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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 BIOSIMILAR USER FEE ACT (BSUFA) REAUTHORIZATION

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## Welcome and Introduction

00:00:01 **Mr. Collins:** Good morning, everyone, and welcome to this public meeting on the reauthorization of the Biosimilar User Fee Act or BsUFA. My name is Jonathan Collins and I'm with the Program Evaluation and Implementation staff in the Center for Drug Evaluation and Research, and I will be your moderator today.

00:00:20 BsUFA is the legislation that authorizes FDA to collect user fees to support the process for the review of biosimilar biological products. The current legislative authority for the program 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 public meeting is to hear the public's views on BsUFA as we consider elements to propose, update or discontinue in the next BsUFA. Today's meeting is an important step in engaging with public stakeholders on features of the BsUFA program. We will continue to engage stakeholders throughout the reauthorization process. In the coming days, we plan to post the Federal Register Notice with details on how to notify the FDA if you would like to participate in reoccurring stakeholder meetings during the reauthorization process. We will email all meeting registrants with the link to the FRN when it posts.

00:01:24 We have a full agenda for today. We will begin with Dr. Mike Davis, Deputy Director of the Center for Drug Evaluation and Research, who will provide opening remarks. Andy Kish, Director of CDER's Office of Program and Strategic Analysis, will provide background on BsUFA and the reauthorization process. We will then hear remarks from the biological product industry. Following remarks from the biological product industry, we will take a short break. After the break, we will hear the public comments. I will then close the meeting around 11:30 a.m.

00:01:57 In the Federal Notice announcing this meeting, FDA provided four questions to help the speakers frame their comments. One: What is your assessment of the overall performance of the current reauthorization of BsUFA FY 2023 through FY 2027 to date? What current elements of BsUFA should be retained, changed, or discontinued to further strengthen and improve the program? What new elements, if any, should FDA consider adding to the program to enhance the efficiency and effectiveness of the biosimilar biological product 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? Policy issues are beyond the scope of the BsUFA reauthorization process. Therefore, comments should focus on process enhancements and funding issues and not on issues of policy.

00:02:59 This meeting is an opportunity for FDA to listen to public perspectives. FDA will not ask questions nor answer questions raised at this meeting. My colleagues, who will be leading and participating in the reauthorization process, are here in person and online. We are listening and we very much value your perspectives. Please keep in mind that you can submit comments to the public docket open until January 2nd, 2026. We encourage everyone to submit their perspectives to the public docket for FDA review. We will post a link to the public docket in the Q&A for this meeting.

00:03:34 A few housekeeping items. This is a hybrid meeting and we have many folks participating virtually today. If your audio or visual connection diminishes, we recommend trying to reconnect through the system. If you experience other technical issues during the webcast, please type your issue into the Q&A or email BsUFAreauthorization@fda.hhs.gov. We will have a 15-minute break at about 10:00 a.m. If scheduled modifications are needed, we will communicate those verbally and post them in the Q&A. For those of you attending the meeting in person, restroom facilities are located down the hall to the right of the conference

room. A video recording and transcription of today's meeting, as well as slides presented, will be published on the FDA website after this meeting. I'll now turn it over to Dr. Mike Davis for opening remarks.

## Opening Remarks

00:04:33 **Dr. Davis:** Hello. Hi. Welcome, and thank you so much for inviting me to give the opening remarks for this meeting. So, thank you for joining us as we open the Biosimilar User Fee Act or BsUFA for public meeting. Today marks an important milestone as we begin the reauthorization process for a program that is central to expanding access to safe, effective, and affordable biosimilar biological products. Ensuring that Americans have access to biological medicines remains a significant public health priority. Biosimilar products help address this need by expanding treatment options for patients who rely on biologic therapies for serious and complex conditions, including cancer and autoimmune diseases. According to information referenced by the Department of Health and Human Services, biosimilars have generated an estimated 56 billion dollars in healthcare savings since 2015, including roughly 20 billion dollars in 2024 alone. These impacts demonstrate how biosimilars can reduce the financial burden on patients and the healthcare system while maintaining FDA's high standards for safety, effectiveness and quality.

00:05:42 BsUFA is now in its 13th year. Since its creation, the program has facilitated the approval of 78 biosimilar biological products for the American public. The program has established an important framework for supporting timely and predictable assessment of biosimilar and interchangeable product applications. Under BsUFA III, we achieved meaningful progress in advancing biosimilar development and review. We introduced new supplement categories, timelines and performance goals to support more efficient review of supplemental biosimilar biological product applications. We established new procedures and performance goals for the

review of use-related risk analysis and human factors protocol submissions for biosimilar biological product-device combination products. We launched a regulatory science pilot program with two demonstration projects focused on advancing interchangeable biosimilar development and improving the overall efficiency of biosimilar product development. We also enhanced our meeting management system, which now includes new meeting types and follow-up clarification opportunities to better support sponsors throughout development. These actions help increase access to high-quality biosimilar products and strengthen the development pathway while maintaining FDA's rigorous approval standards.

00:07:05 As we look towards BsUFA IV, we're building on a strong foundation. At the same time, we must address emerging challenges related to biosimilar development, manufacturing complexity, and the evolving landscape of biological products. The success of BsUFA depends on the active participation of our stakeholders. This includes patients, consumer advocacy groups, industry, healthcare professionals, and scientific experts. We'll continue to engage with stakeholders throughout the reauthorization process. Today's meeting is the first step in the process. We're here to listen, learn, and begin shaping a path forward together. Thank you to our speakers for sharing their expertise and thank you to everyone joining us and for your commitment to this important work. Let us continue working together to ensure that BsUFA IV advances our shared goal of safe, effective and affordable biosimilar medications for all Americans. Thank you.

## BsUFA Background and Reauthorization Process

00:08:11 **Mr. Collins:** Thank you, Dr. Davis. I would now like to introduce Andy Kish, the Director of the Office of Program and Strategic Analysis, to provide background on BsUFA and the reauthorization process.

00:08:32 **Mr. Kish:** Hey, good morning, everyone. Welcome to BsUFA IV. Thank you for the opening remarks from Dr. Davis. I'm glad to see some familiar faces that have been in the BsUFA program since its inception, so it's great to see everyone again. So, this morning, I'm just going to give some background. Some of this will be familiar for a lot of you. For others, I hope it's helpful in understanding where we are in the BsUFA program and some overview of all aspects of it. So, I'll cover some background, touch on our performance and workload in BsUFA III, touch on the financial background and fee structure, and then an overview of what this reauthorization process is.

00:09:15 So, BsUFA-- We can't call it a new program anymore; we can't call it an old program, but it's in between. It's now over 10 years old. And it came about as part of the BPCIA in 2009, and it is interesting that it was passed. It created the pathway and we were also told, "Hey, create a user fee program." So, in many ways, in BsUFA I, we were building the plane as it was flying, which was interesting, but we got it done. So, after consultation with industry and public stakeholders, we did transmit recommendations for the first BsUFA, and that happened in 2012. And just as a kind of-- What we mean by "flying the plane while we were building it", we didn't have any marketing applications or products on the market, or an established drug development process or history with biosimilars at the time of BsUFA I. So, we're now in its 13th year, and since its creation, it's facilitated the approval of 79 biosimilars—potentially more, because that number might be dated from a few weeks ago.

00:10:29 All right. So, quick, really quick, history on the previous BsUFAs. What did they cover? BsUFA I, we figured it out. It was interesting to set up a new user fee program in many ways. We had the reference to the PDUFA program because we didn't have any experience with biosimilars. We were building it as we were negotiating. So, much of BsUFA I, and particularly the fee amounts, referenced the PDUFA fees, except it included a development phase fee, and that was really to generate revenue for getting the staff necessary to do the

reviews. And that is called the BPD fee, which we can get into a little bit more. It did introduce some predictable timelines and review processes, and it was also primarily modeled on PDUFA at that time.

00:11:19 So, moving into BsUFA II, we had some more experience with the program and we were able, at that point in time, to create an independent and efficient user fee structure that was no longer tied to PDUFA but was based on the program costs. We also implemented the review program—that's something we brought over from the PDUFA program—to promote the efficiency and effectiveness of first cycle review. The idea was to really try to minimize the number of review cycles that a biosimilar might need to go through. And we also added commitments to assess this new program, clarify with the regulatory pathway, and enhance staff capacity. So, jumping into BsUFA III, we, as Mike mentioned already, introduced new supplement types and expedited review timelines associated with them, and new timelines for use-related risk analysis and human factor studies. We introduced a new pilot regulatory science program and a focused effort to advance the development of interchangeable products.

00:12:20 Okay. Just a primer on what user fees are, what the construct here at FDA is for our various—particularly medical product—user fees. So, the thought here is that user fees pay for services that directly benefit fee payers. So, that's what distinguishes it from a tax. And these fees are added on top of non-fee appropriated funds, which we call budget authority, and it's really intended to increase the staffing and other resources needed to speed and enhance the process. So, what do we cover in these negotiations? When we're talking with our counterparts, we talk about what new or enhanced process the FDA or industry might seek in the next five years and spend a lot of time on what is technically feasible to do, what other resources are required to do any of those enhancements. And, to be very clear here, there's no discussion of policy that is out of scope of a user fee negotiation. Fee discussions also get into the mechanics of the user-fee programs, deep into the weeds of how fees are collected, the different types of fee

types, what products are covered. And, as previously mentioned, this agreement has to be reauthorized every five years.

00:13:42 Okay. A little bit on finance. So, user fee revenue is really critical to this program. This graph shows the history of funding for the program, particularly what we use for spending to support the staff and the review process. Non-user fee appropriated funds are the gray at the bottom, and then the bluish color is the BsUFA user fee revenue. As of 2024, the user fee revenue funds about 61% of the program. So, it's very critical to maintain the staffing to run this program.

00:14:23 Okay. Fee structure. This is from the FY 26 User Fee Notice, which is on our website if folks want to dive into the details there. But things to call out here is it's a three-tiered fee structure. There's a BPD fee, a biosimilar project development fee. It's a pretty nominal fee and it's been decreasing over the course of multiple BsUFAs. There is an application fee that distinguishes between if you have clinical data or clinical data is not in the package. And then there's a program fee for marketed products. The fees have been relatively stable in this program and haven't been increasing very much.

00:15:08 Okay. Program and performance. Let's get a little bit into the workload. So, in these slides, we are going to have some FY 25 numbers here. Just take those as preliminary. The official numbers will come out in our performance report next year. So, overall, the program continues to have steady growth, which is good for public health. And we're happy to see that both in the BPD program, those folks coming in in the IND phase, and then also marketing applications. And the blue on the bottom is products in the BPD program, and the lighter blue on the top is the original and resubmitted BLA biosimilar applications per year.

00:15:59 Okay. In BsUFA III, we did introduce new supplement types. We've received 65 efficacy supplements under BsUFA III so far. I do want to call out we haven't received any applications in the original category C and E yet, but we have seen a lot of activity in A and D.

00:16:30 Manufacturing supplement workload continues to grow, and notably really in the past two years, FY 24 and 25. Again, 25 numbers are preliminary, so that might be revised when it comes out next year. But those requiring prior approval and not requiring prior approval are both increasing.

00:16:56 Okay. Meeting management is growing. For those of you who are familiar with the PDUFA world, this is a very small number compared to the 4,000 or so we get in PDUFA, but nonetheless, it's still growing and it has, I think might say, manageable or steady growth. So, over a hundred meeting requests annually at this point, particularly per year, that we have to manage across the multiple meeting types. In particular, a lot of requests in the type 2a and b area.

00:17:33 So, our work, our performance goes against-- It is measured in our performance reports that come out every year. We'll cover some of the key core review ones here and just show you the performance.

00:17:52 So, historically, we have met most review goals in this program. It's a high-performing program against some of the key metrics that were measured on, particularly our application review and our supplement review, and manufacturing. So, you can see, historically, for the most part, pretty high-performance. A few years, particularly FY 20, were challenging, but that's, I think, for obvious reasons, overall achieving our goals every year. And we don't have 25 here yet, just because most of those applications are still pending, so there's not much to measure.

00:18:22 Meeting management has improved in this program in particular. Again, FY 25 numbers are preliminary, but we've seen, over the course of the past several years, a marked improvement, and the meeting management and performance goals there.

00:18:58 So there's a number of enhancements also in this program that aren't process or procedural goals, and we are on track at this point to make the vast majority of those. There's nearly a hundred actions required to fulfill the BsUFA III performance enhancement commitments. That includes data or list postings to the public website, updated pilots, programs, processes, guidances, internal operating documents, public meetings, public reports, and third-party assessments. So, a lot of activity is in these commitments, in addition to just our core review goals and meeting management goals.

00:19:46 So, just a quick highlight of what some of those performance enhancement commitments are. And this is all quite detailed in the commitment letter. I'm sure most of you have read it, but if you haven't, it's available on our website for folks to peruse. There's a bunch of commitments around establishing a regulatory science pilot program, commitments around enhancing the review process and sponsor communication, continuing to clarify the pathway, enhancing management of our user fee resources in the financial space, and then improving FDA hiring and retention.

00:20:29 You can find performance data and completed deliverables on our website. The links are here for folks. You can also just type it into a search and find it pretty quickly. Completed deliverables are posted on our website so you can find them in one consolidated place. Also, we released BsUFA performance dashboards, and on these dashboards, you are able to actually pull down the data if you want or go ahead and manipulate it on the website.

00:21:00 Okay, shifting gears to the reauthorization process overview. Okay. So, where are we and what's this overall timeline? We're a little bit more to the left of this graphic where we are in

the approaching end of this calendar year. And this meeting is really important because it kicks off the process, and technically after this meeting, we're allowed to start negotiating and it starts the reauthorization process. So, while having our initial public meeting today, we expect technical negotiations to begin in the spring of 2026, and then also conclude in the early summer of 2026. This is typical to what we've done in all previous rounds of this negotiation. It's a short timeframe, but very productive and fruitful discussions that always result in an agreement. And we're confident that, of course, it will happen again this time. We then have a clearance process. We have to get through FDA and HHS and the various layers of the federal government. We have that process, and then we need to have a final public meeting. We need to do that by the end of 2026 as soon as we can. And then by law, we have to transmit a package that makes recommendations on BsUFA IV to Congress by January 15th, 2027. Then, Congress has about nine months to reauthorize before this program expires. So, it seems very far off, but when you back it all out, we don't have a lot of white space in getting this done.

00:22:46 All right. Really tiny text here. This is the statute. I'm pretty sure that this was impossible to read, particularly for folks in the room. So, I'll just call out a few things, in particular on the next slide. But this is the statute that lays out the reauthorization process. You can also find this online if you're interested or if you haven't seen it before. And this process does require quite a bit of consultation with stakeholders. In particular, there's today, which is very important. There's the public docket that is open now and it closes on January 2nd. Please, we ask you to-- If you have thoughts on the current program and the future of the program, we ask you to please submit your comments to the docket. Every single comment is read and reviewed, so we take that into consideration when we enter into technical negotiations.

00:23:38 Also, for the first time in this program, we are going to have a periodic consultation. This is a new aspect of BsUFA that was brought into the program in the last reauthorization, where not

less than once every month during technical negotiations, FDA will be meeting with patient and consumer groups to get their input on BsUFA IV. That's a parallel process that happens during negotiations. This also happens in the PDUFA and GDUFA program. Please, we ask folks-- There's a docket. I believe that's out for that right now too, or it might not be. Sorry, there are a little bit of delays due to the government lapse of appropriations, but it will be out soon enough, and we'll let folks know if it's not out already. We ask that you please, if you want to participate in that process and you are eligible based on the criteria, sign up by January 30th. There are also going to be public minutes from each one of our negotiations with industry that will be available on our website within 30 days after each meeting. That's a requirement now by law and there will be detailed information there where folks can see what we're discussing. Okay, that's it. Thank you.

00:25:07 **Ms. Bailey:** Thank you, Andy. Hi all. My name is Thamar Bailey. I am a Social Scientist here. I'm actually going to prompt you all to have a 15-minute break. We are going to reconfigure the Teams meeting so that public attendees can attend as well. Right now, we have run into an unfortunate accident. So, we'll take a 15-minute pause here, and then we'll continue with the industry perspective. I thank you for your time and patience as we resolve this. Thank you.

00:26:08 **Mr. Collins:** We will just restart the meeting at 9:40.

## Regulated Industry Perspectives

00:44:59 **Mr. Collins:** Thank you, everyone, for your patience. We appreciate that. We're having a few technical issues, but I think we're ready to go. We will now have remarks from the biological product industry. We will first hear from Juliana Reed, Executive Director, The Biosimilars Forum.

00:45:43 **Ms. Reed:** All right. I have a very long slide deck. So, all right. Just kidding. Going backwards.

00:45:56 You all know, I think, who the Forum is, but I want to talk about, you know, one of the key things that I think we don't recognize here in this room enough is the companies as industry, but also the FDA and our partnership in bringing biosimilars to the U.S., and really, frankly, around the world. And the companies that I have the honor of representing, and the other trades will tell you this as well-- All the companies involved in this are pioneers, and so are the people in this room at the FDA. And we want you to know incredibly how much we always appreciate everything you guys do. It's so important to us. You're wonderful partners on this and very important to us as industry, launching something brand new from the beginning. And, Andy, we did BsUFA I. So, as you said, we were like, "Oh, gosh. We need a user fee program. What do we want it to look like?" And here we are going into BsUFA IV, and that's an incredible achievement that I'm honored to be part of. I'm honored to know all of you, and I think every day we have to remind ourselves how incredibly important this program is. And now we're going into year 20, you know, with BsUFA IV, it'll be 20 years. I do feel old. Thanks a lot, Andy. But this Administration-- We're grateful for what they are trying to do with biosimilars and how important biosimilars are.

00:47:53 One of the things that is really important to us though is also the stabilization of the FDA, of the resources, of the quality, of the safety. And those are key things, too. But we do want to call out when something good is happening, which is important for everyone in this room, again, that biosimilars are a priority for this Administration. We just want to make sure we do it right, keep our quality, and keep our expertise moving forward. 10 years is a long time. It's actually 15 years, and even longer than that, when we started and somebody asked me at a company that was bought by Pfizer, Hospira-- The Board asked me to create a biogeneric pathway at the FDA. And I'm like, "Okay." And we started marching around Washington

trying—and also in all the other countries that you have biosimilars going around—a lot of airplanes.

00:48:55 Biosimilars actually work. And we talk as far as the free market competition. And we remind industry that the savings are real. The access-- We need better access, but also competition in the U.S. and in any other country is better than most-favored-nation pricing. It's better than having negotiations and price controls. And I think, again, when we're in the everyday of this, we have to step out and remind ourselves how important what we are doing is.

00:49:29 They lower cost. If it wasn't for the competition of a biosimilar, the cost would continue to go up. And we know that. And I'm telling you all things that you already know, but I think it's really important to remind ourselves, as we go into negotiations, how important this industry is. If this industry does not succeed and it doesn't become sustainable, the question can be: in the U.S., will there be new generic industries? Will there be a third generation of a generic type model in this country?

00:50:09 So, one of the key things, and I think as you've seen in the void report, is not just the ability to compete and have market access, but the ability now to recognize 10 years or over 10 years of development expertise here at the Agency and with the industry. And that's why BsUFA IV negotiations are critical as an opportunity to improve the development, to improve the process, to make it more efficient and less costly over the next five years. So, that should be a big picture goal for us as we go into these negotiations.

00:50:54 As I've mentioned earlier how much we appreciate all of you and we support you on the outside and we'll do whatever we need to continue to support you, we need and we are advocates for a well-resourced and high-quality scientific BsUFA program and FDA. So, we're out here, and we're going to continue to educate on that and work with policy makers to get some stability over here as much as we can.

00:51:28 So, as we go into these negotiations with all of you, we want to build on our 10 years of biosimilar development and review in the U.S. and also around the world, as I mentioned. It's our opportunity to take a step back, take a look at the BsUFA program, look at what we can change and should change to make it more efficient, look at what is necessary or unnecessary after 10 years. What can we change? What can we also change across the board from an industry perspective? What do you need from us to do? What would we like FDA to do? And take a look stepping back from our current paradigm to step back and maybe create a new one. And so that's how The Biosimilars Forum is approaching this, both as advocates for this program and for the FDA overall. I'm sure I'm very redundant, but I think it's important, you guys, know how much we are grateful for what you do. But we also believe now, as we go into negotiations, we can streamline the process, take away some of the things that are not necessary and not of value, like the suffix, which Dr. Cohen will talk about in the coming years or months. Get it done. But there are things that we don't need any longer, and we have to review those and improve upon them. So, I just look forward to this and just thank you all again and thanks for the opportunity to talk.

00:53:35 **Mr. Collins:** Thank you, Juliana. We will now hear from Scott Kuzner, Senior Director for Sciences and Regulatory Affairs, Biosimilars Council.

00:53:53 **Mr. Kuzner:** Hello, everyone. I'm Scott Kuzner and I serve as the Senior Director of Sciences and Regulatory Affairs at the Association for Accessible Medicines and its Biosimilars Council. Our members include some of the largest biosimilar manufacturers in the U.S. and we thank you for the opportunity to speak today.

00:54:11 The Biosimilar User Fee Amendments, known as BsUFA, have played an essential role in strengthening the biosimilar review process and helping ensure that patients have timely access to safe, effective, and affordable medicines. This impact can be felt throughout the healthcare system. For example, AAM's 2025 Savings Report found that biosimilar medicines

saved the U.S. healthcare system 20.2 billion dollars in 2024. The total savings since the first biosimilar entry in 2015 has reached 56.2 billion dollars. The current Administration has repeatedly emphasized that lowering drug costs is a national priority. A well-functioning BsUFA program is one of the most effective tools we have to deliver on that commitment.

00:54:59 Since the enactment of BsUFA I in 2012, the resources from user fees have been invested in building out FDA staff, infrastructure and procedures, increasing predictability and clarity in the development review and approval of biosimilars. The result has been substantial progress in improving the efficiency and effectiveness of the BsUFA program. This means more biosimilar approvals, which helps to not only ensure patient access, but also encourages market competition that helps keep medicines affordable to the American public.

00:55:35 Through BsUFA II and III, FDA and industry built on the foundation established in BsUFA I, adding further enhancements to the program. These include establishing the program for enhanced review, transparency and communication in BsUFA II, and in BsUFA III, establishing the biosimilar specific supplement categories and implementing improvements to make FDA more efficient, targeted, informative, and clear. Additionally, in order to help facilitate the development of biosimilars, FDA committed to issue guidance documents on critical topics, like differences in delivery devices, and also launched the regulatory science pilot program.

00:56:18 The impact of BsUFA is clear. Since BsUFA I kicked off in 2012, the FDA has approved 79 biosimilars. Forty of these approvals occurred during BsUFA III alone. The FDA approved 16 of these biosimilars in 2025. These approvals represent critical opportunities to lower costs for patients and strengthen the resilience of our supply chain.

00:56:42 FDA's partnership with industry continues to advance biosimilars at an impressive pace. This has been driven by a strong commitment to science and evidence-based regulation. We have

seen meaningful evolution in FDA's approach to biosimilar development review and approval. Today, FDA recognizes that comparative efficacy studies are often unnecessary, as robust analytical pharmacokinetic data already demonstrate biosimilarity. This shift represents a deep trust in science and a willingness to modernize the regulatory framework in ways that maintain FDA's gold standard of quality, safety, and efficacy while reducing unnecessary duplication and cost.

00:57:27 Equally important, FDA's recent statements and approvals demonstrate a modern and pragmatic view of interchangeability. As the Administration has recognized, the two-tiered system unique to the U.S. has been rigged from the start and, as explained by FDA, the scientific reality is that all biosimilars, whether licensed as interchangeable or not, meet the same stringent standards of quality, safety, purity, and potency as the reference products. It is therefore unsurprising that switching studies are no longer the general expectation and the Agency's language increasingly makes clear that, once a biosimilar is approved, it is considered interchangeable from a scientific perspective, even though the legal designation still exists. These actions constitute a positive step toward ensuring that patients benefit from timely, affordable access to biologic medicines.

00:58:23 By aligning regulatory expectations with advancing analytical techniques and scientific consensus, FDA is making the biosimilar pathway more efficient without compromising safety or effectiveness. These scientific and regulatory advancements are helping to unlock greater competition, accelerate patient access, and solidify the U.S. as a leader in biosimilar innovation. Even with this progress, there remains room for improvement. More needs to be done to tackle the biosimilar void. For example, according to a recent study by IQVIA and the Biosimilars Council, only 10% of the 118 originator biologics losing patent exclusivity over the next 10 years currently have a biosimilar in development.

00:59:12 As we look ahead to BsUFA IV, we are eager to continue our strong partnership with FDA to ensure the biosimilar program delivers measurable efficient results for public health. Today, we wanted to mention a few areas in particular. First, application review times are too long, particularly given that submissions will generally no longer have comparative efficacy studies. Second, as FDA has recognized, substantive and nimble dialogue is key, and we look forward to working with the Agency to improve communication practices between FDA and industry, as well as enhancing efficiencies and transparency with respect to the inspections process. Third, we are excited to build on FDA's great strides to increase reliance on analytical data, to streamline development, breaking down unnecessary barriers to U.S. patient access. Fourth, biologic device combination products provide important options for patients, but 351(k) BLA sponsors can be hampered from making device differences that can benefit patient usability and design around patients. BsUFA IV provides an opportunity to evolve the Agency's current approaches to assessing user interface differences and human factor studies. In addition, we wish to optimize device bridging approaches and ask that the FDA provide product-specific guidance for ADCs and bispecific mAbs. And lastly, we look forward to exploring the use of a single global comparator to expedite U.S. patient access to biosimilars.

01:00:49 We value the FDA's commitment to ensuring that the BsUFA program remains agile in a rapidly evolving scientific and policy environment. We also appreciate the opportunity to comment on potential updates to the current BsUFA fee structure to better advance the goals of BsUFA, including facilitating efficient product development and ensuring timely access to biosimilars for patients. A stable and predictable financial foundation to support a well-staffed FDA is essential for the success of the BsUFA program. Earlier this year, reports raised concerns about whether the biosimilars program would meet its statutory requirements for the spending trigger to release user fee funding. These reports underscore the need for a

reauthorization framework that safeguards BsUFA-related resources and prevents disruptions that could slow biosimilar development and limit patient access.

01:01:47 In closing, while the story is still being written, BsUFA has been a success story and one we are proud to continue building together. The agreements' increased efficiencies have brought both tremendous savings and expedited access to the affordable medicines the American public needs. We thank the FDA for its commitment to the BsUFA program, and we look forward to working with you to make BsUFA IV the most effective version yet for patients, public health, and the future of affordable medicines. Thank you.

01:02:30 **Mr. Collins:** Thank you, Scott. We will now hear from Sean Hilsher, Senior Director for Science and Regulatory Advocacy, PhRMA.

01:02:48 **Mr. Hilsher:** Thank you and good morning, everyone. My name is Sean Hilsher. I'm Senior Director of Science and Regulatory Advocacy at the Pharmaceutical Research and Manufacturers of America or PhRMA. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than 850 billion dollars in the search for new treatments and cures over the last decade, supporting nearly 5 million jobs in the United States. PhRMA has been a strong supporter of and participant in the initial authorization and subsequent reauthorizations of the Biosimilar User Fee Act or BsUFA since 2012. We appreciate the opportunity to participate in today's public stakeholder meeting.

01:03:47 Biosimilars are important in helping provide new options to American patients and in increasing competition in the marketplace. PhRMA supports an ecosystem that preserves incentives for innovation and ensures a level playing field for novel biologics and biosimilars.

01:04:03 To help ensure access to safe and effective biosimilars, we need a modern regulatory system that enables FDA to serve public health and patients by providing timely science-based regulatory decisions. That is why PhRMA and our member companies have been a strong supporter of and participant in BsUFA since 2012. Since its inception, user fees provided through BsUFA have helped enhance greater consistency and predictability in the review of biosimilar products by establishing review timelines and continuously enhancing review processes, enabling timely and consistent communication, allowing for meaningful engagement between FDA and sponsors during regulatory review, and providing and strengthening opportunities for scientific dialogue between sponsors and the Agency.

01:04:56 It is important that all stakeholders work together to build on the successes of previous BsUFAs and continue to help ensure patients in the United States have timely access to biosimilars and ultimately benefit from increased competition in the marketplace. This includes ensuring that the biosimilar biological review program continues to do the following: adhere to clear, transparent, established review timelines that meet or exceed BsUFA goals while prioritizing essential review activities; fostering predictability and consistency for sponsors to understand regulatory expectations; facilitating timely science-based, effective and efficient regulatory review, driven by and assessed against metrics-based outcomes, including key performance indicators and the public reporting of relevant review timelines and accountability measures; and engaging directly and continually with the public and relevant stakeholders to provide proactive, timely, and accessible information on regulatory processes and approvals, as well as emerging safety information to maintain the public's trust.

01:06:04 BsUFA IV provides the opportunity for FDA to focus on enhancing core review functions to continue to ensure safe, pure, and potent biosimilars for the American patient. BsUFA has well-established performance goals, and FDA should continue to prioritize meeting and improving upon the goals of the program set out in the agreement. Further, BsUFA IV

provides industry and FDA the opportunity to ensure that review process enhancements introduced in the previous BsUFAs are being utilized effectively and resources are being used optimally. Lastly, under BsUFA IV, FDA should continue to provide opportunities for engagement and communication between FDA and biosimilar applicants for the entirety of the regulatory review process.

01:06:50 In the interest of ensuring the long-term financial stability and sustainability of the BsUFA program, BsUFA IV should focus on streamlining the financial structure of the program to be consistent with the current resource needs of the Agency. Simplifying the user fee revenue process would result in greater predictability for FDA and industry and ultimately support the long-term stability of the program.

01:07:11 In conclusion, BsUFA IV is essential to helping ensure that FDA has the resources to support the science-based review of biosimilars, which will help increase competition in the marketplace, ultimately to the benefit of the American patient. A timely and efficient reauthorization process is essential to fully realize the potential of improvements included in the agreement. PhRMA looks forward to working with FDA, patient groups, and other stakeholders to advance a BsUFA IV agreement that will help support the development of the next generation of safe, pure, and potent biosimilar products. Thank you for your time.

## Public Comment

01:08:03 **Mr. Collins:** Thank you, Sean. Our next session is dedicated to the public comment. Before this meeting, FDA invited everyone who registered for this meeting before November 21st to indicate whether they would like to provide public comment at the meeting. Since we did not receive any requests, we would like to set aside some time now for anyone in the room who wants to make a public comment. If you do, you'll be given a five-minute time limit. We ask

that you start by introducing yourself with your name and affiliation. That said, if anyone wants to make a comment, please head to one of the mics in the audience.

01:08:54: **Mr. Josephson:** All right. I feel kind of left out. I thought I would maybe get to come to the podium. Yeah, because then I'm not--

01:09:14 Hi. I'm Aaron Josephson. I'm the Lead for U.S. Regulatory Policy at Teva Pharmaceuticals. Thanks for the time to speak today. For more than 20 years, Teva has taken steps to cultivate a diverse biosimilars portfolio, focusing on medicines targeting areas including oncology, immunology, chronic diseases, and others. We view biosimilars as a key element to achieving our mission to improve public health owing to the dual impact biosimilars have on the healthcare ecosystem: first, the expansion of patient access to treatments, while second, reducing costs and supporting the sustainability of healthcare systems.

01:10:02 As AAM has reported and we heard about today, biosimilars have saved the U.S. healthcare system tens of billions of dollars, and as more biologic medicines become available to develop as biosimilars, savings to the U.S. healthcare system will undoubtedly grow. This is important not just as a mechanism for reducing ever-rising healthcare costs, but because healthy Americans are productive Americans. The positive effect of biosimilars, therefore, can be understood in a broader context of improving the country's economic and societal health. In this way, what we're doing here today are small pieces of the pie as part of a much bigger objective related to improvements in the healthcare ecosystem.

01:10:52 Through strategic partnerships and continued investment in biosimilars development, Teva is committed to expanding patient options and supporting a more sustainable U.S. healthcare system with those positive downstream economic and social benefits. We appreciate FDA's role in fostering a robust and competitive biosimilars market. FDA's recent announcements related to streamlining biosimilars development were welcome shifts in policy that will lower

development costs and, therefore, make biosimilars development more attractive. Initiatives that reduce unnecessary clinical testing and promote the development of biosimilars are vital steps forward. And the FDA's commitment to science-based regulation and its openness to innovation have positioned the United States as a leader in biosimilars development, ensuring patients have access to safe, effective, and affordable medicines. But make no mistake, the cost to develop biosimilars is still high to support investments in their development and to support delivering these medicines to patients as quickly as possible. The regulatory approval process must, therefore, be efficient, and the BsUFA reauthorization, of course, is the best time to make suggestions for that.

01:12:10 Acknowledging progress made in BsUFA III, several review process issues warrant attention from our perspective. These include supplement review times, information requests, and deficiency response timelines, and the occurrence of late information requests and labeling comments. We look forward to discussing with FDA what changes may be possible to address these challenges to improve transparency, predictability, and efficiency of review. Committing to earlier identification of deficiencies, for example, can significantly improve review efficiency by providing more time for applicants to address the deficiencies. Scheduling and conducting inspections, similarly, enable more time to address any observations that might otherwise inhibit timely approval of a biosimilar application.

01:13:03 The biosimilars regulatory science program created in BsUFA III and funded by industry user fees has enabled FDA to explore ways to produce scientific evidence in support of biosimilars development. It has advanced biosimilars development by increasing reliance on analytical data, reducing the need for large human trials and fostering stakeholder engagement. These efforts have streamlined regulatory pathways, improved efficiency and strengthened scientific evidence, and overall, it has accelerated patient access to safe and effective biosimilars, while maintaining FDA's rigorous standards. Enhanced oversight of where BsUFA research funds

are dedicated can help maintain the integrity of this program and ensure that the funds are used to continue to support timely American patient access to biosimilars.

00:13:54 Lastly, with the shift away from phase III-style confirmatory efficacy studies, the assessment of today's biosimilars continues to rely heavily on analytical techniques. Both the BsUFA fee structure and FDA's organizational structure should reflect this. With respect to fees, we look forward to discussing with FDA how to ensure the fee structure provides the Agency with the resources it needs in the right places. With respect to organization, we encourage the Agency to ensure final sign off of biosimilars applications rests with the office closest to the applications review, and consistent with the Agency's stated policy shift away from large confirmatory clinical trials. Giving OTBB signatory authority is a process improvement that will enable OND clinicians to focus on reviewing innovative medicines, while removing unnecessary administrative complexity from the biosimilars review process. Addressing these and other topics throughout the BsUFA reauthorization process will help, we believe, maintain FDA's position as a leading regulator and the U.S. as a desired market for biosimilars, supporting our shared goal of bringing biosimilars to American patients faster. Thank you for the chance to speak today.

## Closing Remarks

01:15:27 **Mr. Collins:** Thank you. Are there any additional public comments? Okay. Hearing none, that concludes our public comment session and our meeting today. Thank you to all the speakers who took time to share their comments with us. Thank you all for attending, both in person and virtually. Please be advised that the public docket to provide written comments is open until January 2nd, 2026. We encourage everyone to submit their perspectives to the public docket for FDA review. As a reminder, the meeting slides and recording will be posted following today's meeting. We hope that you enjoy the rest of your day. Thank you.