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.

Meeting Roster

Nana Adjeiwaa-Manu

Center for Drug Evaluation and Research, FDA

James Baumberger

American Academy of Pediatrics

Heather Boyd

American Pharmacists Association

Eric P. Brass

University of California, Los Angeles

Patrizia Cavazzoni

Center for Drug Evaluation and Research, FDA

Maria Coyle

The Ohio State University College of Pharmacy

Theresa Michele

Center for Drug Evaluation and Research, FDA

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

Douglas Troutman

American Cleaning Institute

Cornell Stamoran

Pharma & Biopharma Outsourcing Association

Diana Zuckerman

National Center for Health Research

C O N T E N T S

C O N T E N T S (continued)

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

regulated industry.

[Slide 4.]

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

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

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

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

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

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

This meeting is an opportunity for FDA to

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

[Slide 5.]

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

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

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

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

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

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

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

[Slide 6.]

Opening Remarks - Patrizia Cavazzoni

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

the reauthorization of the OMUFA program.

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

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

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

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

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

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

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

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

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

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

The FDA is holding a public meeting to

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

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

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

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

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

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

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

[Slide 7.]

FDA Presentation - Karen Murry

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

[Slide 9.]

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

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

Next slide, please.

[Slide 10.]

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

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

Discussions between FDA and industry led to proposed solutions. Together, they proposed a much more nimble system. Most monograph rulemaking would be replaced by administrative orders. These orders can usually be signed off at the division level, a huge streamlining of the process. Industry would have a clear path for innovation; industry and FDA could act on safety concerns more quickly; regulatory uncertainty would be reduced by a finalization process for proposed monographs; and monograph user fees would add people and IT systems to handle the new workload and commitments.

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

reform.

Next slide, please.

[Slide 11.]

Then on March 27, 2020, CARES was enacted. This was the Coronavirus Aid, Relief, and Economic Security Act, and it included important statutory provisions that reformed and modernized the way OTC monograph drugs are regulated in the U.S. In most cases, rulemaking for the OTC monograph is now replaced by an administrative order process, which is much more streamlined. The system now more easily accommodates innovation by industry. The CARES Act also authorized monograph user fees.

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

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

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

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

Next slide, please.

[Slide 12.]

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

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

Next slide, please.

[Slide 13.]

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

Next slide, please.

[Slide 14.]

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

Hiring has been challenging due to a variety

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

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

Next slide, please.

[Slide 15.]

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

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

Next slide, please.

[Slide 16.]

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

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

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

Next slide, please.

[Slide 17.]

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

Next slide, please.

[Slide 18.]

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

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

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

Next slide, please.

[Slide 19.]

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

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

Next slide.

[Slide 20.]

FDA also committed to issuing a guidance on the format and content of OMORs and a guidance on submissions in electronic format. The content and format guidance includes FDA's recommendations on what content should be in OMORs and the format, which generally follows the common technical document. When requestors begin to submit OMORs, they will need to be in electronic format. The electronic format draft guidance includes recommendations on how to manage the electronic submissions.

Next slide.

[Slide 21.]

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

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

Next slide.

[Slide 22.]

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

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

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

Next slide.

[Slide 23.]

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

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

Next slide.

[Slide 24.]

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

Next slide.

[Slide 25.]

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

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

Next slide.

[Slide 26.]

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

Next slide.

[Slide 27.]

The portal for submission of OMORs will be

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

Next slide, please.

[Slide 28.]

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

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

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

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

Next slide, please.

[Slide 29.]

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

PDUFA.

Next slide.

[Slide 30.]

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

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

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

Next slide, please.

[Slide 31.]

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

Next slide, please.

[Slide 32.]

So we've talked so far about FDA's

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

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

Next slide, please.

[Slide 33.]

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

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

Next slide, please.

[Slide 34.]

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

Next slide, please.

[Slide 35.]

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

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

Next slide.

[Slide 36.]

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

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

[Slide 38.]

Panel 1

DR. ADJEIWAA-MANU: Thank you, Karen.

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

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

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

[Slide 39.]

Presentation - James Baumberger

MR. BAUMBERGER: Thank you very much.

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

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

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

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

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

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

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

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

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

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

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

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

The data that led FDA to label cough and

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

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

There is significant need for FDA to make

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

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

Thank you for the opportunity to speak

today. Thanks so much.

DR. ADJEIWAA-MANU: Thank you, James.

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

[Slide 40.]

Presentation - Heather Boyd

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

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

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

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

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

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

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

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

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

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

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

DR. ADJEIWAA-MANU: Thank you, Heather.

Jessica, we welcome your comments now.

[Slide 41.]

Presentation - Jessica Satterfield

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

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

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

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

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

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

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

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

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

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

DR. ADJEIWAA-MANU: Thank you, Jessica.

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

Diana, as our only speaker in this session,

you may begin.

(Pause.)

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

(No response.)

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

(Pause.)

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

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

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

[Slide 42.]

Panel 2

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

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

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

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

[Slide 43.]

Presentation - Diana Zuckerman

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

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

[Slide 44.]

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

Next slide, please.

[Slide 45.]

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

Next slide, please.

[Slide 46.]

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

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

It creates missed opportunities for use of

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

Next slide, please.

[Slide 47.]

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

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

Next slide, please.

[Slide 48.]

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

effectiveness.

Next slide, please.

[Slide 49.]

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

Next slide, please.

[Slide 50.]

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

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

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

Next slide, please.

[Slide 51.]

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

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

Last slide, please.

[Slide 52.]

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

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

[Slide 54.]

Panel 3

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

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

the Pharma & Biopharma Outsourcing Association.

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

[Slide 55.]

Presentation - Lisa Parks

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

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

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

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

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

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

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

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

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

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

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

and suitability.

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

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

Category 3 ingredient uses.

Third, encouraging FDA to initiate orders. Both the FDA and the industry have pathways to initiate the administrative order process. We encourage the FDA to initiate orders where it possesses sufficient data to support GRASE determinations or changes to the monograph. This will streamline the OTC monograph process and allocate industry resources effectively.

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

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

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

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

This pathway enables the industry to introduce important innovations into the OTC drug market more efficiently, addressing a significant hurdle in the previous monograph system. Ultimately, this aims to offer consumers easier access to improved and convenient dosage forms of

safe and effective products.

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

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

[Slide 56.]

DR. ADJEIWAA-MANU: Thank you, Lisa.

Dan, you may begin.

[Slide 57.]

Presentation - Dan Selechnik

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

Next slide, please.

[Slide 58.]

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

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

Next slide, please.

[Slide 59.]

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

Slide, please.

[Slide 60.]

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

Slide?

[Slide 61.]

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

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

[Slide 62.]

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

[Slide 63.]

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

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

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

[Slide 64.]

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

data has to be generated.

[Slide 65.]

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

[Slide 66.]

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

that remain.

Thank you.

[Slide 67.]

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

Next slide.

[Slide 68.]

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

[Slide 69.]

DR. ADJEIWAA-MANU: Thank you, Dan.

Douglas, please begin.

[Slide 70.]

Presentation - Douglas Troutman

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

Next slide.

[Slide 71.]

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

are lawfully marketed under the law.

Next slide, please.

[Slide 72.]

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

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

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

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

Next slide.

[Slide 73.]

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

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

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

Next slide.

[Slide 74.]

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

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

Next slide, please.

[Slide 75.]

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

address.

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

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

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

Next slide, please

[Slide 76.]

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

[Slide 77.]

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

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

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

DR. ADJEIWAA-MANU: Thank you, Douglas.

Meredith, we welcome your comments now.

[Slide 78.]

Presentation - Meredith Petillo

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

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

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

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

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

These products contribute economically and

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

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

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

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

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

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

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

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

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

For them, to add just one anti-dandruff

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

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

The most common questions IBA received

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

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

Finally, small entrepreneurial brands may

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

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

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

manufacturers.

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

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

[Slide 79.]

DR. ADJEIWAA-MANU: Thank you, Meredith.

Tom, you may begin.

[Slide 80.]

Presentation - Tom Myers

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

[Slide 81.]

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

Next slide, please.

[Slide 82.]

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

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

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

Next slide, please.

[Slide 83.]

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

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

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

[Slide 84.]

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

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

[Slide 85.]

DR. ADJEIWAA-MANU: Thank you, Tom.

Cornell, you may begin.

[Slide 86.]

Presentation - Cornell Stamoran

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

Next slide, please.

[Slide 87.]

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

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

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

Next slide, please.

[Slide 88.]

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

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

Next page, please.

[Slide 89.]

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

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

Next slide, please.

[Slide 90.]

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

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

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

[Slide 91.]

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

[Slide 92.]

Panel 4

DR. ADJEIWAA-MANU: Thank you, Cornell.

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

University College of Pharmacy.

[Slide 94.]

Eric, we welcome your comments.

Presentation - Eric Brass

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

Next slide, please.

[Slide 95.]

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

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

Next slide, please.

[Slide 96.]

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

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

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

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

[Slide 97.]

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

Next slide, please.

[Slide 98.]

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

Next slide.

[Slide 99.]

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

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

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

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

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

[Slide 100.]

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

Next slide please.

[Slide 101.]

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

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

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

monographs to stakeholders be leveraged going forward?

Next slide.

[Slide 102.]

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

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

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

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

Next slide.

[Slide 103.]

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

DR. ADJEIWAA-MANU: Thank you, Eric.

Ruth, please begin.

[Slide 104.]

Presentation - Ruth Parker

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

December 2022, benzene contamination. Benzene is a known human carcinogen. Certain hand sanitizers and aerosolized drug products, including antiperspirants and sunscreens, were recalled during benzene contamination. Recall that the agency is not able to recall products; instead what they do is issue guidance; in May of 2023, diethylene glycol and ethylene glycol contamination of relevance to oral liquid drug products, mostly for children under the age of 5; August of 2023, nitrosamine impurities, and there's an evolving highly technical amount of relevant information related to this. And with all of these, I ask

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

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

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

DR. PARKER: Okay.

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

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

DR. ADJEIWAA-MANU: Thank you, Ruth.

Maria, you may begin your comments now.

[Slide 105.]

Presentation - Maria Coyle

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. COYLE: Thank you.

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

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

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

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

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

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

[Slide 106.]

Closing Comments - Theresa Michele

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

We heard that from every single speaker

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

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

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

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

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

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

[Slide 107.]

Adjournment

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

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

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