportunity to
7 speak today on this industry representation panel.
8 I am Meredith Petillo, Senior Director for
9 Technical and Regulatory Affairs at the Independent
10 Beauty Association, a nonprofit trade association.

11 Since 1974, IBI has been the voice of small
12 and independent cosmetics companies, now
13 representing 600 organizations in the indie beauty
14 and personal care industry. I'm here today to
15 speak specifically on behalf of
16 small-to-medium-sized organizations doing business
17 in the overlap between monograph OTC drugs and
18 cosmetics. This overlap between these two
19 regulated product categories is essential to not
20 only understanding the relevance of businesses in
21 the beauty sector to today's OMUFA meeting, but
22 also in assessing the impact that OMUFA user fees

1 have had on IBA member companies, other small
2 entrepreneurial businesses, as well as the product
3 choice available to U.S. consumers.

4 Today I would like to offer IBA's
5 observations of industry impact from OMUFA to
6 inform reauthorization conversations and
7 considerations as this process moves on to next
8 steps. I will highlight a distinct subset of
9 monograph product categories and their role in the
10 independent and small business sector of the beauty
11 and personal care products industry. I'll also
12 touch upon market accessibility, innovation, and
13 consumer choice.

14 Certain over-the-counter drug products sit
15 at the interface of OTC and cosmetic classification
16 and play an important role in the beauty and
17 personal care product industry. The following
18 product categories are examples that sit at this
19 nexus: sunscreen; anti-acne; anti-dandruff; skin
20 protectants; topical analgesics; oral healthcare
21 products; and antiperspirants.

22 These products contribute economically and

1 also meet consumer over-the-counter needs, but the
2 cosmetic nature of these products also serves as a
3 significant source of innovation and has made many
4 of them very important to consumers. For example,
5 the inclusion of sunscreens into skin care and
6 cosmetic product formats allow for
7 consumer-friendly options that go well beyond the
8 occasional beach day use and into daily
9 application, expanding sun protection options for
10 consumers.

11 Additionally, anti-acne, anti-dandruff; skin
12 protectants; oral care products; and
13 antiperspirants are all products that consumers use
14 as part of their daily routines in basic health and
15 hygiene. These are not products used infrequently
16 for occasional treatment or for an intermittent
17 need.

18 Maintaining a selection of safe, effective,
19 useful, pleasant, innovative, and affordable
20 products that are suitable for all skin and hair
21 types is important to the U.S. consumer. Due to
22 the high investment of self-manufacture, many

1 small-to-medium-sized brands selling OTC anti-acne,
2 anti-dandruff, skin protectants, oral care, and
3 sunscreen products use contract manufacturers to
4 produce their products. Many of these providers
5 are cosmetic product manufacturers who also
6 manufacture OTC products. Given the higher
7 investment required to produce and maintain OTC
8 products in market, OTC formulas are typically a
9 much smaller percentage of the contract
10 manufacturer's product portfolio compared to
11 cosmetics.

12 OTC product manufacturing requires
13 appropriate equipment, systems, and highly trained
14 personnel to meet quality and regulatory compliance
15 mandates throughout the development and
16 manufacturing; on top of this, few requirements for
17 OTC production facilities that are not adjusted for
18 the size of the OTC manufacturing portfolio within
19 the facility.

20 Furthermore, small startup brands often
21 require low production quantities to launch their
22 product lines. It is challenging to identify

1 contract manufacturers who can provide the small
2 order quantities necessary to support an emerging
3 cosmetics business. We're talking production runs
4 counted in hundreds or thousands versus hundreds of
5 thousands or millions of units, so economies of
6 scale don't benefit small producers.

7 This scarcity is compounded further when
8 looking for manufacturers who can produce OTC
9 products at low minimum order quantities. IBA is
10 concerned with maintaining a healthy number of
11 compliant, responsible, and viable monograph OTC
12 contract manufacturers who can accommodate
13 businesses of a wide variety of sizes and scale.

14 Facility fees can affect a small business's
15 choice to enter or exit the OTC manufacturing
16 space. For example, we have an IBA member company
17 who manufactures its own products. The founder is
18 a chemist who formulated a line of hair care
19 products for textured hair. Along with her
20 husband, they both stood up their own manufacturing
21 facility to support their emerging business.

22 For them, to add just one anti-dandruff

1 shampoo SKU would make them of course an OTC
2 manufacturer, and they would incur not only the
3 expense of equipment, systems, and personnel, but
4 also the cost of drug GMP facility compliance, all
5 while paying the same facility fee as the largest
6 multinational pharmaceutical or CPG company. The
7 fee may not be the only deciding factor, but it is
8 a consideration that businesses will be evaluating
9 when thinking about entering the OTC manufacturing
10 space for cosmetic/OTC drugs, and that innovative
11 product may never make it to shelf.

12 This type of decision exacerbates an
13 existing reduction in qualified OTC product
14 manufacturers. After OMUFA went into effect, some
15 small contract manufacturers exited the OTC
16 business following the first fiscal year of
17 facility fees. The circumstances were certainly
18 difficult for many manufacturers. COVID pandemic
19 shutdowns and supply chain disruptions drastically
20 slowed manufacturing and even closed production
21 lines and entire facilities.

22 The most common questions IBA received

1 following the announcement of the first fiscal year
2 OMUFA user fees were, "Is there a small business
3 facility fee and OMOR fee structure? Why not? And
4 how can we afford this, especially during and
5 coming out of an incredibly difficult time of
6 economic uncertainty?" Again, the increase in
7 facility fee may not be the only factor for these
8 companies to exit OTC manufacturing, but it's
9 surely part of the consideration set.

10 Continued reduction in the number of OTC
11 qualified contract manufacturers, especially
12 facilities who will accommodate low minimum order
13 quantity production runs, are likely to lead to
14 further reduced product choice for the consumer.
15 Reduced availability and higher demand for
16 production facilities leads to typical cost-based
17 competition for scarce manufacturing resources. A
18 significant reduction in the number of OTC product
19 manufacturers could create supply bottleneck and
20 reduce redundancy if there is a limited number of
21 manufacturers making these products.

22 Finally, small entrepreneurial brands may

1 not be able to find manufacturers or may be locked
2 out of production if larger customers take
3 precedence in the production schedule, effectively
4 reducing the variety of new products that offer
5 innovation or serve smaller markets, diverse skin
6 and hair types, or niche consumer needs.

7 I spent the bulk of my time today speaking
8 about manufacturing and facilities because it was
9 the most pressing piece of the OMUFA structure that
10 our members raised following passage. Everyone
11 here is very familiar with the existing
12 one-size-fits-all fee structure for both facilities
13 and OMOR requests, so it is known that the fees due
14 are the same regardless of whether you are a
15 facility making one lip balm with an SPF claim or
16 the largest global pharmaceutical or CPG company.

17 For small businesses, this presents, at
18 best, and unequal playing field and, at worse, a
19 barrier to entry, growth, and competition in the
20 sector. It is important to note that OMOR tier 1
21 and tier 2 fees are financially out of reach for
22 small personal care businesses, brands, or

1 manufacturers.

2 For context, IBA is a very small nonprofit
3 association, and approximately 50 percent of our
4 membership sells less than \$1 million per year,
5 making these requests, unfortunately, simply
6 fiscally unattainable. IBA respectfully requests
7 that small business concerns are taken into account
8 in the reauthorization process for OMUFA user fees.
9 Small business considerations should be in place to
10 protect against further significant business exit
11 from OTC manufacturing and to assist with fair and
12 equitable access for the entry of new small
13 business manufacturers into this space.

14 Thank you for your time today. IBA remains
15 a resource for FDA at any time for insights or
16 information regarding OMUFA impact for
17 small-to-medium-sized businesses in the overlap
18 space between cosmetics and monograph OTC drugs.
19 We welcome further discussion at your convenience.
20 Thank you.

21 [Slide 79.]

22 DR. ADJEIWAA-MANU: Thank you, Meredith.

1 Tom, you may begin.

2 [Slide 80.]

3 **Presentation - Tom Myers**

4 MR. MYERS: Good morning, and thank you for
5 the opportunity to be here today to speak. My name
6 is Tom Myers, and I am the General Counsel for the
7 Personal Care Products Council.

8 [Slide 81.]

9 For those of you who don't know us, PCPC is
10 the national trade association for the cosmetics
11 industry. We represent both cosmetics and personal
12 care companies and serve as the voice of business.
13 We have over 600 member companies that represent
14 the vast majority of products that are on the
15 market today.

16 Next slide, please.

17 [Slide 82.]

18 Our comments today will be relatively brief.
19 I wanted to first recognize the importance of this
20 process and the OMUFA work. PCPC has been
21 supportive of monograph reform, and we look forward
22 to participating in the OMUFA reauthorization

1 process. We've been working closely with FDA
2 recently on the implementation of cosmetic reform
3 legislation, known as MoCRA, and we look forward to
4 continuing that successful relationship during the
5 OMuFA process.

6 If you're wondering why a cosmetic trade
7 association is here today, it's because we also
8 represent sunscreen manufacturers and suppliers,
9 and we want to ensure that we bring those important
10 perspectives to this process as well. Sunscreens,
11 of course, are a critical part of a safe sun
12 regimen and necessary to protect consumers from the
13 dangers and damaging effects of the sun.

14 Next slide, please.

15 [Slide 83.]

16 So we've heard from a number of others
17 today, including several of our sister trade
18 associations who preceded me, and we support many
19 of the comments that they made, so I won't repeat
20 them here. I'd also like to acknowledge some of
21 the strides that have been made by CDER in recent
22 years, particularly with regard to things like the

1 deemed final orders, the newer IT systems like OTC
2 monographs at FDA, and the CDER NextGen Portal,
3 which we have found both useful and user friendly,
4 and also the formal meeting guidance, which we
5 found less fun but detailed, and it's important to
6 have clear rules of the road with regard to formal
7 meetings, so thank you for that as well.

8 We welcome the opportunity to work with you
9 towards more fulsome engagement by FDA with
10 regulated community, and continue to move toward
11 increased transparency, including a regular cadence
12 of meetings on those topics that are going to be
13 important to our industry, and I think probably
14 most importantly for us, a better understanding of
15 the process through which FDA accepts
16 scientifically robust new approach methods for
17 assessing toxicology and perhaps ways to accelerate
18 that acceptance.

19 [Slide 84.]

20 So thank you again for the opportunity to be
21 here. We look forward to working together and
22 bringing our member company perspectives to this

1 process in the weeks and the months ahead, and I
2 look forward to working with you, Dr. Michele, as
3 we go forward. Thank you.

4 [Slide 85.]

5 DR. ADJEIWAA-MANU: Thank you, Tom.
6 Cornell, you may begin.

7 [Slide 86.]

8 **Presentation - Cornell Stamoran**

9 DR. STAMORAN: Thank you. Cornell Stamoran.
10 Good morning. I'm speaking today, representing the
11 Pharma & Biopharma Outsourcing Association, or
12 PBOA, which is a U.S. based trade association for
13 contract development and manufacturing
14 organizations or CDMOs. I also serve as VP of
15 Strategy and Government Affairs for Catalent, a
16 leading global CDMO. I'm also a trustee of PBOA.

17 Next slide, please.

18 [Slide 87.]

19 There's a lot of content here; I'm not going
20 to review most of it. Briefly, CDMOs are today a
21 key part of the pharmaceutical supply ecosystem for
22 both prescription and over-the-counter

1 pharmaceuticals, as well as for consumer health and
2 other product categories. We've supported
3 development of more than 80 percent of new
4 molecular entity drugs and new biologics over the
5 last decade, and we provide commercial supply for
6 more than half of new molecular entity and
7 biologics approved over the last five years.

8 Overall, two of every five doses of
9 pharmaceutical products consumed in western
10 markets, including both NDA, ANDA, and
11 monograph-based OTC products, come via CDMOs. Our
12 members currently employ about 35,000 people across
13 170 U.S. facilities, and we'll talk about the
14 global footprints on the next page. While we do
15 support innovation within OTC products, our members
16 do not generally take products to market on our own
17 account, but we produce for companies that do
18 market them.

19 Next slide, please.

20 [Slide 88.]

21 PBOA members do operate around the world
22 with another 180 facilities outside the U.S. and

1 another 15,000 employees. We do provide product,
2 consumer health product and OTC product, from
3 certain of those markets to the U.S. as well. More
4 than 85 percent of these sites are registered with
5 the FDA, the EMA, or MHRA, among other global
6 regulators, for clarity.

7 Next page, please.

8 [Slide 89.]

9 CDMOs are impacted directly or indirectly by
10 most of the FDA's active user fee programs, and our
11 experience there has led us to some core design
12 criteria we hold for user fee based programs, and
13 our participation in those programs are with them,
14 and consistent with that, we presented at the last
15 OMUFA public hearing for OMUFA I in 2016. At the
16 core, we believe a party who receives economic
17 benefit should pay the fees, and the fees should
18 fully recover the actual or best estimated cost of
19 providing such services. We do applaud the
20 progress the FDA has made in time reporting and
21 other things to better inform that cost
22 understanding. Past experience, as with OMUFA I,

1 also shows that there's downside impact if fees and
2 value are misaligned, including an impact reduction
3 of available capacity to serve a market and support
4 innovation, which we've seen in the past.

5 Next slide, please.

6 [Slide 90.]

7 We continue to support OMUFA's fundamental
8 goals and approach, and recognize and applaud the
9 significant progress made by the FDA, to date,
10 despite the impacts of the pandemic and the many
11 competing priorities for the FDA's focus. Versus
12 the first OMUFA hearing, today's economic
13 conditions are different for OTC and consumer
14 health demand, which has in recent years caused a
15 contraction of available CDMO supply for monograph
16 OTC products and consumer health products via
17 facility closures, consolidation, downsizing,
18 insourcing, and because of geopolitical issues as
19 well, so that's important context to note here.

20 As the program focus turns to OMORs, we will
21 seek further transparency of both efforts and
22 outcomes, and we've seen this, too, with other

1 maturing OMUFA programs, more transparency on
2 volumes of inputs, volumes of outputs, and process
3 understanding. We'll seek to ensure that the FDA
4 effectively redeploys and fully leverages OMUFA
5 funded resources to support the evolving program
6 focus before seeking to expand staffing, and
7 finally, to ensure that the cost, again, for any
8 program extensions or enhancements are borne by the
9 parties who received the economic benefits thereof.

10 [Slide 91.]

11 We do very much look forward to contributing
12 to the development of OMUFA II and appreciate the
13 opportunity to speak today. Thank you.

14 [Slide 92.]

15 **Panel 4**

16 DR. ADJEIWAA-MANU: Thank you, Cornell.

17 That concludes our session on regulated
18 industry perspectives. Our final session is on
19 scientific and academic expert perspectives. We
20 will hear from Eric Brass from the University of
21 California, Los Angeles; Ruth Parker from Emory
22 University; and Maria Coyle from The Ohio State

1 University College of Pharmacy.

2 [Slide 94.]

3 Eric, we welcome your comments.

4 **Presentation - Eric Brass**

5 DR. BRASS: Good morning, and I appreciate
6 the opportunity to share some thoughts with you
7 this morning. I understand the purpose of today's
8 meeting is really about process, but as an
9 outsider, quite frankly, I have limited insight as
10 to the processes involved at a granular level.
11 Rather, I would hope that an understanding of what
12 these processes are intended to accomplish will
13 help guide optimization of the processes to meet
14 those ends, and that's the tact I'd like to take
15 today.

16 Next slide, please.

17 [Slide 95.]

18 I want to begin with an overarching
19 perspective, and that is, my interests in this area
20 all derive from a belief that increasing access to
21 safe and effective drugs can improve personal and
22 public health. In this context, what's the role of

1 the monograph and monograph reform? Well, clearly,
2 historically, it has facilitated the use of
3 ingredients that were recognized as safe and
4 effective.; it ensured consumers received
5 information through labeling needed to use those
6 products that contain monograph ingredients; and it
7 was able to promote innovation in improving access
8 to safe and effective drugs by the public.

9 Next slide, please.

10 [Slide 96.]

11 So how should the monograph evolve? Well, I
12 think it's critical to establish clear priorities,
13 and more importantly, that those priorities should
14 be based on changes with the largest opportunity to
15 impact personal and public health. There's
16 obviously a large list of things that could be
17 done, but we need to understand what will have the
18 largest impact.

19 We have some examples involving monograph
20 ingredients over the past decade. These involve
21 the challenges of pediatric overdoses involving
22 monograph ingredients. This was led by voluntary

1 actions taken by a number of those participating
2 today in response to a CDC-led PROTECT initiative
3 that was voluntary and collaborative. Importantly,
4 the initiative was driven by data identification of
5 possible interventions with public health impact.

6 To illustrate that, can I have the next
7 slide, please?

8 [Slide 97.]

9 Work by the CDC using emergency department
10 visits identified pediatric unsupervised accidental
11 ingestions of acetaminophen as a significant
12 contributor to emergency department visits. The
13 data identified liquid formulations as a major
14 contributor to these exposures. Laboratory
15 research show that flow restrictors can limit
16 access to the liquid contents of containers, and
17 all this led to a 2011 initiative to use flow
18 restrictors on liquid acetaminophen products. The
19 trends associated with these exposures could be
20 assessed using data from the National Poison Data
21 System, which was done in collaboration with the
22 Rocky Mountain Poison and Drug Center.

1 Next slide, please.

2 [Slide 98.]

3 Now, what you can see in the top panel is
4 the number of reported exposures from accidental
5 pediatric ingestion of acetaminophen products over
6 time. Prior to 2011, you can see a relatively flat
7 trend, followed by a sharp decrease in exposures
8 temporarily associated with the introduction
9 voluntarily of flow restrictors in 2011. That's
10 seen more clearly in the lower panel, which
11 normalizes the data of products sold and separates
12 liquid and solid formulations. And again, you see
13 the sharp decrease in exposures associated with
14 liquid formulations temporarily associated with the
15 flow restrictors, with no change in the solid
16 formulations.

17 Next slide.

18 [Slide 99.]

19 The CDC emergency department also identified
20 a problem with medication errors with pediatric
21 acetaminophen products when they're used for
22 therapeutic intent; that is, caregivers giving

1 these products to children intending to treat the
2 indication on the label. This problem also led to
3 a number of voluntary actions.

4 Again, even though these are a monograph
5 ingredient, these actions were taken voluntarily.
6 There was standardization of tabular formatting for
7 dosing, often including both weight and age;
8 standardization of milliliter units on the dosing
9 instructions; use of leading zeros in numerical
10 presentation of dosing instructions, including a
11 calibrated dosing device consistent with dosing
12 instructions; a dosing device that was not
13 significantly larger than the highest dose; and an
14 effort to standardize the acetaminophen
15 concentration in liquid formulations, which also
16 was endorsed subsequently by an FDA guidance.

17 Again with Rocky Mountain, we looked at
18 National Poison Data System exposure data, and on
19 the next slide, you can see while prior to 2011 the
20 signal was noisy, following 2011, there was again a
21 sharp decrease in the number of of exposures
22 associated with medication errors. That was also

1 temporally associated with a decrease in the sale
2 in the lower line of the more concentrated liquid
3 acetaminophen formulations and an increase in the
4 more standardized 160 milligram per 5 ml
5 formulations.

6 [Slide 100.]

7 But we also learned other things from this
8 experience. First, the absolute number of these
9 medication error exposures was relatively low on a
10 national level, particularly when compared to the
11 problem of accidental pediatric exposures. More
12 striking was that a full 66 percent of these
13 exposures resulted from administration of
14 caregivers to children under the age of 2. Again,
15 these were with therapeutic intent, the caregiver
16 trying to give benefit to the child, but without
17 dosing instructions on the label, other than to
18 call a healthcare professional, the caregiver felt
19 that they needed to do something, administered the
20 drug, recognized that they had overdosed, and
21 called the poison center.

22 Next slide please.

1 [Slide 101.]

2 So looking forward to the future, how can
3 the processes and authorities that have been put in
4 place and evolving best be used? As I've already
5 indicated, priority should be based on personal and
6 public health impacts of the specific issues under
7 consideration. These decisions should be data
8 driven to the degree possible. An obvious example
9 from the work I've showed you is to address the
10 challenge of acetaminophen labeling for children
11 under 2, where information provided to caregivers
12 has the potential to decrease the established trend
13 of medication errors.

14 I'd also emphasize that we need to consider
15 health benefits from reform and not just risk
16 reduction. Again, making effective drugs available
17 to consumers has the opportunity to improve
18 personal and public health, and innovation should
19 take advantage of that opportunity as well.

20 While the original monograph was created, in
21 part, under necessity of the changes in laws in the
22 70s, the question is, can the advantages of the

1 monographs to stakeholders be leveraged going
2 forward?

3 Next slide.

4 [Slide 102.]

5 A key question and one you've heard alluded
6 to earlier is how to incentivize innovation from
7 the various stakeholders? For example, can and
8 should ingredients be added to the monograph?
9 There are many NDA ingredients with
10 well-established records of safety and efficacy.
11 Should these be considered monograph candidates?
12 What are the advantages and disadvantages to
13 stakeholders of such action, and are those even
14 understood across the community?

15 Should the monograph be viewed as an
16 alternative to the NDA process? And if so, why and
17 why not? There's obviously a number of complex
18 issues involved here, some of which you've heard
19 about today, including timelines, confidentiality,
20 exclusivity, and other factors that determine
21 whether or not there's, in fact, incentive for
22 innovation across this space.

1 You've also heard communication among
2 stakeholders is critical, that I endorse. In data-
3 driven decision making, the sources of data are
4 often outside of the FDA's current purview, and how
5 can that information be best obtained? Cooperation
6 is going to be critical to ensure that the FDA has
7 the data it needs and that stakeholders have the
8 opportunity to provide that data.

9 There needs to be transparency as to those
10 priorities and activities. I thought the annual
11 forecast was an excellent example of how such
12 transparency can be accomplished, but it's unclear
13 whether that instrument is being used optimally in
14 terms of whether what's on the forecast is actually
15 what dictated activities in the ensuing year.

16 Next slide.

17 [Slide 103.]

18 So I thank you very much for your attention
19 and the opportunity to share these thoughts, and I
20 look forward to the success of monograph reform
21 going forward. Thank you.

22 DR. ADJEIWAA-MANU: Thank you, Eric.

1 Ruth, please begin.

2 [Slide 104.]

3 **Presentation - Ruth Parker**

4 DR. PARKER: Thanks so much. I appreciate
5 the opportunity to be a part of the conversation
6 here, and as usual, I've learned a lot. Let me
7 offer my wholehearted congratulations and
8 appreciation to all those who've worked to really
9 make this happen to the point that we are today.
10 It's incredibly complicated, it's complex, and I
11 don't doubt that many times those involved have
12 felt like they're rolling a [indiscernible] ball
13 uphill.

14 Overall, I think there are very significant
15 and needed improvements that really should benefit
16 all, and especially the public, and I hope that
17 remains our primary target, the health of the
18 public. The reauthorization clearly offers an
19 opportunity for improvements in enhancing the work
20 that this is all about anyway.

21 Let me just also say that this all kind of
22 reminds me of the transition that those of us who

1 are part of clinical medicine lives with, the
2 electronic medical record. I love the slide that
3 was presented early about the paper catalog, so let
4 me welcome the agency and all others to the
5 digitized world because that's what will be
6 happening moving forward.

7 I think that actually offers some incredible
8 opportunities, and some of my comments will relate
9 very specifically to the fact that you are indeed
10 able now to move from a paper catalog to the world
11 that is digitized, where all of us are living
12 anyway. I also recall the constant training, the
13 updates, the time, the orientation that are all a
14 part of what we hope are eventually improved
15 quality, improved safety, and outcomes for the
16 public.

17 You asked us a question about current
18 elements of OMUFA that could be modified or added
19 to ensure the efficiency and the effectiveness of
20 the monograph drug activities, and I think many of
21 you know a whole lot more about the details within
22 that, and I think a lot of the devil is in the

1 details in something that's complicated. But the
2 two zones that I would underscore, one relates to
3 labeling, not unlike Eric who just went before me,
4 and I'll just say that for OTC products, labels
5 really matter. The devil does live in the details
6 with labels, and dosing instructions are not minor.

7 We see this term in the regulations about
8 minor dosing changes, and I raised similar caveats
9 about the need to be very specific here. What is
10 minor about dosing, and what do you mean by minor
11 dosing changes? And how will this relate
12 specifically to pediatric age populations where
13 we've already heard concerns raised? And how does
14 it relate to multi-ingredient products, which have
15 always been a safety concern in my mind? How will
16 label changes relate? Will there be more
17 multi-ingredient products? How will this relate to
18 exclusivity? I see that as one area for increased
19 attention and collaboration between the parties
20 moving forward.

21 In general, I'm concerned about the low and
22 lean budgets that are being proposed. Those were

1 graphically captured early on in this. I think
2 it's really going to be important with
3 reauthorization to ensure that the funding
4 resources, both for OMOR and for the facility fees,
5 are adequate to support both review and monitoring.
6 Monitoring for safety is the purview of the agency,
7 and I think it's really important, with this
8 opportunity of the funding, to look at whether or
9 not the levels can support what's needed.

10 Safety is a concern for all medications.
11 It's especially a concern for over-the-counter
12 products where there is no learned intermediary,
13 and there's a heightened need for consumers to
14 understand and know safety warnings, safety
15 concerns, and labeling. And I'm concerned that
16 these fees are not adequate to really be able to
17 support the opportunities that we have, especially
18 in the digitized world, for the kinds of monitoring
19 and the kinds of review that ensures safety.

20 So let me speak just a little bit to that.
21 I'll use an example. Eric just used a specific
22 example, and I'll use a couple others as I talk a

1 little bit more about my concern with fees overall.
2 And as I said, I have concerns about low fees for
3 OMOR and facility fees, but the comments I'm going
4 to give you will relate more to whether or not the
5 fees are adequate to enhance manufacturing quality
6 to ensure safety.

7 Drug manufacturers are, indeed, required to
8 ensure the safety and the quality of their drugs.
9 OMUFA offers this opportunity to improve the
10 oversight of manufacturing quality regarding
11 safety. Four recent examples, several that have
12 heightened relevance to this, our time of living in
13 a pandemic and the safety of over-the-counter
14 products. I'm going to mention these four, and as
15 I mention them, think about whether or not the fees
16 proposed will allow us to do what we'd like to do
17 to make sure we're doing the best for the public
18 regarding product safety.

19 2020 methanol and hand sanitizers, the FDA
20 had a list that included 150 hand sanitizing
21 products with guidance to industry in 2021,
22 describing reports of fatal methanol poisoning of

1 consumers who ingested alcohol-based hand
2 sanitizers that were manufactured with methanol.
3 There were also some reports of dermal toxicity.
4 In January of 2021, the agency for the first time
5 had issued a countrywide import alert for any
6 category of drug products, and this was alert for
7 alcohol-based hand sanitizers from Mexico. These
8 are both serious safety concerns for hand
9 sanitizers at the time of a pandemic.

10 December 2022, benzene contamination.

11 Benzene is a known human carcinogen. Certain hand
12 sanitizers and aerosolized drug products, including
13 antiperspirants and sunscreens, were recalled
14 during benzene contamination. Recall that the
15 agency is not able to recall products; instead what
16 they do is issue guidance; in May of 2023,
17 diethylene glycol and ethylene glycol contamination
18 of relevance to oral liquid drug products, mostly
19 for children under the age of 5; August of 2023,
20 nitrosamine impurities, and there's an evolving
21 highly technical amount of relevant information
22 related to this. And with all of these, I ask

1 about whether or not the fees proposed are adequate
2 to ensure the safety when there are manufacturing
3 quality issues.

4 Let me sort of step back and say, the other
5 piece of this, to me, that's incredibly important
6 is the consumer base and communications regarding
7 the OTC product safety and whether or not these are
8 being adequately addressed for improvement for the
9 proposed fees adequate to enhance and monitor the
10 critical health communications regarding
11 up-to-date, relevant, important safety concerns, be
12 they related to warnings or be they related to
13 label issues.

14 DR. ADJEIWAA-MANU: Ruth, you have about a
15 minute and a half left.

16 DR. PARKER: Okay.

17 Now that the FDA is digitized, and the OTC
18 monograph process is digitized, I think it's an
19 exciting opportunity to think about how the
20 digitized OTC world best communicates in consumers
21 facing critical health information regarding
22 safety.

1 Finally, in terms of the added language for
2 reauthorization, I would think about pulling out
3 potential high-yield uses of AI, data sharing, data
4 analytics, monitoring for safety concerns, and
5 adherence to regulations, and how collaboratively
6 we all move forward in the digitized world with the
7 ultimate health of the public as our North Star.
8 Thank you.

9 DR. ADJEIWAA-MANU: Thank you, Ruth.

10 Maria, you may begin your comments now.

11 [Slide 105.]

12 **Presentation - Maria Coyle**

13 DR. COYLE: Good morning. Thank you all for
14 the opportunity to participate in the panel today
15 and for accommodating my participation at a
16 distance. My name is Maria Coyle, and I'm an
17 Associate Professor of pharmacy at The Ohio State
18 University College of Pharmacy, and a board
19 certified specialty care pharmacist at our Wexner
20 Medical Center in Columbus, Ohio. I've been a
21 faculty member working in pharmacy education for
22 more than 20 years and a licensed Ohio pharmacist

1 working in patient care for more than 30 years,
2 both in community practice settings and in
3 interdisciplinary medication management programs at
4 Ohio State.

5 A highlight of my professional career has
6 been my participation on the Nonprescription Drug
7 Advisory Committee, working with FDA over several
8 terms, including most recently as the chairperson
9 for 2022 and 2023, so I think you all can see that
10 it's not at all surprising that I have a
11 significant and ongoing interest in the OTC
12 medication and monograph process. I'm here today
13 to share various perspectives from all of those
14 experiences as academician, as clinical innovator,
15 as a healthcare provider and patient advocate, and
16 also as a consultant, a caregiver, and regular user
17 of OTC medications.

18 The role and importance of over-the-counter
19 medicines in patients' healthcare has been front
20 and center throughout my entire career. There are
21 hundreds of over-the-counter drug ingredients
22 available, and literally thousands of products

1 available in the retail space. I regularly counsel
2 patients on analgesics, topical antiseptics and
3 topical antibiotics, sunscreen use, allergy, cough
4 and cold medications, and many others. Many of
5 these medicines, all of the ones that I've just
6 mentioned, are regulated through the OTC monograph
7 process. Nearly every patient that I encounter
8 will use OTC products, and average households spend
9 hundreds of dollars each year on OTCs.

10 We know that this use is likely to increase
11 over time, and it's due to many reasons. There's a
12 shift more and more from some prescription to
13 over-the-counter availability of medications; the
14 prevalence of mild or self-limited diseases that
15 can be easily treated over-the-counter are
16 increasing; and there are other factors like health
17 system pressures, where accessibility to providers
18 or geographic limitations definitely limit how
19 easily a consumer can get to a physician or other
20 prescriber.

21 Consumer preferences and convenience are
22 also incredibly important, and in my time at EMDAC,

1 I've really come to appreciate the significant
2 voice of consumer advocates and the impactful and
3 often very moving testimonies of patients regarding
4 the importance of OTC in their lives. Simply put,
5 the reliance on and demand for safe and effective
6 OTCs is on the rise. FDA is doing important work
7 in revising and reforming the OTC monograph
8 program.

9 You've already heard the pharmacists are
10 frontline healthcare providers. Sometimes I am the
11 first or even the only point of contact for a
12 patient who's in search of healthcare, so it's
13 really crucial that I and my colleagues provide OTC
14 recommendations that are grounded in a deep
15 clinical understanding of how they work and their
16 risks, and a confidence in the regulatory process,
17 especially the OTC monograph process because it
18 does encompass so very many of those products.
19 It's very exciting and reassuring to see monograph
20 reforms in process, especially over the last few
21 years, and I really look forward to the ongoing
22 positive impact that this work will accomplish.

1 I realize that I'm the last speaker of the
2 day, and I want to just state that I do agree with
3 many of the viewpoints and perspectives already
4 shared very eloquently by my pharmacy colleagues
5 early in the professional panel and some of my
6 academic colleagues in this last panel. The ideas
7 that I have are being presented generally because,
8 like many others, I'm not as familiar with the
9 detailed processes of OMUFA, but I do have a couple
10 of areas that I would like to highlight that I
11 think are worth restating and worth consideration
12 as FDA works into revising those detailed
13 processes.

14 First, I just want to underscore the
15 importance of streamlining logistics. As we move
16 into reauthorization, opportunities to continue to
17 expedite and, as needed, enhance flexibility of
18 regulatory processes is absolutely necessary. I
19 often tell my trainees when they're thinking about
20 how to innovate in clinical practice, "Let's think
21 about the simplest model that will do the job, and
22 then continue to make it better as it's

1 implemented," and that's really where FDA is
2 currently with OMUFA.

3 Many monograph ingredients have a long
4 history, but there is a lot that we are learning.
5 New clinical information, novel combinations, new
6 products, new dose technologies, and updated
7 delivery systems result in an ever-increasing and
8 often bewildering set of options for consumers. It
9 can be really hard to change and to stay up with
10 current changes, but efficient processes on the
11 regulatory side will help ensure timely access to
12 the most compliant and effective OTC medications.
13 This serves the public good.

14 I would also encourage that the progress
15 toward establishing a more systematic and robust
16 surveillance program about the OTC monograph
17 ingredients is necessary. We heard before that
18 monograph reform is in the early stages, focusing a
19 lot on capacity and infrastructure building in
20 these early years, but there is so much work to be
21 done in terms of reviewing OTC monograph
22 ingredients.

1 Just as with prescription pharmaceuticals,
2 we should be expecting to reconsider the relevance,
3 importance, and safety and effectiveness of
4 monograph ingredients to maintain health and
5 prevent illness on a regular basis. Medical
6 understanding is changing, research methods have
7 evolved, and technologies and patient expectations
8 are all moving targets.

9 Prescription medicines, as I mentioned,
10 continue to move into the OTC space, so the
11 landscape that informed best product selection, or
12 even the available products from decades ago, are
13 no longer relevant in all cases, and I'll just
14 underscore this with an example that's been brought
15 up before.

16 Earlier this month, EMDAC met to review
17 updated science on the clinical efficacy of OTC
18 phenylephrine in the cough-and-cold monograph.
19 Much of our discussion and the discourse of the day
20 was centered around, quote/unquote, "new data."
21 This new data emerged in 2015 with several
22 publications that were available that year, and

1 2015 is not new. At the time the publications were
2 made available, science was with us but,
3 unfortunately, the regulatory landscape was not
4 really conducive to making updated changes in a
5 quick manner. But, fortunately, monograph reform
6 in the 2020s has allowed us to now address this
7 important initiative, and resources to continue
8 this work is just critically important.

9 I'll say it again just to underscore this
10 point. Science can be fast or slow, but we really
11 don't want regulatory capacity and infrastructure
12 to be the rate-limiting step or barrier that
13 prevents the latest science from reaching
14 healthcare practice.

15 Another point that I want to make is just
16 that I do believe that transparency and
17 accessibility of information is critically
18 important, and I applaud the efforts that the FDA
19 has made to make monographs condensed, up to date,
20 technically correct, and available literally
21 through the the click of a button through the
22 computer --

1 DR. ADJEIWAA-MANU: Maria, you have about a
2 minute and a half left.

3 DR. COYLE: Thank you.

4 -- and I do encourage them to continue that
5 work.

6 I would just like to piggy back off of
7 Dr. Parker's comments and just reinforce the
8 importance of drug facts labeling, and also
9 thinking about consumer education initiatives
10 beyond the drug facts label. We live in a digital
11 world, where tools and interactive platforms rule
12 much of our daily life, and I think there is an
13 opportunity for them to enhance the OTC space as
14 well.

15 All of these recommendations require that
16 the FDA is able to prioritize their necessary
17 investments, in funding, personnel, and in
18 infrastructure. I would also encourage them to
19 consider collaborative participation with
20 stakeholders like professional organizations and
21 the public; so are there ways to make that
22 collaboration a little bit more bidirectional?

1 In summary, I'm really encouraged by the
2 recent changes that we've seen with OMUFA. I look
3 forward to OMUFA II in continuing this work and
4 underscore the importance of a broad focus on OTC
5 monograph ingredients as a pathway to better public
6 health. Thank you.

7 DR. ADJEIWAA-MANU: Thank you, Maria, and
8 thank you to all of our speakers for your comments
9 today.

10 We will now wrap up the panel presentations
11 with remarks from Theresa Michele, Director of
12 FDA's Office of Nonprescription Drugs.

13 [Slide 106.]

14 **Closing Comments - Theresa Michele**

15 DR. MICHELE: Well, a big thank you to
16 everyone for being here today. As I summarize what
17 I've heard today, there's been a lot of good
18 information that's been put out there. One theme
19 has run through it all, though, and I just wanted
20 to emphasize that, which is the importance of OTC
21 drugs to the American consumer.

22 We heard that from every single speaker

1 across the board, and I think that's why we're all
2 here today, is because OTCs are so critical in our
3 daily lives, we want to make sure that we have the
4 best processes here at FDA to support that need;
5 that all the products on the shelf are safe and
6 effective and we do the best job that we can for
7 public health.

8 The other theme that I heard kind of run
9 through this is how OMUFA has changed things. It's
10 given us more tools, more abilities to innovate, to
11 ensure the safety and efficacy of products and to
12 ensure that those labels are right. This is good
13 for public health, but it's also good for industry
14 because I know that all the people sitting here in
15 this room, all of those of you who have presented
16 publicly, and the many people who are listening
17 today, have the thought in mind that we want to
18 ensure that those products that people are
19 purchasing are helpful to them. If they're not,
20 they're not going to purchase them again or they're
21 going to go to their physician and try to get
22 something better or something that's different, and

1 the goal is to make sure that they do that when
2 it's right for their personal health.

3 So in all of this, I wanted to say thank
4 you. We've heard a lot of positive comments of
5 things that we can potentially do to make the
6 product and the whole process better, better for
7 all of us, as a win-win for industry, for public
8 health, for consumers, and most of all, to make
9 sure that all of us involved in the process work to
10 the end of the day to ensure that those safe and
11 effective products are available for consumers.

12 So with that, I'll close in thanking all of
13 the people who have come together today to give us
14 ideas for this program going forward. I think
15 we've heard a lot of important wins for the program
16 in the first iteration, and we look forward to some
17 important wins for the program in the next
18 iteration because those wins ultimately are wins
19 for everybody. So with that said, I'll also thank
20 those of you who are online with us listening and
21 those of you who are in the room listening. I hope
22 many of you are inspired to submit comments to the

1 public docket, and I thank you for your attention
2 today.

3 [Slide 107.]

4 **Adjournment**

5 DR. ADJEIWAA-MANU: That concludes our
6 meeting for today. I'll echo Theresa in saying
7 thank you to all of the speakers who took the time
8 to share their comments with us. Thank you also to
9 those of us who came in person or logged in to
10 listen to the meeting today.

11 As a reminder, as Theresa mentioned, the
12 public docket will be open until October 27, 2023.
13 Thank you all, and we hope you enjoy the rest of
14 your day.

15 (Whereupon, at 11:41 a.m., the meeting was
16 adjourned.)

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