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FOOD AND DRUG ADMINISTRATION

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Center for Drug Evaluation and Research / Office of Communications

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PUBLIC MEETING ON THE REAUTHORIZATION OF THE GENERIC DRUG USER FEE AMENDMENTS (GDUFA)

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Participants

Meeting Moderator	Mark Ascione
Commissioner of Food and Drugs, FDA	Marty Makary
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FDA Participant	Rob Lionberger
FDA Participant	Michael Kopcha
FDA Participant	Ivy Sweeney
Industry Representative	Giuseppe Randazzo
Industry Representative	Joel Carpenter
Open Comment Period Participant	Diana Zuckerman
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Open Comment Period Participant	Nimi Chhina
Open Comment Period Participant	Basil Considine

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Welcome

00:00:45 Mr. Ascione: Good morning, everybody. We're going to go ahead and get started. If you want to find seats, there should be plenty of room. All right. Good morning and welcome to the Public Meeting on the Reauthorization of the Generic Drug User Fee Amendments, or GDUFA. My name is Mark Ascione. I'm with the Office of Program Strategic Analysis within the Center for Drug Evaluation and Research. I will be your moderator today.

00:01:20 GDUFA is the legislation that authorizes FDA to collect user fees to support the process for the review of generic drug products. The current authorization of the program, which is GDUFA III, expires in September of 2027. Preparations are therefore underway to begin the process to reauthorize the program for fiscal years 2028 through 2032. 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.

00:01:53 Today's meeting is an important step in engaging with public stakeholders and on the features of the GDUFA Program. We have a full agenda today. We'll begin with Dr. Martin Makary, the Commissioner of the FDA, who will provide opening remarks. Then we'll have presentations given by-- From FDA given by Iilun Murphy, Director of Office of Generic Drugs; Rob Lionberger, Director of Office of Research and Standards; Michael Kopcha, Director of the Office of Pharmaceutical Quality; and Ivy Sweeney, Deputy Director of the Office of Human and Animal Drug Inspectorate. We'll then have presentations from regulated industry. A Public Comment Session will occur at the end of the meeting for those who submitted a request in advance, and if time allows, we'll hear open public comments from people who are attending here in the room. I'll then close the meeting around 12:40.

00:02:52 Each speaker throughout has a time limit. If we do have a full agenda, we'll do our best to adhere to that timeframe. I've let speakers know, but for those who I didn't talk to, warning card. When two minutes are left in your time, I'll have this up. I'll be sitting in the back there and this will be telling you time. Time to wrap up.

00:03:13 In the Federal Register notice announcing this meeting, FDA provided questions to help panelists for their comments. What is your assessment of the overall performance of the GDUFA program to date? What aspects of GDUFA should be retained, changed, or discontinued to further strengthen and improve the program? What new features, if any, should FDA consider adding to the program to enhance efficiency and effectiveness of the generic drug review process? What changes, if any, could be made to the current fee structures and amounts to better advance the goals of the agreement, including facilitating product development and timely access for consumers?

00:03:54 Policy issues are beyond scope of the GDUFA reauthorization process. Therefore, the presentation should focus on process enhancements and funding issues and not on issues of policy.

00:04:04 This meeting is an opportunity for FDA to listen to public perspectives. FDA will not ask questions nor answer questions raised at the meeting. Even if you cannot see us in person, please know that my colleagues who will be leading and participating in the reauthorization process are here. We are listening and very much value your perspectives. Please, also keep in mind that you can submit comments to a public docket that's open until August 11th. We encourage everyone to submit their perspectives to the public docket for FDA review. You'll receive the link to the public docket in the follow-up email next week.

00:04:36 A few housekeeping items. This is a hybrid format. We thank all the speakers for their effort to prepare for this meeting, and we thank viewing participants for your

patience as we navigate this hybrid meeting. If your audio or visual disconnects or diminishes, we recommend trying to reconnect through the system. If you experience other technical issues during the webcast, please email the GDUFA reauthorization inbox at gdufareauthorization@fda.hhs.gov. We'll not have a formal Q&A session today. We will have a 20-minute break around 10:30. If there's any modifications, we'll announce that at that time. For those of you who are attending in person, there are restroom facilities available down the hall if you go out of the conference room and down to the right. Also, there is a kiosk outside of the great room where coffee and snacks are available for purchase. A video recording and transcription of today's meeting as well as slides presented will be published on the FDA website after this meeting.

00:05:37 Now I'll turn it over to Dr. Makary, FDA Commissioner, for some opening remarks.

Opening Remarks

00:05:45 Dr. Makary: All right. Thanks so much, Mark. Good to see everybody. I love the size of this room here because it's fitting for the audience, right? This is like the American College of Surgeons Conference. My first talk as a faculty member at Johns Hopkins was in a gigantic auditorium at the National Conference-- International Conference. 20,000 surgeons attend this conference some years, and I got up there at the podium thinking I'm going to be able to have a big impact in the field with my research. And as I looked out beyond the sort of bright lights that always shine on the stage, I noticed there were only two people in the room, and they were sitting in the front. And so, my enthusiasm deflated, and I didn't know what to say, so I just said what I was taught to say. I said, “I want to start off by thanking both of you for being here.” And they looked back at me and said, “We're just here because we're giving the next two talks.” And that was about the level of interest in patient safety in my talk.

00:07:03 Well, good morning and welcome. This is GDUFA IV, and in this public meeting we're going to get some good stuff done. I was just talking with the wonderful Jacqueline Corrigan-Curay, who we're so lucky to have, and trying to maximize her time with us about the pre-user-fee days at the FDA and they were not pretty sometimes. There would be applications brought in by truck and dropped off. Paper applications. We still have a giant annex, I think in Annandale, which we're going to go visit to try to reduce the mountains of paper that we store and the expense of those papers. But giant boxes of applications were getting dropped off. And one individual had said that when they had personally dropped it off, because companies sometimes would not rely on the mail delivery systems, they could see an application from nearly a year ago that they dropped off still in the receiving area. And that was a little bit of a taste of the massive variability and the responsiveness of the FDA burdened with a variable number of applications with uncertain adaptability of the funding pre-user-fees.

00:08:35 So, there's an important role for the user fees. And this meeting is important because it marks a milestone in our ongoing commitment to ensure that Americans have access to safe and effective, affordable generic drugs. Affordability of drugs is a massive priority for this President. Affordability is really an access issue. If you believe in improving access to care, you should believe in the importance of making medications affordable. Well, many people can afford medications because they are generic and because they are affordable generics. Along with congressionally appropriated funding, the support of the GDUFA user fees paid by the generic drug industry has helped the FDA take a number of actions to increase better predictability and the timeliness of our assessment of these drug applications. We have a simple job in the world of drugs, and that is Congress has charged us to look at applications in a timely fashion and to determine if those drugs are safe and effective.

00:09:51 As of May 31st, in GDUFA III, we have approved or tentatively approved 2,465 ANDAs. It's pretty remarkable. It's amazing. I'm getting to know more and more of the staff here; of the Agency. I've been here just a hair over a hundred days and I'm getting to know more of the staff and it's just remarkable the volume and the scientific acuity that goes into these approvals. Of those 2,465, 226 were first generics, 325 were generics with competitive generic therapy designation, and 354 were complex generics. The real-world impact of this work is significant. Generic drugs now account for approximately 90% of prescription drugs dispensed in the United States, saving patients in the healthcare system perhaps roughly over $400 billion each year. Under GDUFA III, our approval of first generics has brought competition to previously monopolized markets, and our focus on complex generics has expanded access to affordable versions of critical medications for conditions like cancer, HIV, and rare diseases. And some of my predecessors, namely Scott Gottlieb, they have done a tremendous job in trying to increase the number of generics available to Americans.

00:11:28 As we look to GDUFA IV, we're building on this strong foundation while addressing emerging and ongoing challenges such as supply chain vulnerabilities, which is a real problem that is not that glamorous to fix. In other words, if you fix supply chain vulnerabilities, very few people in the United States will notice and come up to you and say, “Thank you for fixing that supply chain vulnerability.” And so, this is important work just like sewage treatment facilities are important projects in local governments, but because they are long-term projects, sometimes they are not prioritized, but they are critically important. So, we need to address supply chain vulnerabilities. And some of you have been doing that.

00:12:19 Now, I know you'll say afterwards, “Yeah, there were only 50 people here.” But there were 2 million watching by livestream and that's fine. That's okay. This is a narrow area, but important. The success of GDUFA is not on FDA alone.

Participation of our stakeholders, some of whom are represented here today, both in industry and the public, always important, is a crucial element in how we continue to engage with folks through the course of the reauthorization process. And we do it for all the user fee programs. So, this meeting is just a first step. We are here to listen and learn. I think Sangula asked me on this little conversation that we're posting; we sit in our office and talk and get ideas, and people come in and meet with us, and then we'll debrief and we'll have these conversations. And sometimes we'll say, "You know what? Let's just take this conversation out to the chairs, out in the lobby, and turn the camera on." Because we want people to understand exactly what we're thinking. Sometimes it's not that polished, but we want to be sort of raw and unfiltered and transparent. So, we do these little things, no makeup on, at least for me. And we just talk about what's on our mind. Well, Sangula asked me yesterday, "What would you say is your leadership style?" And I never thought about a question that profound, but I just told her what I believe and have always believed in the people that have modeled leadership to me, and that is be on the ground and listen. Be coming there headstrong, and we're going to do all these things and get in line, you know, you'll fall on your face. But if you listen, you'll have great ideas presented to you. And so, we are here to listen today. So, thank you for sharing. Thank you for bringing your ideas to the FDA and I look forward to another very productive set of discussions here for GDUFA IV. So, thank you.

00:14:40 Mr. Ascione: All right. Thank you, Dr. Makary. I will now like to introduce Iilun Murphy, Director of the Office of Generic Drugs in CDER, to provide background on GDUFA and an overview of GDUFA III.

FDA Presentations

00:14:59 Dr. Murphy: Thank you. Good morning. I'm delighted to be here today on behalf of the Generic Drug Program. All right. My presentation will provide an overview of the generic drug user fee amendments covering both the program

structure and its significant achievements in improving access to affordable generic medicines. More specifically, in the first part of the presentation, I'll touch on the background information and the evolution of GDUFA. Then, the current fee structure, and then the reauthorization process. In the second half, I'll give an overview of GDUFA III's accomplishments and impact on generic drug access.

00:15:38 Let's begin with the operational framework of GDUFA. GDUFA represents a transformative approach to generic drug regulation; now in its third, five-year cycle since establishment in 2012. GDUFA I laid the foundation by establishing standardized review timelines and ensuring regulatory parity between domestic and foreign manufacturing facilities through risk-based inspection approaches. GDUFA II focused on two critical objectives. One was to reduce review cycles to approval, and two was to increase approvals of quality generics. This was achieved through enhanced prioritization processes and expanded communication touchpoints with applicants.

00:16:20 GDUFA III is our current phase. Emphasizes efficiency, optimization, and complex generic drug development, having addressed the historical backlog of applications where we're now fine-tuning processes to maximize each assessment cycle's effectiveness, with particular focus on enabling access to complex generics that traditionally lack competition. The GDUFA fee structure provides the foundational aspect of finances that enables FDA to maintain predictable review timelines and support comprehensive generic drug oversight. User fee revenue has become increasingly vital to the program sustainability. The program has evolved from 45% user fee funding in 2013 to over 80% in 2024, demonstrating both the program success and the critical importance of stable fee revenue for maintaining operations.

00:17:19 GDUFA III authorizes four distinct fee types. There's the ANDA application fees, DMF fees, annual facility fees, and annual program fees based on applicant's size

tiers. This structure ensures broad base support while recognizing different industry participants varying capabilities or incapacities.

00:17:48 For FY25, our target revenue of 638 million is strategically allocated across fee categories to support comprehensive program operations. The reauthorization process requires extensive advanced planning to ensure a seamless program continuation as well as stakeholder engagement. GDUFA's five-year authorization cycles require more than two years of preparation. Our current timeline includes formal negotiations beginning this fall, commitment letter development through early 2026, public review of recommendations through the winter of 2026, and congressional consideration leading to reauthorization by September 2027, for implementation October 1st.

00:18:36 The reauthorization process is designed for stakeholder input, including Federal Register notices, public meetings, monthly consultation, opportunities during negotiations, and publication of the negotiation meeting minutes to ensure broad participation in shaping the program's future. Today's meeting initiates our formal stakeholder consultation process. Public comments are accepted through August 11th. During negotiations, stakeholder representatives can participate in monthly meetings with FDA and interested parties should register by September 4th. Details are in the FR notice. All negotiation meeting minutes will be published within 30 days to maintain transparency.

00:19:22 Having established the program framework, I'll now discuss why GDUFA is essential through concrete examples of our achievements in improving generic drug access and the measurable benefits to American patients and healthcare consumers.

00:19:37 The generic drug program is fundamental to American healthcare with over 35,000 FDA-approved generic medicines. As Dr. Makary mentioned, generics represent more than 90% of prescriptions filled in the United States. Our mission centers on

ensuring Americans have access to high quality, safe and effective generic drugs. Generic approvals increase patient access through market competition, lower drug prices, and supply chain diversification. These benefits also help mitigate drug shortages, which is a critical public health concern.

00:20:12 In 2023, the U.S. healthcare system saved over a 400 billion from the availability of generic medicines. For every dollar invested in the generic drug program, approximately 580 dollars in savings are generated. In 2024, FDA studied and estimates 19 billion in savings from just the 742 generic applications approved in 2022 alone. This demonstrates the direct relationship between generic competition and reduced drug prices. Market entry of even a few generic competitors yields prices significantly below brand prices.

00:20:50 The generic drug program carefully tracks work outputs and publicly post monthly metrics. Just from the first half of GDUFA III, we have some metrics highlighted here, which Dr. Makary mentioned, with over 2,300 approved or tentatively approved generic applications, with over 200 first generics, over 300 competitive generics, and over 300 complex generics. First generics provide access where no generic competition previously existed. And because of their importance to public health, FDA generally prioritizes review of submissions for these products as well as the CGT products.

00:21:26 And here are just a few of the first generics that we approved recently. These approvals hopefully lead to more affordable options for those patients managing serious health conditions such as stroke, diabetes, and cancer.

00:21:41 The generic drug program supports development and assessment of products leveraging multiple communication tools. The high volume of ongoing dialogue demonstrates robust industry engagement. Pre-ANDA meetings facilitate early problem solving for complex products. Large numbers of post-approval supplements

indicate healthy market activity. Over 28,000 communications with applicants show commitment to collaborative development. These metrics reflect GDUFA III's goal of enhancing applicants' ability to develop complete submissions.

00:22:15 In addition to direct correspondence with applicants on individual ANDAs, FDA staff takes steps to provide clarity for generic drug developers regarding how they can meet the requirements for approval. Published guidance's, when final, describe Agency's current thinking and make recommendations to industry on regulatory and scientific issues related to generic drugs. The guidance is implemented; new enhancements to GDUFA III to maximize the efficiency and utility of each assessment cycle. We have published 30 draft and final general guidances covering scientific and administrative topics, as well as issued more than 20 internal and external MAPPs.

00:22:56 This April 2024 drug guidance addresses critical data integrity concerns for bioequivalence studies. Data integrity issues can impact filing app, acceptance, assessment, and approval decisions, as well as post-approval actions such as therapeutic equivalence ratings. FDA emphasizes culture of quality, whether related to good clinical practice or good manufacturing practices. Reliable data forms the foundation for scientific decisions and public trust. We issued this guidance as part of our Drug Competition Action Plan, which seeks to improve the efficiency of generic drug development review as well as approval process.

00:23:38 FDA takes the new understandings of efficient approaches for developing generic drug products and assessments of bioequivalents to write new or updated recommendations related to bioequivalence issues and product quality. These are communicated to the generic drug industry through continual publication of new and revised product-specific guidances, otherwise known as PSGs, as well as general guidances. As a commitment under the GDUFA III, FDA issues PSGs for 90% of non-complex new chemical entities that are approved on or after October 1st, 2022,

within two years after the date of approval. For complex products approved in NDAs on or after October 1st, 2022, FDA issues PSGs for 50% of such NDA products within two years after the date of approval. And for 75% of such NDA products within three years of the date of approval. And we are successfully meeting these ambitious targets.

00:24:38 FDA holds scientific meetings on targeted topics based in stakeholder feedback as part of our effort at expanding collaboration and communication with the industry to streamline product development. As a recent example, in April, FDA collaborated with Center for Research on Complex Generics to host a workshop on implementing FDA's in vitro permeation test guidance recommendations. Participants could join virtually for free or in person for a very nominal fee. Where possible, we consider alternative methods to establish bioequivalence rather than requiring clinical studies, which can be expensive. For complex products, such as topicals, historically comparative clinical endpoint studies were needed, but then again, these were costly and time consuming. This hands-on workshop addressed procedures that applicants have found difficult to implement. Best practices were shared for different scenarios that might arise. Our subject matter experts were available to provide an interactive experience, so participants could learn practical skills as well as ask questions to gain more knowledge.

00:25:44 Scientific excellence is fundamental to FDA's mission. Evidence-based decisions ensure both safety and accessibility, and innovation in scientific approaches accelerates generic availability. The GDUFA Science and Research Program is an essential component of FDA's public health protection mission. The outputs ensure regulatory standards reflect current scientific insights and modern tools and support accurate assessment of generic drug quality and equivalence. We want to accelerate approval processes through embracing novel technologies in order to expand patient

access across many product categories. My colleague, Dr. Rob Lionberger, will expand on this topic following this presentation.

00:26:30 Annual public meetings ensure transparent priority setting based on stakeholder input. The recent June 2025 workshop focused on three key areas: complex active ingredients, in vitro methods, and tablet capsule efficiencies. Research outcomes expand understanding and contribute to advanced characterization methods. And as an example, we are evaluating nitrosamine impurity methods to address emerging safety concerns. And certainly, AI and machine learning integration represents the future of regulatory science, and we're looking to leverage these tools effectively.

00:27:04 Generic drug development requires global coordination and collaboration. International collaboration enhances efficiency and reduces regulatory burden. We know that shared scientific standards benefit patients. The generic drug cluster was launched in June 2021 as a confidential forum and includes seven international agencies. This facilitates knowledge sharing and best practice alignment and addresses common regulatory challenges collaboratively. 2024 focus areas included bioequivalence approaches and in vitro testing methods. Collaboration also strengthens global generic drug oversight such as sharing data integrity concerns that arise. A year ago, in July 2024, ICH adopted the guideline M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms. This is notable because it was the first ICH guidance dedicated to generic drugs and provides recommendations for conducting BE study during development and post-approval phases for orally administered, immediate-release solid oral dosage forms such as tablets, capsules, granules, and powders for oral suspension. Global effort on this guidance establishes consistent bioanalytical method validation requirements across ICH regions. This reduces regulatory complexity for sponsors, and furthermore, agreements made reduce the number of studies needed to establish bioequivalence for many products.

00:28:35 In closing, GDUFA has been instrumental in providing the resources and framework to support critical programmatic activities that directly impact patient access to affordable medicines. Through the two successful cycles, we've demonstrated our commitment to timely ANDA reviews, guidance publication and science-driven regulatory clarity that streamlines generic drug development. The metrics we've shared today from our robust approval numbers to our extensive stakeholder engagements show significant progress. However, we recognize that enhancing patient access to safe, effective, and affordable generic medicines remains an ongoing mission. We're committed to building on our successes while addressing emerging challenges in an evolving pharmaceutical landscape.

00:29:22 Looking ahead, we're particularly excited about leveraging cutting-edge scientific approaches to enhance our regulatory efficiency and scientific rigor. Our FY 2025 research priorities highlight our commitment to expanding AI and machine learning tools, advancing model-integrated evidence approaches, and developing more efficient bioequivalent methodologies for complex products. These innovations will enable us to conduct our work with increased precision, efficacy and scientific depth. Our success depends on continued collaboration with industry, international regulatory partners, and our other stakeholders, including the public.

00:30:01 We look forward to our ongoing engagements that will help us refine and enhance the GDUFA Program to better serve patients who depend on access to affordable generic medications. Thank you so much. Rob Lionberger, I'll turn it over to you.

00:30:28 Mr. Ascione: Thank you, Iilun. Now, as Iilun said, Rob Lionberger is next, the Director of Office of Research and Standards. He'll discuss the GDUFA's Science and Research Program.

00:30:47 Dr. Lionberger: All right, thank you very much. Very glad to be here to talk about our Science and Research Program.

00:30:52 But first I want to make sure everyone understands clearly why a Science and Research Program is so important to generic drugs. If you compare it to our new drug programs, again, most new drug programs generally conduct clinical trials to establish safety and efficacy. The generic products rely on these findings, but we focus on the pharmaceutical science and clinical pharmacology that allows us to identify what needs to be the same. And this is so critically important because if we didn't have this scientific foundation, the only thing would be left with-- You want to be another manufacturer of this product? Conduct another clinical study. And I think that's really why the science and research activities in the generic program are essential to what we do. And this is especially important for the category of products that we call complex generics. For these products, the normal things we do for simple tablets and capsules, looking at the blood levels after oral administration, just aren't there. They aren't available, they aren't relevant. So, we have to do something else and that something else has to be based on a strong scientific foundation. And if we don't have that, then there's no pathway for these complex generic products.

00:32:01 So, I've been at FDA over 20 years. When I joined FDA, there was a list of products. You can't have a generic for a peptide. You can't have a generic for an inhaler. You can't have a generic for a complex injectable. We just don't know how to do these things. And over my career, we've really made so much progress on this, and I think the GDUFA Science and Research Program has been essential to the development of this whole area of complex generics, making competition in these areas possible.

00:32:28 And I want to just compare a little bit about what the landscape looked like 20 years ago. There, most of the generics that came in were for solid oral dosage forms. There were some solution injectables, there were some topical semi-solids, creams and ointments, and then the other complex generics, there was just this very small fraction of them. Compare that to 2024. Only half of our submissions are for the oral dosage forms. You and the industry know that these are becoming commodity

products, very low cost, focused on high efficient development. There's been growth in the topical and injectable solution areas. The liquid-based dosage forms delivered through different routes than community pharmacies. There's a stable need for topical dermatological products. But the big increase is in the other complex generics categories, going from 3% to 13%. And so, this really is the new pillar for the generic industry and also the area where the highest fraction of the products lacks generic competition. And so, it's become critically important to the generic industry, but also to the public that's looking for affordable versions of complex products.

00:33:45 And over the past implementation of GDUFA, we've made incredible progress in this area. We now have approved generic dry-powder inhalers for inhalation products. We have a completely new approach for topical products that does not rely on clinical endpoint studies. We've approved generic versions of very complex long-acting injectables using release controlling polymers. We've approved generics of recombinant peptides. All of these things 20 years ago were just the list of things you couldn't do, and now they've been completed and opened up to competition. We've really established the use of quantitative medicine for these more complex products, for locally acting products, for inhalation products, so that predictive models can help us develop more efficient bioequivalence approaches. Other transformations include recognizing the importance of combination products and the user interface for the device constituent parts. This is something that wasn't on the radar 20 years ago. Now it's an important part of development. It's essential for patients that they're able to use their products effectively. But this is an entire emerging area that has to be considered through generic drug development.

00:34:56 We've been able to go through and understand the full scope of which of the products in the Orange Book are complex and why this allows us to plan our development of guidances and our research plans to identify future and upcoming needs. And the regulatory science part of GDUFA has fed directly into our

regulatory programs, specifically through our pre-NDA meetings and our product-specific guidances. These are both two key parts of the GDUFA commitment letter that are integrally linked to our Science and Research Foundation. And I want to share a little bit about why these are important and how they're connected.

00:35:32 So again, our product-specific guidances. You go to our website; over 2,000 brand products. Very specific and clear. What are the studies, what are the-- That are needed to develop a generic version of those products. And these are important across every product category that we're working in. For the non-complex products, clear advice about the bioequivalence study leads to high first-cycle adequate weights for the bioequivalence study, the most critical in vivo parts of our generic drug applications. Because there's clear scientific advice, there's commitments around delivering that in a timely manner for the timeframes, for industry's developments. And for complex products, the product-specific guidances are a place where we clearly and transparently communicate the new scientific advances that come out of the GDUFA Science and Regulatory Program. Again, under the GDUFA Program, there are more than 300 product-specific guidances that provide a bioequivalence approach that's much more efficient than the previous approach. So, again, alternatives to clinical endpoint studies. These enable effective and clear competition for these products.

00:36:42 But we recognize, even when there's product-specific guidances, that complex generics raise many scientific and regulatory challenges. Even when there is a product-specific guidance. If it's a new method, something that's not standardized, this isn't an assay that's been used before, so it's not in the USP. There's development. Iilun mentioned our IVPT workshop on helping industry address challenges in using new methods for bioequivalence. These are things where direct communication with FDA is essential at many points during development for product submission to be successful. Again, this is a new program that began in

GDUFA II, continued into GDUFA III. We've received more than 800 pre-ANDA meeting requests since they've become part of our program. And I think these create great value for industry in actually moving the complex products from an idea to a submission. And they're really the baseline for improvement and expansion of these interactions around complex generics in the future.

00:37:43 Again, we've accomplished a lot, but if we look forward, again, there's still many products without generic competition, and there's not going to be generic versions unless there's a company that's willing to invest in the development of that product. I believe that efficient and clear regulatory systems can help make that decision more possible, right? If there's clarity through product-specific guidances, through pre-ANDA meetings, and identifying the most efficient way that you can develop those products, this can help companies decide that they want to compete in those areas because they know clearly what's expected. And over time, we've shown that the research program has been making consistent efforts to reduce the regulatory burden and develop more efficient bioequivalence approaches. I think both of these streams really are intended to make it very clear what's needed to compete for complex generics.

00:38:43 And I just want to give two simple examples of the value that regulatory science investments can make for the generic program.

00:38:52 So, one is mentioned by Dr. Murphy in her presentation about the M13 implementation. But I want to indicate the link and the connection and how that began through the Regulatory Science Program. In 2019, at our regulatory priority meeting, we heard from the industry that felt that they were doing a lot of unnecessary bioequivalence studies. FDA prioritized research in this area. We collected data and collaboration from industry on studies that they had done that they thought wasn't needed. We implemented a risk-based approach globally through the ICH process. Specifically within FDA, we revised over 800 product-specific

guidances for immediate-release products to recommend fewer bioequivalence studies. We estimate that if this takes full effect, there'd be about 200 less bioequivalence studies each year. You know how much your bioequivalence studies cost. If I have to do them in the government purchasing, that would cost me this much money. And so, this is a, you know, again, significant and continuing benefit of science investments to develop efficient regulatory systems.

00:39:59 Another element that is going to be incredibly important for public health is access to competition for the GLP-1 peptides. And I just want to share a little bit about why are these products complicated to make generic products. The brand products often are produced via recombinant technology, a cell-based method, and are provided in drug device combination products such as pen injectors and autoinjectors. So, the generic products as you're developing them, must develop-- Will have to develop a device that's similar enough that patients will use it effectively. I have to navigate the patent landscapes around that. As well I have to develop an efficient way to synthesize the peptides. I have to control the purity and impurities of those so that there's no difference in immunogenicity, and I have to be able to demonstrate that to FDA. All of these complex scientific issues need to be resolved to have a successful product in these areas. And our Science and Research Program is investing in these areas as well as a focus of our pre-ANDA meetings.

00:41:02 And again, even beyond these areas, there are still over 300 currently marketed complex products without generics sales over 60 billion dollars a year. Just to give examples of 10 of them on the left side here. But all of these products have complex scientific issues. Many of them are combination products that have device constituent parts. The Science and Research Foundation really enables our advice and our discussions around these. And if you compare the markets and the savings-- Savings for the industry, the savings for the consumers to the investment that we're

making in our GDUFA's Regulatory Science Program, very significant return on investment here for the future of the complex generics industry.

00:41:42 And just in closing, GDUFA's Regulatory Science Program provides the scientific foundation for the generics of complex generics. And the regulatory programs needed to make this effective. Our product-specific guidances, the pre-ANDA meetings; they follow directly from these scientific advances, and that's what enables high quality product-specific guidances that support new approaches. That means also when you have pre-ANDA meetings on these complex generics, you're interacting with people who have expertise and understanding of the scientific issues around these products. And so, I look forward to our negotiation process and developing a system for complex generics that's even more effective in the future. So, thank you all very much.

00:42:35 Mr. Ascione: All right. Thank you, Rob. Next up we have Michael Kopcha, the Director of the Office of Pharmaceutical Quality, who'll be talking about pharmaceutical quality i relation to the generic drug process.

00:42:58 Dr. Kopcha: Appreciate that. Thanks, Mark, for the introduction. For those of you that don't know me, I'm Mike Kopcha. I'm the Director for the Office of Pharmaceutical Quality. During my time today, I want to discuss how OPQ as well as the GDUFA Program have enabled continual improvement related to pharmaceutical quality. And typically, one of the ways I start, if most of you are familiar with my presentations, I usually start out with this particular slide. The reason being that I want to stress what pharmaceutical quality means not only to this UFA Program, but to all of the UFA programs and to the products that we oversee. Everyone deserves confidence in their next dose of medicine and pharmaceutical quality assures the availability, safety, as well as the efficacy of each dose that a consumer or patient will take.

00:43:47 So, with this foundation in mind, let's explore how OPQ embodies these principles through our commitment to continual improvement. So, OPQ is committed to a culture of continual improvement, particularly regarding the quality assessment process. Now, you notice I refer to this as an assessment process. Some people refer to it as a review process. I don't really like the term review, because I think it minimizes really the process as well as what these individuals do; that do these assessments. Because what they're actually doing is not just reviewing the assessments that come in, they're actually critically assessing all of that work that comes in and making decisions based on what's presented to them. So, by regularly examining and improving our process, OPQ quality assessments remain relevant, accurate, as well as aligned with best practices that are out there. This commitment to continual improvement reinforces OPQ's quality lifecycle approach. It is a lifecycle approach. So, we start from INDs all the way through to ANDAs. Our culture of continual improvement isn't just the concept, though. It puts into practice through enhanced operations across OPQ. So, let me give you a little idea how we are actually making this a reality then.

00:45:03 So, enhanced OPQ operations, OPQ is-- Got a little ahead of myself there. OPQ's quality lifecycle approach is about efficient and effective quality assessments throughout the process, as I mentioned. From investigational new drugs, INDs, to new drug applications, NDAs, as well as to abbreviated new drug applications and all post-approval changes that are submitted to our Office as well. This approach allows for holistic decision-making, not just focusing on what's in front of us, but we now have a more holistic or lifecycle approach or understanding of the particular products that are coming our way. And we get involved very early in the assessment decision making, as you can imagine, and that decision making will impact later stages. So, the decisions we make now on INDs, NDAs, is going to affect what decisions we're going to make when we get to ANDAs. So, our assessors need to

have that lifecycle understanding to be able then to make those decision-- Decisions based on what's happened prior to that ANDA coming to the Agency.

00:46:04 So, to increase our organizational agility, OPQ implemented a comprehensive cross-training initiative for assessors. So, they are cross-trained at all levels now, and the staff completed both pre- and post-marketing submission training. So, they understand, again, that lifecycle approach, that holistic approach, is really the approach that we are taking. This means that assessors are now able to handle both pre- and post-marketing assignments within the GDUFA Program. We also generally increase OPQ's efficiency by harmonizing internally, as well as streamlining processes to reduce redundancies as well as administrative burdens. Everybody's trying to do that, especially in this day and age where we have a limited number of staff, limited amount of funding, that's presented to us.

00:46:49 So, we generally increased our efficiencies by harmonizing these processes to be able to address those issues. So, while we've made significant strides in enhancing our internal operations, our commitment to improving extends well beyond our borders or the U.S. borders. So, let me examine how those accomplishments work then on more of a global stage.

00:47:12 So, OPQ is a commitment to continual improvement in quality assessment process; is our guiding light in our ongoing international harmonization efforts. The ICH M4Q, efforts that are going on, better establishes the location and organization of quality information that's coming into these submissions. So, we want to start harmonizing this. We want to start to better establish that, so people know where to look when these applications come in, and it makes the review process just that much more efficient. Again, taking this lifecycle management approach. It also helps with digital transformation of that information, so that we don't necessarily need to do things with paper and pen anymore. The M4 revision guideline reached step one

at ICH, which is the expert sign-off, and that happened spring of this year and is projected to be adopted as a final guidance in 2027.

00:48:03 OPQ also contributed to the publication of ICH Q12 guideline that harmonizes management of post-approval changes as well. ICH Q12 is fully implemented and available for all participants. Training material, including videos and related manuals of policies and procedures, or what we call MAPPS—yes, we love our acronyms at the FDA—were published last year ensuring OPQ assessors are adequately prepared to be able to handle those types of submissions. So, as we continue to harmonize internationally, we're also investing in cutting-edge technology to revolutionize our work. One of our most exciting innovations is the knowledge-aided assessment and structured application, or what we call KASA. I know you've heard about this before, but we continue to make improvements. We continue to evolve that program, that particular platform as well.

00:48:55 So, KASA is a data-driven platform for structured quality assessments—the key being here structured quality assessments—that supports knowledge and risk management across products and facilities throughout that product's lifecycle. So, the KASA system advances CDER's quality assessment of applications by capturing and managing the information that we receive about inherent risk and control approaches that are being taken at those facilities.

00:49:19 The systems include predefined risk algorithms. So, we use risk algorithms to help us do this work, and data integration that can address product design as well as manufacturing and facilities in a structured format. Again, all of this is structured, so that it becomes very easy to find this information and be able to assess that information.

00:49:39 KASA performs computer-aided analysis and provides a framework for a structured quality assessment. That's the whole point behind that. With the implementation of

the KASA system, review disciplines for solid oral dosage products—again, right now it's solid oral dosage products—have access to sophisticated analytics and search capabilities. However, KASA will continue to expand across more quality assessment domains in the future.

00:50:03 So, with that being said, what I want to do now is let's understand what-- Now that you understand what KASA is, let's take a look at how far we've come with this groundbreaking system.

00:50:12 So, you have your timeline here. In 2021, KASA was released, and it allowed it to aid in the assessment of about 40% of ANDAs. That was back in 2021. That was four years ago. Again, for solid oral dosage products as well as biopharmaceuticals and the manufacturing components that come into those assessments. After major updates to the interface in data analytics, KASA 4 then was released in 2023 to cover drug substance for generics as well as for new drugs and for drug master files. So, you can see we've staged the improvements of the KASA system.

00:50:46 KASA 5.0 now, which should be available this year, actually expands coverage to a majority of dosage forms, including liquid dosage forms, and will encompass more than 95%-- 95% of generic drug products. So, we've gone from 40% now almost up to 95%. The new releases also cover microbiology disciplines as well. So, I want to put that in there. While KASA represents a significant technology advancement, we're also innovating our assessment process, which is what we need to continually do.

00:51:18 So, let me introduce you-- Well, reintroduce you to something you may be familiar with, which is our integrated quality assessment process approach, or what we call IQA. So, IQA is made possible by a multidisciplinary team, as you could imagine, comprising FDA discipline experts who work collaboratively on the regulatory submissions. So, we bring them together in these integrated quality assessments. It's

integrated with those experts to do the quality assessment. So, we work with those individuals closely together so that we're able to do those assessments quickly with the group as a whole.

00:51:54 While OPQ has long used IQA, we're continuing to improve its workload management as well as its monitoring abilities. An assessment workload dashboard will help leaderships manage staff's workload and distribution, because as you could imagine, we need to make sure that everybody is kind of equal in terms of the workload that they have. Because before we'd see some people had too much of a workload, other people had some capacity, so we needed to resolve that issue. And we did that by being able to put this workload capacity component into our integrated quality assessment program. And this leads to more efficient assignments and improved workload balance across all of the OPQ disciplines.

00:52:33 So, we won't necessarily need to create this balance by hand though, because we've created an algorithm which actually automates that process. So, we're trying to decrease the amount of involvement in some of this more routine, redundant type of work. That's not really where these assessors should be spending their time and attention. So, we developed these algorithms to help them be able to manage that work without their direct involvement necessarily in that work. So, the tool will automate the assignment decision-making process by considering obviously the application type, the assessor's product familiarity with the particular dosage form, and staff availability. So, we're bringing those three things into that algorithm to make that assessment.

00:53:13 Aligned teams then are put together. It's being modified to improve the assignment flexibility workload. And these aligned teams are drawn from smaller pools of individuals across the assessment disciplines to assign IQA teams that have cohesiveness, that are collaborative and familiar members. It's well known and well published that teams that are comfortable with each other, that continually work with

each other, that know each other's styles and/or idiosyncrasies are more efficient and effective. And we try to keep those teams together because of that, and it helps them to then be able to work together. They know what the expectations are with each other. They know how to interact with each other. So, it just makes that assessment process that much more efficient, that much more collaborative, that much more integrated.

00:53:58 So we're looking forward to a new aligned team structure, which will create even further consistency among these teams, assessing both small and large molecules. So again, we're trying to cross-train and we are cross-training the assessors to be able to handle all types of molecules, all types of dosage forms, and work across all of the UFA programs, whereas before there were more or less that kind of working on specific application types, specific application programs. So, these efforts then will allow more agility and streamlining assessment process. So, as you can see, our quality assessment processes are evolving, but our innovation doesn't stop there. So, let's explore some of the other newer tools that we're utilizing as well.

00:54:42 So, we've covered quality assessment. So, let's consider these tools that are enabling regulatory innovation in other areas, starting with our quality management maturity or QMM Program, one of the most promising areas of regulatory innovation. So, let me explain to you how this innovation is working and to help improve quality management in the industry itself.

00:55:05 So, CDER's QMM Program aims to encourage establishments to implement quality management practices that go beyond current-- Current good manufacturing practices or CGMP standards. CGMP standards are at the bare minimum. I've been in this industry for a long period of time. I remember when I was an undergrad, and I'm not going to tell you how long ago that was, but even then, these issues are still here that many years later. So, it just amazes me that people are just kind of hovering on this borderline of meeting CGMPs. We need to raise the quality standard within

the industry itself, and we believe, I believe, that this QMM program will help us raise that bar.

00:55:49 In 2024, OPQ launched the voluntary QMM Prototype Assessment Protocol Evaluation Program using lessons learned from a QMM pilot program to develop these prototype assessment protocols. The current program aims to evaluate whether the prototype as designed can enable assessments of established quality management practices. We had to try it out. We developed these protocols. Well, do they work or don't they? So, we had to go out and test them to see if they actually did what we wanted them to do. And then we also took those and provided establishments with actionable feedback.

00:56:23 So, while I don't like using this term, but this is kind of akin to having FDA come in- - I'm going to say this word anyway, but I kind of put it in quote, as a “consultant,” if you will, to take a look at your quality systems. It's not a punitive system; it's not a punitive program. A lot of people misunderstand that about QMM. We come in to evaluate your program, your quality program, and understand your quality management, and then share that back with the company. And that's where it goes. That's as far as that information goes.

00:56:53 So, what we want to do though is that we want to be able to tell companies where they need to improve, and then hopefully they will take that seriously. And then this should then begin to raise the bar of their quality management maturity within that particular company.

00:57:10 So, the initial volunteers were solicited through a Federal Register notice that was published in 2024 for this first pilot program. 27 drug manufacturing establishments actually volunteered. And out of that 27, we selected nine, and that included three generic drug establishments. So, there were generic drug companies; one third, 33%, volunteered that were generic drug companies. We conducted orientation for

participating establishments just to make sure people understood the expectations and the requirements of the program and what we were there to do and how this would benefit them as well as benefiting us.

00:57:44 Following evaluation, each establishment received a detailed report summarizing their strengths, as I mentioned, and opportunities for improvement. So, we wanted to make sure that we acknowledge both where you're doing well and where there's areas for continual improvement. Post-improvement assessment follows up with the first-- This year's first participants are ongoing, and should be completed by September of this year, providing that feedback to those nine establishments. We received feedback from these establishments indicating that the establishments-- That these assessments were valuable to them and they would encourage other establishments to participate as well. So, in fact, different establishments from some of the same companies wanted to and have applied for the second year of this program as well. That's how much they valued the input.

00:58:31 So, the outcomes of this program will help inform the refinement of QMM assessment protocol and process and further demonstrating OPQ's commitment to continual improvement and raising that quality bar across all of the industry. So, the QMM Program has already shown great promise, but we're not resting on our laurels on that. So, let's take a look at what's next for this groundbreaking program.

00:58:53 So, looking ahead, this year OPQ intends to publish a paper summarizing the lessons learned from the 2024 program, so we could share that more broadly and that the industry can see what it is that we've done and how the program works. It would also cover refinements to the protocol and an approach to improve the consistency of scoring. Yes, we do score each of the areas that we audit. We have to. And then this way you then know, or companies will know, what areas need improvement, which ones are doing well in, and then as they continually to hopefully improve those

areas, then those scores should go up. So, there's a way to monitor improvement as well.

00:59:29 We're also going to share anonymized scores for the nine assessments. Again, they will be anonymized. We're excited to note that an FRN was posted from April to June of this year, soliciting volunteers to participate in the second-year program. We received a rather large number of companies and facilities that wanted to participate, but again, we selected nine from that list.

00:59:54 While QMM is a relatively new program that focuses on manufacturing establishments, we're also leveraging AI, artificial intelligence, to improve our internal processes. So, let me introduce you to our Analytics-Driven Supplement Evaluation Tool. Yes, we like these fancy names, and as you can imagine, it does have an acronym. And we call it ASE. One of the ways that's easy for me to remember it's because there's a commercial out there that says, “ACE is the place.” Well, ASE is spelt a bit differently, but that's kind of how I remember this one.

01:00:26 So in fact, this program itself also uses AI use cases that supports the triage and staff assignment process for the assessment of post-approval changes or CBEs, changes being effected. So, we use-- Again, let me just reiterate that. Uses an AI use case that supports the triage, the triage of the CBEs that come in, and staff assignment process for the CBEs. So again, this is an automated process making use of artificial intelligence, again, to take this routine or redundant work away from the assessors and put it into an AI system and let that generate how we then actually parse out the CBEs. It uses a convolutional neural network model in combination with a rule-based approach, but ASE produces an output that helps staff triage the CBE submissions, which is extremely helpful. The output of the AI component contributes to the triage and staff assignment processes, and also-- It also summarizes the submitted information to support then the decision making. It supports the decision making of the assessor. It does not make the decision. I want to

be very clear about that, because people get confused when they hear about AI, and they always ask us, they ask me, “Well, Mike, is AI making all the decisions for OPQ?” The answer is no. It's a tool. It's a tool that helps us save time. It helps summarize data, but it is the assessor. That's why I don't like that term reviewer, because they actually critically assess and look at what's in the submissions and they make the decisions, not the AI model.

01:02:07 So, ASE is just one example of how we're using advanced analytics. Another powerful tool is our Quality Surveillance Dashboard, and that's called QSD. So, Quality Surveillance Dashboard is a dynamic and interactive facility-based dashboard for consistent assessment of facilities and quality signals. So again, we've got this dashboard. A lot of people like to look at the graphics, they remember things more easily than just looking at charts or tables. So, it's really a nice tool that allows them to do that. And the dashboard was designed to provide assessors with the ability to navigate details about each facility's products and an overall timeline of the facility's quality history. So, it's at the fingertips now of the assessors to pull up that information. It helps with surveillance; it helps with the assessment. It also helps with inspection. So, it's really a multi-use dashboard that's been put together. The user interface incorporates interactive visualizations that enable users to discover and share insights regarding those facilities, as well as the manufacturing capabilities and product quality information from those facilities.

01:03:13 Soon, the integration of data collected from KASA is then going to be used to continue to build that database within the Quality Surveillance Dashboard. So, we always want to make sure that what we develop interacts with all of the other systems that we have as best as they can and as far as they can, because you want to be able to have that interaction and have those systems work with each other. Otherwise, they'd only be of minimal use to us. So, soon the integration of data collected from KASA will enhance analytics within the QSD, something we're very

much looking forward to. So, this way we have those analytics on our hands and the assessors then don't have to do this manual work. Again, that's time consuming. Better to spend their time doing the assessment, not pulling all this data together. And that's where AI and these advanced analytics come into play.

01:04:01 So, these innovative tools are crucial, but they're not the only way we're driving progress. So, let's shift gears and examine how our research initiatives are enabling generic drug approvals. You heard about the research programs under GDUFA. You heard it from Dr. Lionberger, you heard it from Dr. Murphy as well. So, I'm not going to bore you with going over what they've already done, but I do want to share with you some of the research that we've done that's critical from a scientific standpoint to be able then to develop, evaluate an approval of the quality generics that are coming into us, ensuring drug safety and efficacy. So, to give you a concrete idea of our research efforts, let me share some of the highlights from our work during GDUFA III.

01:04:46 So, OPQ collaborated with OGD and others on more than 70 research projects to support generic product development and ANDA assessment. So, it's used in both places. It helps assessment as well as it helps us to do inspections as well by doing this research. Some research highlights include control strategies and analytical methods for nitrosamine impurities. I think somebody-- Most of you are well familiar with this issue. An evaluation of immunogenicity for synthetic peptide drugs. Dr. Lionberger talked about that just a little while ago.

01:05:20 Additionally, OPQ supported in vitro bioequivalence approaches for complex formulations such as ointments, liposomes, creams, things along those lines, implants, as well as complex routes of administration such as topical, inhalation, as well as ophthalmic. So, since 2022, OPQ and OGD collaboratively conducted 44 NDA triage meetings to identify knowledge gaps in our product-specific guidances and resulted in the initiation of seven research projects to specifically inform

additional guidance development. So, these research initiatives aren't just theoretical, they have real-world impact. It's not doing research for the sake of doing research. It's got to be based in the work that we do.

01:06:08 So, what I like to do then is give you some examples of how our research has enabled groundbreaking generic drug approvals. So, as I mentioned, GDUFA-funded research—and again, this is GDUFA-funded research—has been instrumental in enhancing scientific knowledge and tools, especially for complex generics. In 2023, we approved the first generic naltrexone extended-release injectable suspension to treat alcohol and opioid dependence, which uses a complex polymeric microsphere technology. So, this approval makes a significant achievement due to the scientific advancements that enable development as well as manufacturing, as well as demonstrating bioequivalence for this complex generic product. GDUFA-funded research on long-acting injectable products such as this has systematically advanced scientific understanding and helps us develop new development tools as well.

01:07:02 In 2024, FDA approved the first generic teriparatide injection for osteoporosis treatment, a significant milestone for peptide drugs, which must address potential immunogenicity risks. It's always an ongoing issue. As a peptide drug, teriparatide poses immunogenicity risks. I think most of you're aware of that, again, Dr. Lionberger mentioned that a little while ago, requiring generic drug developers to conduct impurity comparability studies and address any differences, that-- Of course, those differences may lead to immunogenicity risk. OPQ labs developed assays to assess unwanted immune responses elicited by these impurities in these drug products. And research increased the reliability of these assays, such that immunogenicity risk of the teriparatide drug product was compared to enable the approval of the first ANDA. So, there's a lot of work that goes on to allow these drugs then to be approved at the ANDA level.

01:08:00 These approvals, which were facilitated by internal and external research collaborations demonstrate how FDA research priorities have addressed scientific insights or given us scientific insights, improve assessment methods, and help improve drug availability for both patients as well as consumers. So, as we've seen from quality assessment improvements to cutting-edge research, GDUFA has been instrumental, there's no doubt about it in advancing pharmaceutical quality.

01:08:29 So, in closing. I hope you've seen that the generic drug user fees have enabled regulators and industry to mutually benefit patients in an evolving world and ensure that patients remain the top priority in our decision making as well as in our operations. Before I conclude, I want to leave you with a key message that encapsulates the essence of our mission and the importance of GDUFA.

01:08:56 Here we go. Continual improvement and innovation are keys in assuring drug quality. GDUFA has provided the resources to make this possible, so let us continue to assure quality medicines are available to the American public because, quite simply, our lives depend on it. No doubt about that. So, I'd like to thank you for the privilege of your time and attention, and I'll turn it back over to Mark.

01:09:27 Mr. Ascione: All right, thank you, Mike. I just want to make sure I get Ivy's title correct on this. So, now we'll hear from Ivy Sweeney, the Deputy Director of the Office of Human and Animal Drug Inspectorate on FDA-- On the FDA Drug Inspectorate. Ivy.

01:09:46 Dr. Sweeney: Right, thank you. Thank you. Today I'm actually serving as the Acting Director of the Office within the Office of Inspections and Investigations. As many of you are aware, generic-- GDUFA fees and non-user fee appropriations, they've been crucial in funding for personnel involved in generic drug regulations, including those inspecting generic drug facilities. Today I'm happy to provide some updates on the Inspectorate and FDA drug inspections overall. Firstly, however, I'll

speak about a topic that is probably on the minds of many, and that's the FDA's May 6th news release regarding the expansion of foreign unannounced inspections before I get into more general items. Next slide. Next slide?

01:10:37 So, let me speak a little bit about unannounced inspections. The FDA conducts about 12,000 domestic inspections and about 3,000 foreign inspections each year for all commodities, and typically pre-announcements are mandatory for all medical device surveillance inspections, some bioresearch monitoring inspections. In addition, there are some other commodity inspections, as needed, are pre-announced. The primary purpose of pre-announcing specifically during foreign inspections is to ensure the appropriate records, personnel, will be available so that we may execute an effective inspection.

01:11:11 In general, the Agency usually announces foreign inspections in advance, partly due to logistics such as arranging travel, access to facilities, securing visas, and partly because of the high cost of conducting foreign inspections. Foreign trips typically consist of multiple facility inspections and they can be costly, frequently with airfare being one of the major contributors to those costs. Unlike domestic facilities, where English is the required form of communication, English is not always a requirement for foreign facilities, and therefore, arranging translation services in advance is another important factor when considering a foreign inspection for FDA.

01:11:49 Finally, the legal authority to enter a domestic facility versus a foreign facility is different. An FDA Form 42, a notice of inspection, is not required to be issued for foreign inspections due to several factors related to jurisdictional limitations and practical considerations. So, FDA does operate on the U.S. law and does not have the same regulatory authority in foreign countries as it does domestically. And so, the Form 42, that notice, it serves as a formal notice under the U.S. regulatory framework, but this framework has a limited applicability in foreign jurisdictions. In addition, there are some sovereignty considerations. Foreign inspections often

require coordination with local regulatory authorities and must respect the host country's sovereignty at times. So, issuing formal regulatory notices may conflict with certain diplomatic protocols or local regulatory processes. Other considerations are practical and operational factors. Many of our foreign facilities are conducted on a voluntary basis, where the facility allows and agrees FDA conduct the inspection, and so the formal notice could be seen as to discourage cooperation from some foreign manufacturers.

01:12:59 In addition, foreign inspections may be conducted under mutual recognition-- Mutual recognition agreements, cooperative agreements with foreign regulatory bodies, and other international frameworks that have their own procedural requirements. As many recall during the COVID-19 pandemic of 2020, inspections were being pre-announced due to restrictions implemented by many facilities; control visitors, staff, and public safety reasons. However, we've come a long way since then and I'm happy to report that the percentage of unannounced inspections across FDA has increased back to pre-pandemic levels. Next slide.

01:13:37 Now, the U.S. Government Accountability Office conducted a study which was published and released in 2022, and in that study, one of those recommendations was that FDA incorporates some leading practices into the design of its unannounced inspection and translation pilot programs. And so, FDA began implementation of a foreign unannounced inspection pilot, also known as the FUIP, back in March 2022, and the pilot was focused on conducting unannounced foreign human drug inspections in India and China where the majority of our foreign firm drug facility inventory resides.

01:14:12 Now, outside of the foreign unannounced inspection pilot, unannounced inspections have been occurring but have been limited in nature due to the reasons I shared. Foreign unannounced drug inspections are also conducted where possible by our in-country personnel stationed overseas and for some for-cause inspections, where

compliance matter or drug safety issue is being investigated. Over the last five years, the number of foreign unannounced drug inspections has been steadily increasing in part due to the pilot. As a matter of comparison, in fiscal year 2024, about 89% of domestic drug inspections were unannounced, and about 12% of foreign drug inspections were announced. Next slide. Unannounced, excuse me.

01:15:00 As mentioned, FDA has been conducting this pilot mostly in India, in China, since early 2022. The pilot program was actually published into public law later that year in December 2022. The FDA-- Excuse me. The Food and Drug Omnibus Reform Act of 2022, which was enacted in part of the Consolidated Appropriations Act of 2023, includes the provision that mandates a pilot program for increased unannounced foreign drug establishment inspections and important development as the pilot program requires resources, trained personnel, processes, and money.

01:15:35 So, this section of the law directs FDA to evaluate the differences between pre-announced and unannounced human drug inspections and the impact of announcing inspections in advance of the inspection. So, the pilot includes a requirement to assess the differences between the amount and types of deficiencies found during the unannounced and pre-announced foreign human drug inspections, and it assesses the cost and benefits associated with the two. The Agency was also charged to identify the barriers in conducting unannounced inspections of foreign human drug establishments, the challenges to achieve parity between domestic and foreign human drug establishment inspections, and the approaches needed to mitigate any negative effects that are caused by conducting unannounced foreign human drug inspections. Quite a feat and quite a challenge for FDA to undertake. Next slide, please.

01:16:28 So, happy to report the unannounced pilot is still in progress, approximately 50% complete as of June of this year. Challenges, I'll share some of those right now, with the unannounced drug inspections thus far include some staffing, logistical cost

related issues. There have been some post-COVID delays in getting the pilot inspections conducted in China after the pandemic. Those have mostly been resolved. We did have a slowdown this year in conducting some of the pilot inspections in part due to process changes and improvements that are ongoing internally related to coordinating logistics and conducting some of those inspections. We've had some limitations in support staff this year. The pilot still continues, meaning unannounced inspections are still occurring, and the foreign unannounced inspections under this pilot. They frequently require multiple investigators per inspection, adding a strain to existing resources. The Drug Inspectorate is balancing pilot resourcing needs with resourcing needs to meet other inspection work plan goals.

01:17:32 And I will just share here that some of the facilities that have been inspected are GDUFA-funded facilities. So, in regard to those logistical challenges I alluded to, we have encountered difficulties at times finding reliable, safe ground transportation in some areas, coordinating translators for inspections, maintaining confidentiality of the inspection due to information we must provide to local governments and hotels to secure and access safe lodging for our staff.

01:18:01 Despite that, we do have some successes. As I mentioned, we were able to get quite a number of these inspections done unannounced. A lot of what we've gathered so far is really to help inform what next steps we will take and how best we can improve the program to ensure that we're able to improve parody with the style of conducting these inspections in comparison to domestic ones.

01:18:26 Further, one of the cost challenges related to some of these inspections does have to do with the availability of translators; I mentioned the cost of air travel as limiting factors that the agency continues to overcome as we expand the use of unannounced foreign inspections. As the pilot-- As I mentioned, as the pilot continues, this valuation will continue on. However, next slide, please. A lot has been learned to

date with the foreign unannounced inspection pilot. We've seen over the last five years, as I mentioned, increasing the number of unannounced drug inspections up to as much as 24% in some countries in part due to the pilot. And in addition to inspections in India and China, FDA has been conducting unannounced foreign drug inspections in other countries on a limited basis. And so, I'll call your attention to the news release of May 6th, 2025, and this aims to expand the unannounced foreign inspections at FDA-regulated facilities including drug manufacturing facilities. And as the details of the expansion of foreign inspections across the board are still being worked out, just know that it will apply to multiple commodities, not just drug facilities, and it could also mean an increase in the number of unannounced foreign inspection expansion in other countries outside of India and China.

01:19:45 As a reminder, FDA is authorized to take regulatory action against any firm that seeks to delay, deny, or limit an inspection, or refuses to permit entry for an unannounced drug inspection or device inspection. Now, this news release should serve as advance notice that firms can anticipate that their next foreign inspection may be an unannounced one. Firms are encouraged to ensure that FDA personnel attempting an inspection are provided access without delay. Next slide.

01:20:17 Now, the expansion of the unannounced foreign inspections, as I mentioned, will also apply to facilities engaged in generic drug manufacturing. And as seen on this slide, the number of GDUFA-paid facilities has been increasing over the years. And likewise, our ability to ensure we are keeping pace with timely risk-based inspection completion remains just as important in application approvals, routine surveillance needs, and ensuring as an agency we are being timely in our decision making. GDUFA fees, including non-user fee appropriations, fund personnel involved in generic drug regulations, including some of our investigator workforce.

01:20:55 During a GDUFA-funded inspection, various aspects of a generic drug manufacturing facility and its operations are reviewed to ensure compliance with

quality and safety standards. Current good manufacturing practices are assessed to determine a facility's adherence to CGMP regulations. As mentioned just now, these are basic regulations. Manufacturing processes, methods, and formulations are verified to those described in the ANDA. Data integrity, facilities quality control system, and changes in amendments to the manufacturing processes to the approved ANDA are also reviewed during a GDUFA inspection. Overall, these inspections are conducted to ensure the generic drugs entering the market are safe, effective, and of high quality. Next slide, please.

01:21:43 All right. Many of you may or may not be aware, we did undergo a reorganization on October 1st, 2024. The Office of Human Drug Inspectorate was born, if you must. It has the primary responsibility of ensuring all inspections of drug facilities, including those funded by GDUFA, are being completed timely and using risk-based inspection approaches to performing that function.

01:21:11 As many of you are aware, on October 1, 2024, there was an FDA reorganization that it did impact at the time what was the Office of Regulatory Affairs, which became the FDA's Office of Inspections and Investigations. The Office of Pharmaceutical Quality Operations, OPQO, is now the Office of Human and Animal Drug Inspectorate. Now, mark you. This change actually served a number of purposes. Our four-field divisions that were formally in that office has now become six-field divisions that support our domestic operations, and we were also able to consolidate our pre-approval managers, and these are our folks who oversee a number of our time-sensitive, and at times GDUFA-funded, pre-approval inspections. They were consolidated into a single division, and our dedicated foreign cadre staff are housed with our Foreign Drug Division, and they oversee all of our foreign drug inspections and our primary points of contact for the unannounced-- Foreign unannounced pilot.

01:23:22 Now, as of June of this year, OHADI has a total of 210 investigators. Our workforce does remain strong. 16 of those are foreign-drug-dedicated cadre members. 194 of the 210 are OHADI field investigators stationed across the United States, and that includes our national experts. 86 of those field investigators are funded by GDUFA. Now, FDA continues to maintain offices and staff in other countries, for example. A number of our drug investigators are stationed in China and India alongside other FDA personnel in those countries, and this allows the Agency to be strategically positioned to provide oversight to the notable volume of drug facilities in those countries. Next slide, please.

01:24:10 Now, the Drug Inspectorate's Workforce capacity continues to be critical to us, ensuring that adequate oversight of facilities involved in all aspects of generic drug manufacturing are maintained. Now, our FDA drug investigative workforce is highly skilled and knowledgeable. They are expected to be able to cover a wide variety, often complex, drug manufacturing processes during any inspection, and our staff must remain ready, prepared to also be responsive to investigate signals, complaints, field alerts, and so forth to ensure the safety and trust in the products that are currently on the market. Now, we continue to put investments to train this workforce. Maintain and advance their skillset continues to be crucial to our workforce. And ensuring the right personnel with the right experience are being recruited and selected, as always, plays an important role. In addition, the retention of our staff is equally as vital in ensuring this workforce capacity is maintained.

01:25:08 Now, though for the most part the Drug Inspectorate was not directly impacted by the recent rifts, we did see a number of employee departures, retirements, that have had an indirect impact. And while our operational processes are being revamped and centralized, we continue to look for best practices, ways to improve efficiencies needed to support our core inspection, investigational operations. To facilitate some of these inspections and record reviews, we have tools such as remote regulatory

assessments, remote interactive evaluations that are available and may be utilized when appropriate. In addition, the Agency utilizes mutual recognition agreements between FDA and foreign regulatory authorities, which allows us to rely upon information from drug inspections conducted by each other's within each other's borders.

01:25:56 Now, due to the recent hiring freeze, the hiring of additional investigators was on hold for a short period. However, we have resumed recruitment and hiring of new drug investigators. There are currently some open announcements. We are hopeful the importance of the investigator role to public safety will allow us to fully staff the Drug Inspectorate and address any losses of attrition we have seen this year. As mentioned, we currently have about 210 drug investigators. We'd like to see that workforce continue to increase so that we can get to capacity. This will allow us to not only meet the needs of our current work plan but be in a better position to expand foreign unannounced inspections, provide efficient oversight to facilities being brought online domestically.

01:26:42 You heard from a number of speakers today describing the complexity and the resource investments required to provide accessible, safe, and effective generic drugs to the U.S. population. Today, I shared with you some past currents and future plans with respect to the foreign unannounced inspections and the Drug Inspectorate's commitment to remaining that gold standard we are known for around the world by ensuring we are prioritizing our recruitment, our training, our attention of the drug investigative workforce. The Agency's ability to conduct inspections remain one of the critical pieces of its oversight responsibilities, and we're excited to be part of the kickoff conversations surrounding the next round of generic drug use of the amendments, working lockstep as an Agency to ensure safe, effective, generic drugs are made accessible to the American public in a timely manner. Thank you. Let me turn it back over to our moderator.

01:27:39 Mr. Ascione: Thank you, Ivy. That brings us to our break, so we'll return back here at 10:50. For those here in the great room, I'll remind you that restroom facilities are out the doors here, down the hall to the right, and there's a kiosk right out the doors that is available for coffee or snacks for purchase. So, we'll see you back here at 10:50. Thank you.

Industry Presentations

00:04:03 Mr. Ascione: All right, let's get back to it. So, welcome back, everyone. A few reminders. If you're experiencing any technical difficulties, do please email the GDUFA reauthorization inbox at gdufareauthorization@fda.hhs.gov. Also keep in mind that you can submit public comments until August 11th. That docket will be open and the email with the link to it will be sent out as part of the summary for next week. We do encourage everyone to submit their perspectives.

00:04:37 A couple other reminders for those in the sporting world. Tadej Pogacar on stage seven of the Tour de France back in yellow, defending champ, and American Taylor Fritz over in England is down two sets to one at Wimbledon semifinal. And a reminder for the speakers: I'll put this up with when you have two minutes left in your timeframe and this one I'm asking you to please wrap up. That'll be true for all the way through to the rest of the presentations today.

00:05:08 All right. Before the break, we heard from FDA. Our next session is on regulated industry perspective. First, we have Giuseppe Randazzo, Senior Vice President, Sciences and Regulatory Affairs from the Association of Accessible Medicines. So, Giuseppe, please come on up here.

00:05:47 Mr. Randazzo: Thanks, Mark. Before I begin, I want to express my sincere thanks to the FDA for convening this important Public Meeting. From Commissioner Makary to Dr. Corrigan-Curay, to Office Directors Dr. Murphy, Dr. Kopcha, we appreciate your continued leadership and commitment to the GDUFA program. I'd

also like to thank Dr. Rob Lionberger and Ivy Sweeney for presenting today on behalf of the Office of Research and Standards and the Office of Inspections and Investigations respectively. The work of these offices, OGD, OPQ, OII, and Office of Compliance is essential in ensuring that generic drugs are assessed and inspected in a timely manner. In doing so, patients have continued access to safe, effective and high-quality generic medicines. And last but certainly not least, a special thank you to Kathleen Davies, Kim Taylor, Dat Doan, and all the many FDA staff who made all the work behind the scenes happen and made this meeting possible. Good morning.

00:06:48 As Mark mentioned, my name is Giuseppe Randazzo and I serve as the Senior Vice President of Science and Regulatory Affairs at the Association for Accessible Medicines. Our Association members collectively manufacture over half of the FDA-approved generic medicines dispensed in the U.S. On behalf of our members, we thank you for the opportunity to speak here today.

00:07:11 I'm going to go over some background, which you've probably seen in the previous presentations, so bear with me. I wrote this before seeing those presentations, so I'll repeat some things. The Generic Drug User Fee Amendments Act, or GDUFA, has played an essential role in strengthening the generic drug review process and helping to ensure that patients have timely access to safe, effective and affordable medicines. Generic drugs and biosimilars, as you've heard previously, represent 90% of all prescriptions dispensed in the U.S., but what you have not heard previously was, but remarkably only 13.1% of the spend on prescription drugs.

00:07:49 Over the past 10 years, savings from generic drugs and biosimilars have totaled over 3 trillion dollars. Why do I bring this up? Just to point out that these savings underscore the essential role generic medicines play in supporting and sustaining our healthcare system, delivering unparalleled value to patients, payers, and taxpayers

alike. Continued investment in the generic drug program is critical in maintaining both access and affordability in the American healthcare system.

00:08:23 Since the enactment, in GDUFA I in 2012, the influx-- Hold on. Yeah, okay. I'm just making sure the pages are correct. Since the enactment of GDUFA I in 2012, the influx of resources from user fees has contributed to substantial progress in improving the efficiency and effectiveness of the Generic Drug Review Program. The GDUFA Program supports investments in FDA staff and infrastructure, enabling a more efficient review process and more predictable review timeline. Before GDUFA, as mentioned previously, generic applications review times were slow and unpredictable, and the Agency was impacted or facing a backlog of more than 2,800 unreviewed ANDAs. Thanks to the establishment of this program, the backlog of unreviewed applications were eliminated and median ANDA approval times have dropped significantly. This work helps not only to ensure patient access, but also encourages market competition, which helps keep medicines affordable for the American public.

00:09:29 In GDUFA I, the Agency met many of its assessment timelines—trust me, I know—which improved predictability and while the first-cycle approval rates certainly improved during GDUFA I, many applications did not receive first-cycle approval, and then there was GDUFA II and GDUFA III. These GDUFAs were built on the foundation established in GDUFA I. With each subsequent GDUFA reauthorization and with the help from industry, the FDA committed additional resources to improve first-cycle approval rates. This was done through a variety of different mechanisms. None more important than the improvement of communication between FDA and industry.

00:10:08 Structured opportunities for communication, such as pre-submission meetings, mid-cycle review updates, post-complete response letter meetings, and post-warning letter meetings, provide industry with critical information about FDA's expectations,

so that they can be assessed or addressed, excuse me, more quickly, with the goal of fewer assessment cycles, conserving both FDA and industry resources.

00:10:35 Another area of improvement in each reauthorization, and this was previously mentioned on a slide or two from other speakers, has been the timely issuance of product-specific guidances, or PSGs. Industry is thankful for the policy staff and the subject matter experts who facilitate this process. PSGs outlined their recommended methodology for generating evidence to support ANDA approval. User fees have supported the timely development and maintenance of these guidances. In return, these guidances have facilitated the development of high-quality generic applications by providing clarity and predictability on FDA's regulatory experience expectations. And as you saw from Rob's presentation, what is done on the complex generic side as well.

00:11:20 GDUFA II and GDUFA III also provided additional resources to support the development of review of complex generics. These products pose unique scientific and technical challenges that can impede the development of generic versions. The regulatory science initiative under GDUFA has helped guide the development of more technically challenging products. Some of these complex products include inhalers, long-acting injectables, and topical formulations, many of which previously were without generic competition. With this, it is very obvious the impact of GDUFA is clear.

00:11:58 In 2024 alone, FDA has approved over 700 generic drugs, including more than 100 first generics. These represent critical opportunities to lower costs for patients and strengthen the resilience of our supply chain. With all of the success, there is still room for improvement.

00:12:16 As we look ahead to GDUFA IV, we are eager to continue our strong partnership with the FDA to work to ensure the generic drug program delivers measurable

results for both regulatory efficiency and more importantly for the public health. In GDUFA IV, we look forward to discussions on how to further streamline the ANDA assessment process, how we can increase transparency for applicants, how we can enhance support for generic, excuse me, complex generics, how we can expand the use of modern review tools, and how we can ensure the program remains agile in a rapidly evolving scientific and policy environment.

00:12:56 We also look forward to working with the FDA to improve the inspection and post-inspection process. These improvements can help facilitate the incorporation of inspection findings into the ANDA assessment in a timely or more timely manner so that the inspection decisions do not unnecessarily impede ANDA approvals. Other areas of focus in GDUFA IV could include advancing global harmonization and addressing persistent challenges such as drug shortages and barriers to market entry.

00:13:28 In closing, GDUFA is a success story, and one we are proud to continue to build together. GDUFA is a vital tool that supports the development of generic medicines for industry and enables the FDA to efficiently assess the-- And improve them, excuse me. Ultimately, this expands access to safe, affordable treatments for the American patients. Again, we thank the FDA for its commitment to the GDUFA Program and we look forward to working with you to make GDUFA IV the most effective version for patients yet and for public health and for the future of affordable medicines. Thank you.

00:14:16 Mr. Ascione: All right, thank you, Giuseppe. Next up we have Joel Carpenter, the Executive Director of the Bulk Pharmaceuticals Task Force. Joel.

00:14:28 Dr. Carpenter: Good morning, everyone. I am-- Just need to quickly pull up my notes here. Okay. So, welcome this morning. I'm here to talk about the Bulk Pharmaceuticals Task Force and our expectation for the upcoming GDUFA negotiation. Dr. Makary talked about four specific topics and has-- Which came out

in the FDA data call a while back and I will address each of those four. I believe my colleague Giuseppe actually touched on exactly those four and I will probably repeat a few of the things he has said. So, he queued me off.

00:15:15 Just as an introduction, the Bulk Pharmaceuticals Task Force has been around for more than 20 years. It was originally under the umbrella of SOCMA, but we've broken into an independent organization in 2020. We have 16 member companies and one consultant and it's actually a wide range of member companies. We have very small companies that are just one site and a few pots and pans. Copperhead is one example of that. We have other members who are basically fine chemical producers but have carved away part of their plant into a GMP unit and so they have a GMP area and then they have regular fine chemicals.

00:15:54 And then we have some big folks who are global in presence, people like Evonik and MilliporeSigma, who are broadly participating in the game here, both on the drug substance and on the drug product side. So, we've got a very varied interest within our organizations. We represent both small and large organizations in our group. And many of these have other facilities worldwide like Piramal in India, but it also has facilities in North America. The same thing with Evonik. So, I speak for the domestic API industry. We do have a sister organization in the European Union called APIC-- API Committee. And so, they really look at it from a European perspective and they're a member of the Suffolk organization, which is sort of equivalent to ACC here in the United States. And so that's a little bit of a background about the organization.

00:16:51 Previous in these GDUFA negotiations, you had a fellow named John DiLoreto participating in GDUFA I, II, and III. With sadness, I tell you that he passed away last year, unfortunately, from cancer and I stepped into his role here starting in 2023 when he was beginning to have issues there. And so, this is not my first time at GDUFA negotiations, but I was in GDUFA I for one or two meetings, but I will be

sitting here at the GDUFA IV negotiation as your participant or representing the API industry. So, I'm the guy. So, keep that in mind.

00:17:32 Our value proposition to industry is basically to be-- I mean, a value proposition to two of my membership is to be the face of the API industry with health authorities both domestically and worldwide. And so, we are sort of the interface between API producers and people like yourselves at FDA and also with Health Canada and the Therapeutic Goods Administration and I can name a number of other organizations worldwide. We also do a lot of collaboration amongst ourselves on RA and QA issues. Issues will come up and we will powwow together and discuss, you know, "Hey, what's the best way to approach it?" Sometimes we write comments to various Federal Register notifications that come out there, and so you'll see my name on a number of those things. Right now, we're commenting on the USP's new program for-- New way of looking at controlled room temperature. And so, you can see the types of things we work on.

00:18:30 We also have an education component. Because there's always new people coming into the regulatory affairs world. And so, we help our member companies with the education side there as well.

00:18:42 And so a little bit about me. I have my training; I'm a Ph.D. Organic Chemist from the University of Texas in Austin. Austin, back in the 1980s, was a really fun city to live in. I'm not so sure it's true still, but I've been part of this group since 2008, and I've led this group since 2023. I have 33 years of industrial experience, and I have 17 years actually in API manufacturing. So, I do have steel-toed shoes; I do have a Nomex jumpsuit; I do have a hard hat; I do have goggles. And so, I've been out and about in API manufacturing sites. So, I'm very familiar with the day-to-day activities that go at the live locations. Let's see. I live in Baton Rouge and so that does present a logistics challenge for me attending all these meetings in person. I'm originally from New Orleans and so I'm definitely from the south. And another little factoid

about me, I have a 16-year-old tortie cat who tells me when to get up in the morning. So, that's about it.

00:20:01 Giuseppe talked about the benefits of the GDUFA Program and I want to highlight some of these exact same points that he made. Really-- It is really impactful to the overall public health in the United States, looking at GDUFA I going forward. I take medicine probably more than I would like and the fact that we are doing better with our foreign inspections-- I take a lot of generic drugs. The fact that we are doing better with our foreign inspections definitely gives me more assurances that I'm getting good medicines. And so, I really appreciate the game that how that has evolved over the years here.

00:20:41 Another thing we hated at first, my industry hated at first, were completeness assessments. We thought that was annoying and difficult and we have grown to love them. It really helps us get our notes together, get our filings together, so that we can make a good filing to the FDA and you guys are happy with what we give you and everything is working out much better. So, that got off to a rough start for us, but we are ever so thankful that that program came out of GDUFA I. And also, another offshoot of that. It allows for a more timely review of ANDAs and DMFs themselves; the fact that we got our package together correctly upfront with you guys. And so that's been a win-win. And so, we like quick reviews or we like thorough quick reviews and having a really well put together dossier really helps with that.

00:21:43 Another topic. There is greater transparency between FDA and industry about where things are at and moving forward. We have these quarterly implementation meetings, which we think is absolutely wonderful. It allows us to get our concerns out in front and on a timely basis as opposed to waiting for the next round of GDUFA negotiation. I think that's been a very powerful tool and so we definitely want to continue with that. I think it's very strong. And also, a couple of years ago you guys

offered a DMF training program and my membership loved it and we would love for you guys to do it again, because it was a very strong program, very well received. I know you made videotapes of it all and we can go back and see it again, but it would be worthwhile to take another look at that.

00:22:33 As far as opportunities to improve. So, Dr. Sweeney spoke this morning, and I think she took a lot of wind out of my sails, because she's promoting or she's going forward with exactly one of our big asks, which is getting the foreign inspectorate up in-- Program up in better shape. Unannounced inspections, we feel are much more meaningful, much more impactful and really better assess the state of matters. And so, I think she's doing a great job there. We just want to see more of that and maybe with other countries as well, not just India and China. And I recognize we're in a pilot phase of this and so this program will evolve over time, but Dr. Sweeney's program, I think really needs to be fully supported.

00:23:24 One other thing we struggle with, and this was a mention in somebody else's slide. An ICH Q12. There was some training offered on that, on how to implement. My organization really struggles with post-approval changes and Q12 does offer some new tools. You look out there changes to an approved NDA and ANDA from 2004. That's a pretty old guidance and it may be worthwhile taking a second look at that, but my people really do struggle with post-approval changes. And so that would be another area where we feel like we can really benefit from more work in that area.

00:24:04 Transparency on the status of particular filing reviews. And so, if we submit an amendment while something is under review-- My people send amendment to a DMF when something is already under review. That can greatly impact the timelines of the GDUFA goals, right? And so, we really would like more clarity or more visibility into seeing when something started review and when it done review, so we don't mess with that drug master file in the middle of all that. And so that would be very beneficial for us.

00:24:41 And another thing is dealing with the timeline for goals, the GDUFA timeline goals and the perception amongst my people is that they are not always adhered to. And so, we'd like to see a little bit more work done in that area there.

00:24:59 With regard to how industry has changed in the course of GDUFA III, I think the elephant in the room is COVID, right? That really changed a lot of things. And we used to think of quality only in terms of impurities, management, and form, whether the crystal structure is correct or whether the particle size is correct. But COVID introduced the concept of supply chain security to quality, and FDA has embraced this. And we think that's a good thing. You look at our partners, our drug product manufacturers and how they purchase things. And then you look at the API industry as it is domestically and security supply really needs to be a consideration. So, a little bit of work in that area is warranted.

00:25:53 I attended the ASPR meeting, did I get that right? A couple of weeks ago. And that seemed to have been one of the mantras that was repeated over and over again, about supply chain security. And they viewed it in context of national security as well. And so, I feel like this is really how things are changing and this is kind of where we need to be going to because, as a slide mentioned earlier, accessibility is very important for medicine and particularly for API industry, which is so much dominated by our foreign brothers and sisters out there, that the domestic generic industry really needs a little bit of a boost here because people buy on price a lot.

00:26:41 Okay. And what is-- Changes we expect through 2032? Trump's administration has made it very clear that it's interested in reshoring and friendshoring medicines, both the APIs and also finished dosage forms. And so, we feel like the next couple of years that will be really very much the focus of what we are working on here and how to revive the domestic generic industry. And so, that's what we think is going to be happening. And I recognize the work that the ASPR folks are doing there.

00:27:20 So, if you want to contact me, my email is J Carpenter written all as one. J as in Joel, carpenter@bptf.us. And if you would like to visit our website at www.bptf.us. So, that's all I have to say today and thank you.

Open Comment Period

00:27:58 Mr. Ascione: Thank you, Joel. So, that now brings us to the Public CommentSection of the meeting. I will call up each person individually. Diana, you can come on and up. So, first we have Diana Zuckerman, President of the National Center for Health Research.

00:28:22 Dr. Zuckerman: Okay, are my slides up?

00:28:23 Mr. Ascione: Yep, they should be.

00:28:24 Dr. Zuckerman: Okay. All right, there we go.

00:28:27 Mr. Ascione: All right, we have the clock on.

00:28:28 Dr. Zuckerman: Okay, thanks so much. Hi, I'm Dr. Diana Zuckerman, President of the National Center for Health Research, and I appreciate the opportunity to speak to you today. My perspective is based on my 35 years of working on issues pertaining to the safety and effectiveness of medical products. I have postdoctoral training in epidemiology and public health and was a faculty member and researcher at Vassar, Yale and Harvard before moving to Washington to work as a congressional investigator on FDA issues in the U.S. Congress. And I've also worked at HHS and the White House.

00:29:10 Our research center is a nonprofit think tank that scrutinizes the safety and effectiveness of medical products, and we don't accept funding from companies that make those products or any companies or entities that have any financial interest in our work. And I like to say I'm one of FDA's biggest fans, because I fully appreciate the Agency's importance. And as a Founding Board Member of the Alliance for a

Stronger FDA, I work with nonprofits and industry to increase appropriations for the FDA.

00:29:49 We all know that our healthcare system relies on generic drugs and frankly would collapse without them. I wish appropriations would be sufficient to support all of FDA's essential work, but we all know that FDA needs user fees to ensure getting safe and effective medical products to market in a timely manner. But it's also true that speed is not the most important part of that equation, even though it is very important. So, there have been a lot of statements, impressive and inspiring statements, from the FDA this year about transparency and the need for the FDA to regulate industry and not-- Rather than be-- I should say, rather than be influenced by unduly cozy relationships. And an important step in the right direction would be for negotiations for user fees to include patient, consumer, and public health advocates instead of only including industry and the FDA behind closed doors.

00:30:59 And unfortunately, all user fee negotiations, including GDUFA, have focused on what industry wants and needs and what they're willing to pay for, and not on what patients and consumers want and need. But that being said, we're in this together. We're all in this together. And I just want to say on a personal note, I have relied on generic drugs to save my life. I've taken them for cancer and I've taken them for high blood pressure. So, I really understand how important it is that we all work together, and that trust in generic drugs is essential to make healthcare affordable for everyone.

00:31:43 And I am concerned that that trust in FDA and in generic drugs has eroded lately. And that's why GDUFA needs to show very clearly that user fees will focus on ensuring that generic drugs are truly equivalent to brand name treatments in all the ways that matter to patients. Speed should be secondary, because when patients realize that some generic drugs are ineffective or unsafe, it harms companies whose

products are safe and effective. You may be wondering why I haven't changed my slides. Okay, here we go.

00:32:24 So, the performance goals have really focused on a lot of important issues, but often on speed. And there are a few very important safety and efficacy performance goals that have been part of GDUFA in the past and we want to make sure they will be in the future. And that does include the number of inspections conducted by domestic or foreign establishment location and inspection type and facility type, and the median time from beginning of inspection to Form FDA 483 issuance, and these other median time issues that you all are very well aware of.

00:33:10 But last summer, the FDA determined that Synapse, which is a company in India, "faked and forged" data submitted to the FDA and FDA withdrew the bioequivalence rating of 400 of their drugs, but they're still on the market. And, worse yet, neither patients nor pharmacists have access to the names of those drugs. And that really is unfair. Obviously to patients, but also to the companies that are doing their job correctly, because you're competing against some of these generic drugs that have been faked and forged.

00:33:54 Valasure has also conducted research showing a sizable number of generic drugs are substandard. Sometimes they have too much of a dose, sometimes they have too little, sometimes they are contaminated. There are a lot of problems. So, for that reason it is-- I mean, I've heard a lot about what GDUFA has accomplished, and I agree, but GDUFA should include metrics showing that these kinds of problems are being addressed and that generic drugs truly are safe and equivalent to brand name drugs. That's the promise of generic drugs; that's the promise of the FDA. And that promise needs to be really explicit and metrics are one of the ways to show that GDUFA is part of the solution to these issues.

00:34:52 Some of the missing monitoring metrics are the very issues that FDA is proud of in how they describe the role of generic drugs, that they must be pharmaceutically equivalent, they should-- That companies need to show they're capable of making the drug correctly, that they're capable of making the drug consistently, that the active ingredient is the same as the brand name and the same amount gets into the body, and that the inactive ingredients are actually safe and that the drug does not break down over time. So, these are the very same things that FDA has emphasized. And what we are asking is how can we have metrics that show that this is being met, that these standards are being met. And I agree with previous speakers that the post-market surveillance aspect is very important. Once the product gets on the market, we still need to make sure that it continues to be safe and effective and equivalent.

00:36:04 And I want to close by saying we are all working together. We all need to work together to help keep our healthcare affordable or as close to affordable as possible, and that partnerships with patient, consumer, and public health groups as part of the GDUFA process and everything that the FDA does is really important to all of us. Thank you.

00:36:50 Mr. Ascione: Thank you, Diana. All right. Next up we have Andrew Zacher, Senior Director, Regulatory and Public Policy at Amneal Pharmaceuticals. Andrew, come on up.

00:37:11 Mr. Zacher: Okay. Good morning, everybody. As you can see, my name is Andrew Zacher. It's really nice to be back at FDA as an alum. See everybody in person here at White Oak today.

00:37:25 Today I'm here representing Amneal Pharmaceuticals where I serve as Senior Director of Regulatory and Public Policy. Amneal is a leading U.S. manufacturer of generic drugs. We make injectables and biosimilars. Our unwavering focus is on making high-quality, affordable medicines accessible to patients nationwide. We're

deeply committed to ensuring that no patient is left behind due to medical shortages, and we share a common goal of finding sustainable long-term solutions to strengthen our healthcare system. And at the risk of being slightly repetitive of what everybody has already said today, I want to take a quick moment to just highlight the profound impact that the GDUFA Program has had for patients.

00:38:10 Since its enactment in 2012, GDUFA has accelerated access to affordable generics by improving efficiency and predictability of the FDA's approval process. Before GDUFA, unpredictable timelines and limited resources often delayed generic drug approvals, reducing competition, and limiting patient access. In the first few years following GDUFA's creation, its value is very clear. Nearly 25% of all generic drugs ever approved by the FDA were approved in just the first four years after GDUFA's enactment. This achievement not only led to substantial healthcare savings but also increased patient confidence in generics. Since then-- Sorry. Since then, GDUFA has allowed the FDA to further reduce timelines, enhance communications industry, and improve overall quality of generic products.

00:39:04 Performance reports consistently show that GDUFA has led to faster application reviews, better inspection quality, and more transparent processes, enabling timely approvals and broader market competition. Over the past decade, GDUFA has helped generate more than 3 trillion dollars in savings for patients. In short, by providing FDA with stable funding and to streamline and expedite reviews, GDUFA is essential to expanding patient access to affordable medicines.

00:39:34 Looking ahead, the upcoming GDUFA reauthorization is a critical opportunity for the FDA and stakeholders to address the mounting challenges facing the generic drug sector. Our industry is indeed confronting significant challenges such as market consolidation, persistent shortages, and unsustainable pricing pressures. These complex and interconnected issues threaten the long-term sustainability of our sector and our ability to provide patients with affordable medicines. The current race to the

bottom in environment that makes investment-- Makes investment in advanced manufacturing and quality improvements difficult for many companies, which has led to more frequent drug shortages, especially for older low-margin generics. Combined with regulatory hurdles and supply chain constraints, this has created a very fragile market where patient access is increasingly at risk.

00:40:24 As we confront these challenges, the reauthorization of GDUFA is more important than ever. While these issues threaten the long-term sustainability of the sector, and more importantly, patient access to affordable medicines, the ongoing success of GDUFA highlights the power of collaboration among stakeholders, including regulators, industry, congress, patient groups and consumer advocates.

00:40:47 The program's collective-- Collaborative development process ensures that diverse perspectives are considered and shared goals remain at the forefront. In an environment where both regulators and manufacturers are being called upon to do more with less, the reauthorization process is an important opportunity to find creative solutions, like leveraging advanced technologies and improving process efficiencies to ensure affordable high-quality medicines continue to reach patients. By working together through public meetings and negotiations, we can set new priorities that sustain a resilient generic marketplace that's responsive to evolving healthcare needs. Amneal appreciates the chance to be part of this important discussion and looks forward to constructively working with FDA on GDUFA reauthorization. Thank you.

00:41:47 Mr. Ascione: Thank you, Andrew. Next, we have Nimi Chhina, Vice President Global Regulatory Affairs, Operations Policy and Intelligence at Teva Pharmaceuticals.

00:42:09 Dr. Chhina: Good morning. I am one of the last few people between lunch and you guys, but I do have some points to make and I'm going to try and weave in some

points that were already made earlier today. Very impactful and insightful presentations both by industry presenters, FDA presenters and the Open Public Hearing thus far. I'm honored to make these comments here today on behalf of leading provider of generic drugs Teva Pharmaceuticals. I'm Dr. Nimi Chhina. I serve as Vice President for Global Regulatory Affairs, Operations, Policy and Intelligence at Teva. Like my colleague just before me, I'm also an FDA alumni and very happy to be back here at the White Oak Campus.

00:42:53 A little bit about Teva first. In the U.S., Teva markets over 500 generic prescription products in more than 1,500 dosage strengths, packaging sizes and forms, including oral solid dosage forms, injectable products, inhaled products, transdermal patches, and topical formulations. 300 million generic prescriptions per year are filled with a Teva product in the U.S. Teva generics saved the U.S. healthcare system an estimated 375 billion over the last decade and 35 billion last year in 2024 alone. Teva manufactures a significant portion of its medicines domestically producing over 6.5 billion doses annually in the U.S., 93% of which are used by American patients.

00:43:41 Teva's U.S. operations contribute over 600 million in manufacturing investment, support over 6 billion in gross domestic product, or GDP, including 2.5 billion in labor income. Teva operates eight manufacturing sites across the country, directly employing over 5,000 Americans and indirectly supporting over 40,000 additional U.S. jobs.

00:44:06 Firstly, we would like to thank the Agency for convening this public meeting on GDUFA IV today. As speakers before me have indicated as well, GDUFA reflects a vital joint commitment from the FDA and the generic drug industry to continuous improvement in the generic drug review and approval process.

00:44:24 A strong GDUFA Program is vital to timely U.S. patient access, to affordable, high quality, safe and effective generic medicines. As Dr. Makary, Dr. Murphy, and AAM speaker, Giuseppe, as well indicated, there are many metrics that highlight the importance of generics to the U.S. market. Despite the importance of generic drugs sector in the U.S., there remain challenges with development, review, and timely FDA approval of generic drugs. GDUFA I, which established the Generic Drug Review Program in 2012, encompassed three key aims.

00:45:01 First and foremost, safety. As Dr. Zuckerberg also emphasized the importance of safety of generic drugs, GDUFA I started off with the aim on safety by ensuring that industry participants, both foreign or domestic with parity, are inspected using a risk-based approach. We also learned from Dr. Sweeney on efforts on that regard that continue to be enhanced. The second key aim was access. By expediting the availability of low-cost, high-quality generic drugs based on greater predictability and timeliness in the review of generic drug applications. And the third key aim was transparency. In part, by improving FDA's communications and feedback with industry in order to expedite patient access-- Product access, my bad.

00:45:50 We can all agree that these three aims—safety, access, and transparency—from the inception of the GDUFA Program and as stated in the GDUFA I Commitment Letter, remain relevant today. Current iteration, GDUFA III, which runs through 2027, introduced new enhancements with the intent of reducing the number of review cycles for ANDAs and foster the development, assessment and approval of complex generics.

00:46:17 As we look ahead, there is a continued need to sustain and strengthen this focus on complex generics and to reduce the number of review cycles and promote first-cycle approvals. Complex generics are a heterogeneous set of products, including those with complex APIs, such as peptides and oligonucleotides, and those with complex routes of administration or those involving a device such as inhalers or autoinjectors.

Dr. Lionberger very eloquently articulated some of the complexities associated with complex generics, including, for example, immunogenicity assessment and device aspects that he talked about.

00:46:56 As highlighted by previous speakers, many complex products still don't have generic competition. A white paper from the USC Brookings Schaeffer Initiative for Health Policy titled "*The FDA could do more to promote generic competition. Here's how*" analyzed three main areas, one of which was regulatory barriers to complex generics approvals. The paper noted that because of the challenges in establishing bioequivalence, a significant number of complex non-biological products with long expired exclusivity face little or no competition from generics in the U.S. The authors examined a set of complex products identified in a study by the government Accountability Office. They found that 24 complex non-biological drugs from that GAO list had no remaining exclusivity, but generic entry had occurred for only about half of those that were not discontinued. Where entry occurred, it took on average 15 years post-loss of exclusivity for the first generic to enter the U.S. market.

00:47:59 Another study titled "*Potential savings from accelerating US approval of complex generics*", that is available on the AAM website, compared Canada, E.U. and U.S. approvals of complex generics and found that three of the seven products studied had no generic competition in the U.S., but were approved elsewhere, were drug-device combinations. The study estimated that generic competition in the U.S. for the seven complex products in that analysis would yield annual median savings estimated at 1.3 billion U.S. dollars. The study concluded that these significant savings could have been realized already if the pending ANDAs for those complex generics had been approved earlier by the FDA. These and other such studies and findings highlight the importance of facilitating efficient development, review, and timely approval of complex generics.

00:48:50 Dr. Lionberger also eloquently articulated and highlighted FDA's Generic Science and Research efforts to help with this. As noted in FDA's release of the fiscal year 2024 GDUFA Science and Research report, an insufficient scientific understanding can create uncertainty about how to develop a complex generic product or how to demonstrate that it is bioequivalent to its brand name reference listed drug.

00:49:15 The pharmaceutical industry also plays a crucial role in facilitating the FDA review and approval of complex generics by addressing scientific and technical challenges and fostering better communication with the Agency. A potential solution for GDUFA IV may include a dedicated complex generic development program to enable enhanced engagement between FDA and the applicant during development and review. Such a program could help with earlier identification and resolution of review issues, paving the path to timely approval, and therefore timely patient access to high quality medicines.

00:49:51 We applaud the Agency for their commitment to meeting GDUFA performance goals, and we request the Agency to collect and share metrics for first-cycle approvals for complex generics. Such parameters are critical for meaningful change in supporting timely patient access to affordable medicines. We commend the FDA and the Office of Generic Drugs in particular for initiating the transparency pilot for enhanced communications last year. It is an important step in the right direction to facilitate effective communication, especially in cases when the GDUFA goal date is missed or where there is a complex regulatory issue identified.

00:50:27 Industry sponsors often can provide answers to help resolve complex regulatory issues. However, there are limited opportunities for FDA industry engagement on such issues. It would be meaningful to arm the Agency with the ability to engage the sponsor as complex regulatory issues are emerging to facilitate mitigation and early resolution. We encourage the Agency to consider incorporating principles in the next GDUFA reauthorization to promote regulatory predictability, adherence to GDUFA

goal dates, exercising timely, transparent communication and early engagement with industry sponsors to help mitigate and resolve complex regulatory issues.

00:51:08 Another concept we propose for the Agency's consideration is to explore the application of the least burdensome principle to generics review. The least burdensome principle encourages FDA to determine the minimum amount of information necessary to adequately answer a regulatory question in the most efficient manner. Although the least burdensome principle is codified in sections of the Federal Food, Drug, and Cosmetic Act related to devices, no statutory change may be needed for FDA to implement the principles for generics or any other regulated commodity.

00:51:42 Lastly, I must express our excitement about the developments and announcements related to digital innovation and potential use of artificial intelligence at the Agency. I especially note comments made by Dr. Lionberger and Dr. Kopcha earlier today. Incorporating digital innovation and smart use of AI, automation and machine learning can streamline generic drug development and assessment and help the Agency meet enhanced performance goals and potentially faster review timelines.

00:52:09 Before I close, I would like to highlight that drug shortages, non-FDA-approved compounded drugs, and supply chain resilience have become increasingly important issues in the U.S., as also alluded to by Dr. Carpenter in his comments earlier today. Between 2018 and 2023, a total of 258 unique active ingredients went into national shortage per FDA's report to Congress. Strength of the Generic Drug Review Program is instrumental for timely patient access to FDA-approved affordable drugs, as well as for sustainability of the generic drug industry and a resilient U.S. drug supply chain.

00:52:33 I would like to end by expressing our deepest gratitude again to the Agency for soliciting public input on GDUFA reauthorization. We look forward to a productive

negotiation with the Agency to find solutions to bring safe, effective, high-quality genetic medicines to American patients as quickly as possible. Thank you so much.

00:53:18 Mr. Ascione: Thank you, Nimi. Next, we have Basil Considine, medical student from George Washington University, Sinai Hospital, Baltimore.

00:53:41 Mr. Considine: Hello. I'm going to be going in a little bit of a different direction from my colleagues so far. My name is Basil Considine and I am a healthcare education and healthcare practitioner. Thank you for the opportunity to speak today. I'm going to be sharing a little bit about the impact that GDUFA has had on patients and on healthcare practitioners and tell you a little bit of my story and the story of one of my patients in voicing my support for reauthorizing and renewing GDUFA and continuing to find new ways to improve, to streamline, to enhance this process that has improved the lives of millions of Americans.

00:54:29 I've worked in and around healthcare for most of my professional life, including as a practitioner, as an educator, and as an administrator. I have worked for 13 years as a nursing leader and educator, but before that I was working on supervising quality improvement projects and working on ways for nurses and medical students on their journey to becoming physicians to find ways to identify barriers to patients, being able to take medications, to get them on a timely fashion, to stay with them and stay out of the hospital. I have in my career trained more than 500 nurse practitioners and more than 200 hospital administrators, and I'm currently a faculty member at Abilene Christian University and myself am undergoing retraining as a medical student at George Washington University's regional medical campus in Baltimore at Sinai Hospital.

00:55:37 In my professional experience, the generic drugs approved via GDUFA have been and are some of the most powerful tools that we have for keeping patients out of the hospital and for giving them a better quality of life. Many of our patients have things

that we can treat with drugs like antibiotics and antivirals that cure them, but far more that pass through my patient panel, that present in my clinic, are living with chronic conditions that have years and decades of treatment, where hypertension worsens, where heart failure increases and we need more drugs and to tweak the regimens. And GDUFA has provided more and more options that they can actually afford, that we can tweak when a patient starts to have trouble swallowing. We can switch from a whole set of pills throughout the day to an extended-release version that the FDA has been able to approve and that the manufacturer has been able to bring to market.

00:56:42 You've seen today-- The previous speakers talk about some of these savings, and so I won't belabor this point. I'll just point out that some of the countries that I've lived in, the savings for a single state is more than that entire countries' gross national product, and that when I first began teaching a class on improving patient outcomes at the Boston Medical Center all the way back in 2005, that GDUFA did not exist as something in practice. And I remember the first time when one of my students wrote a paper about the need for more generics, and then to see the GDUFA process evolve over the years has been wonderful to see those ideas, those proposals, to be able to go into action.

00:57:38 One of the first patients that I talked to when trying to find out why they weren't taking their blood pressure medications told me that they had run out and that they were waiting on their granddaughter to come back from India with a new batch of medications, because they could not afford the brand name medication that they had been prescribed. And at the time, we didn't have an approved generic, but we do now. And when a similar case like that came up just two weeks ago when I was at Sinai Hospital, we were able to not only prescribe the generic form, but through our Meds-to-Beds Program, give them a three-month supply before they left the hospital to make sure that they weren't running out because they went home and they were

too tired. They weren't running out because they were trying to decide whether to pay their electric bill or fill their meds. And those are some of the things that GDUFA has made possible.

00:58:49 I want to tell you about one of my patients. Henry. Pseudonym, because patient privacy is important. When I first met Henry, he was retired and living entirely on his Social Security income. He had no pension, he had no 401k, only the taxes that he'd paid on his wages were coming back to support him now. And I don't have to tell you that there've been a lot of price increases with inflation these last few years, and I don't have to tell you that their Social Security really hasn't kept pace. Most of his income, such as it was, was going to rent, food, health insurance and out-of-pocket health spending.

00:59:38 He had, I think, done pretty well for himself. He'd saved up a good nest egg to support him in his retirement, and then his late wife came down with cancer and that emptied out their savings, sold the house, moved into an assisted living facility, and then his insurance company dropped their coverage of the brand name medication that he had been taking. And he had a seizure, and he didn't come into the hospital then. It was only after two weeks of growing seizures in intensity and in frequency that he came to the emergency room and saw me.

01:00:24 Now, there are a lot of things that we could say about improving patient education. But you've heard there are a lot of drugs out there and there are a lot of different drug forms, and most patients don't know that there is a generic form involved, that they don't know when one has become available. They just know, “I've been on this pill for years and years and years and I need this pill to stay healthy.” And when his insurance dropped his coverage, Henry looked at it and realized that he could pay his rent or, with the particular insurance situation that he had, he could pay for that medication out of pocket. And so things got worse until he couldn't bear it anymore.

01:01:12 And when talked with a social worker, looked at his medication history and realized that his prescription had never been updated, that he was not aware, nor was his PCP, aware that there was a generic drug that he could afford that cost less than a 10th of that brand drug. When I told him that we could get his meds and that our social worker could even waive the copay for the first three months and that afterwards it would only be about $60 out of pocket, he started to cry.

01:01:52 Now, I don't know what things you look forward to in your life. Henry had more than a few years. He said that the reason he was crying wasn't just because he could afford this med, but because his granddaughter was pregnant and was about to deliver the baby, and that he didn't think that he was going to make it until there because he was seizing so much.

01:02:24 And it's patients like Henry, where the drugs approved by GDUFA have given him his life back, a life free from the free-- The fear of that seizure. A life where he can look forward to those things that are so important to him. It is stories like that that bring me here to share a little bit of my story and say, as a health practitioner, moving from one level of administering medications to prescribing them; as a health educator, working to train nurses to inform patients and educate them about the options that will let them continue to receive their lifesaving medications within their budgets; as someone who's worked in hospital administration to try and improve outcomes and keep people out of the hospital. For all these reasons, I'm here to say I wholeheartedly support the reauthorization of GDUFA and all of these proposals from industry and from the FDA to do what really matters to improve the lives and the health of Americans. Thank you.

01:03:57 Mr. Ascione: Thank you, Basil. So, we do have some time. At this point we can open up to anybody else in the room who wants to make a public comment. If you do, a couple things. You'll be given a five-minute time limit. We ask that you start

by introducing yourself with your name and your affiliation. But if anybody wants to make a comment, please come up to the podium now.

Closing Remarks

01:04:27 Mr. Ascione: All right. Seeing that there are no takers, that does conclude our Public Comment Session. Thank you all. Please be advised that the public docket-- The public docket is available until August 11th as a chance to provide written comment for the FDA to read. That's another place to be able to do it. A link will be sent when-- With the follow-up emails after this event. So, that concludes our meeting for today. Thank you to all the speakers who took the time to share their comments with us. Thank you to everyone who logged in to listen to the meeting today. We hope you all enjoy the rest of your day. Thank you.