Public Meeting on the Reauthorization of the Biosimilar User Fee Act – Adobe Connect Closed Captioning Transcript

This transcript reflects the closed captioning from the live meeting. It has been edited from its original format to include speaker names and exclude dialogue regarding technical difficulties.

Maria Barhams Sagoua:
Good morning and welcome to this public meeting on the reauthorization of Biosimilar User Fee Act or BsUFA. My name is Maria Barhams Sagoua and I'm with the staff in the Center for Drug Evaluation and Research and I will be your moderator today. BsUFA is legislation that authorizes FDA to collect user fees to support the process for review of biosimilar biological products. It currently authorized the program, BsUFA II expires in December 2022. Preparation is underway to begin the process to reauthorize the program for fiscal's 2023 through 2027. The purpose of today's virtual public meeting is to gather input and recommendations from the public in advance of discussions that will occur with the regulated industry. Today's meeting is an important step in engaging public stakeholders on features of the BsUFA program. We have a full meeting agenda today . We begin with Patrizia Cavazzoni, acting Center director of CDER who will provide opening remarks and then Andrew Kish, the director of the Office of Program and Strategic Analysis at CDER will follow with the presentation on the background of BsUFA and reauthorization process. With and have panels providing presentations on perspectives from the following types of groups. Consumers and patient advocates, healthcare professionals, regulated industry and scientific and academic experts. The director of the office of therapeutic and biosimilars will provide FDA remarks. For individuals who submit a request online, a public comment section will occur at the end of the meeting. I will then close the meeting amount 12:30. Stakeholder panels include a series of speaker presentations. Eat speaker will have 10 minutes to present their organization's perspective on BsUFA. As we have a full agenda we have to adhere to the timeframe. It's my responsibility to let speakers know as they approach their time limit. In the FDA Federal Register notice announcing this meeting, FDA provided three questions to help panelists frame their comments. What is your assessment of the overall performance of the BsUFA program to date? What current elements should be retained, changed or discontinued to further strengthen and improve the program? What new elements should FDA consider adding to the program to enhance efficiency and affect deafness of the biosimilar, biologic review process? Policy issues are beyond the scope of the BsUFA reauthorization process and the presentation should focus on process enhancements and not on issues of policy. This meeting is an opportunity for FDA to listen to public perspective. FDA will not ask questions nor answer questions raised at the meeting. And even though you can't see us in person, please know my colleagues who will be reading and participating in the reauthorization process are here and listening and we value your perspective. Please keep in mind you can submit comments to the public docket open until December 19th. We encourage everyone to submit their perspectives to the public docket for FDA review and you can find a link to the public document in the announcements Bock. A few housekeeping items. The public meeting is conducted entirely on a virtual platform in response to the COVID-19 pandemic. We think all speakers for their efforts to prepare for the meeting and we thank participants for your patience as we navigate the virtual meeting. If your audio or video connection diminishes we recommend trying to reconnect through the system. If you experience other technical issues during the webcast, type your issue into the technical issues box or email Emily dat Ewing@FDA.HHS.gov. We will have a 20 minute break at 10:30 and if schedule modifications are needed we will communicate that in the announcements box as well. I now turn it over to Dr. Cavazzoni for opening remarks.

Patrizia Cavazzoni:
Good morning, everyone. And thank you, Maria, for the introduction and thank you to everyone for coming this morning. The purpose of the public meeting is to collect a wide variety of stakeholder perspectives as we consider what to retain and what to change in the next iteration of BsUFA. Today's meeting is an important step in engaging with public stakeholders and teachers of the BsUFA program. Historically there have not been a clear pathway for follow-on stew biologic products which typically carry higher prices than small molecules. The biologic price competition and innovation act of 2009 was intended to generate press petition in the biologics market by providing an abbreviated approval pathway for biosimilar biological products. BsUFA was started in 2012 to help secure the necessary revenue that FDA needed to support the review of biosimilar marketing applications under the abbreviated approval pathway. And to help ensure that the public gains timely access to FDA approved biosimilar, biological products. Since then, FDA has utilized BsUFA resources to facilitate efficient and timely review of biosimilar's. Accelerating the availability of biosimilar therapy applications while maintaining FDA's high standards for efficacy, safety and quality. With

the input of industry and public stakeholders for BsUFA II, FDA make changes to elements of the BsUFA program. FDA implemented a review program similar to the one used for new molecular entities, NDAs and original DNAs in BsUFA with the goal of increasing first cycle biosimilar application approvals and decreasing the number of reduced cycles to reach approval. FDA also published new or updated guidance to further clarify the abbreviated approval pathway for biosimilar biological products. FDA also established a new independent and efficient restructured based on BsUFA costs to improve predictability of program funding. At the same time, we implemented several commitments to enhance the management of BsUFA resources. In BsUFA to date, FDA has increased the predictability of the biosimilar review process, increased communication and transparency during biosimilar development and the application review, and helped advance biosimilar marketplace competition for access to patients and consumer choice for product approvals. FDA has approved a growing number of biosimilar's, a majority of these were approved during BsUFA II consistent with the program growth and experience gained during BsUFA 1. Participants in the BsUFA II review program have offered positive feedback about FDA's transparency and communication. FDA has also completed a number of additional deliverables related to BsUFA II including guidance, reports, public meetings and website postings. the success of BsUFA relies on the input of stakeholders. Continuing to evolve BsUFA, engaging with public stakeholders on the future of the BsUFA program is a crucial step. At this meeting and in the public docket, we invite you to share your perspectives as we consider whether to retain, to change or discontinue elements of the current BsUFA. Biosimilar's have a great promise and the FDA remains committed to increasing the availability of safe and effective biosimilar and interchangeable products for the patients who need them. BsUFA is intra-goal to this effort. We thank you for attending virtually. We thank the panelists were being here and we look forward to a productive meeting. Thank you.

Maria Barhams Sagoua:
Thank you, Dr. Cavazzoni. I would like to now introduce Andrew Kish, director of the Office of Program and Strategic Analysis and CDER to provide background on BsUFA in the reauthorization process.

Andrew Kish:
Thank you, Maria. I will spend a few minutes this morning going through some of the background on BsUFA . In particular, touching on the legislative background, finance and fee structure, workload, the BsUFA II commitments in the reauthorization process. So as Dr. Cavazzoni mentioned, BsUFA came about a number of years ago as the Biologics Price competition and innovation act of 2009 which directed FDA to come up with the user fee program for 351(k). That put in place the BsUFA 1 and after a period of stakeholders and FDA transmitting recommendations to Congress in January, 2012. That led to the passage of BsUFA . Some things to point out at the time and this is something to note because quite different from PDUFA and how it came out. In 2011 and 2012 we were discussing what it would look like and there were no marketing applications or products on the market as biosimilar's. We didn't have any established direct development process or history related to biosimilar's that were put in place in BsUFA 1. Granary to the ninth year comparing to PDUFA in its 28th year. And as already noted by Dr. Cavazzoni, BsUFA facilitated approval of over 28 biosimilar biological products for the American public. A little more on some of the highlights from BsUFA I and . The process was in place it but we did have history of biosimilar's but in included fees for products in the development phase which helped put in place to generate revenue for the review process and as folks are more familiar with on the PDUFA side the fees are assessed a program fee which is when a product reaches the market. That wasn't quite feasible with BsUFA I. Also introduce predictable timelines of the review process and goals and primarily modeled on PDUFA. And the tradition to BsUFA II, that saw sufficient information on the program and the cost of the program where we could create independent user fee structure based on the biosimilar program cost. We also implemented a review program to promote efficiency and effectiveness of the first review cycle and minimize review cycle so modeled after the program and folks who are familiar with PDUFA which was put in place in PDUFA where they created structure and touch points throughout the review process. And it added commitments to assess the program, clarify the regulatory pathway and enhance staff capacity. So the basic BsUFA construct is fee funds are added to appropriated funds and intended to increase staffing and other resources to speed and enhance the review process. User fees pay for services that directly benefit fee payers. When we get into discussions, what are some of the key questions we have? What are new or enhanced processes that FDA will want or industry seek to include in the next five your cycle? What is technically feasible to do during that timeframe? What resources are required to implant and sustain those enhancements? And no discussion of policy. And I think everyone can attest to that spin through these discussions in the past that it's very technical and these are technical negotiations and a lot of details that have to be worked through. A little on

the financial background and fee structure. User fee is critical to the program. If you look at the graph presented here from 2013 until 2019, and as of FY2019 user fee revenue is about 64% of the program which is the light blue color on the graph. And somewhat similar to other programs, user fee revenue has outpaced budget authority available for the program. Quickly touching on the current fee structure. The FY2021 notice highlights it if you want to get into more details and the background and calculations themselves. The target revenue for biosimilar's for the fiscal year is about $42 million. Much smaller when you compare this to PDUFA and incredibly a critical thing that's critical to program success. Fees are paid by a biosimilar fee and there is application fee and program fee. Workload and performance. Fee support, a number of work against performance goals, 28 specific review, procedural and meeting management goals along with other commitments. You see a number of these in the table provided. It's around the review of the application that comes in around supplements, clinical holds, meeting minutes. FDA, we are on track to meet our core review performance goals for FY2020. We just closed out FY2020 and those numbers are being finalized and from current performance, it looks like we are on track to make the performance goals. That includes original biosimilar BOA resubmitted and manufacturing supplements and other items. A quick look at workload. One measure of workload which is the number of development programs that are active and the number of applications that come in is one measure you see from the beginning of BsUFA I through FY2020, the program for 10 used to grow in program development. A note on meeting management. And this was a pain point raised as meeting management continues to be a challenge for us in this program. You can see in the table provided, those in green means we met the goal and those in red means we missed the goal. I will say some are quite small numbers, so you might miss one or two and then you missed the goal. It's still a town trust and important to notice that those who advance these and hold meetings are also on the new direct side, so they are meeting as workload and cannot be looked at in isolation of the workload on the new drug side. There are additional BsUFA II commitments. We are on track to meet those performance enhancement commitments and what are they? There are over 50 actions in the BsUFA II commitment letter. Those include new or updated pilots, programs or processes, postings, public meetings, public workshops, guidance is, public reports and hiring goals. Just briefly touching on performance enhancement commitments. They are listed in detail in the BsUFA II commitment letter which can be found on our website and included ensuring effectiveness of the program, clarifying the regulatory pathway, commitments around capacity for biosimilar guidance for reviewing communication, enhancing management of user fee resources and hiring and retention goals. I won't read through all of this, but just touching on what are some commitments within those sections includes implementation of the program, the review program mentioned earlier on. Assessing the program through a third-party. Performance goals around proprietary names and updated guidance is. Draft guidance is and final guidance is to clarify the regulatory pathway. And then strengthening capacity to help put out guidance is and to develop maps and sops and review templates and to deliver information to the public in outreach and system commitments to enhance the purple book. Something that is new in BsUFA II and also in PDUFA was enhancements around user fee resources which included implementing a capacity planning capability and model rising time reporting and a number of steps to increase financial transparency and efficiency. And it's something that is unique to BsUFA's management of carryover balance . At the time of BsUFA II , the carryover balance was a bit higher than it would be now if you look at the financial report and the FDA and industry agreed to commitments around FDA working to reduce the carryover balance. That is throughout the course of BsUFA II. There is a number of commitments around hiring and retention including modernizing the hiring system infrastructure, increasing capacity to support the hiring function, establishing a dedicated scientific staffing unit, setting clear goals around hiring, and also bringing on a third-party to assess our progress in hiring and retention. The performance data and completed deliverables are available to you and can be found on our website using the links provided here. If you want to dive into more details, completed deliverables can be found in the first link. There is also a new BsUFA performance dashboard that will give you the ability to interact with data on our current and historical performance. I encourage folks to look at that and you can even download the data if you want to look at it in more detail. The reauthorization process. By statute we are required to do a number of things including transmitting recommendations to Congress not later than January 15th, 2022. So we work backwards from that timeline, that's why we are having the public meeting now. The public meeting is starting the consultation process that we will go through and working forward as Dr. Cavazzoni mentioned to collect your thoughts and feedback from a broad spectrum of folks that have interest in the biosimilars program. We then engage in ongoing conversations with industry to come up with parameters and what might be in the BsUFA III agreement and when that is completed there will be a public review of the recommendations so another public meeting and opportunity for folks to provide comments through a public meeting or the Federal Register. I will disclose high-level priorities from the FDA perspective on BsUFA III . It's critical to ensure stable funding for the program as we move forward and think about the next five years of the cycle. Enhancing regulatory verdict

ability and efficiency is also a top priority. Enhancing operational capabilities, efficiency and agility. And also looking to address information and scientific gaps to facilitate more efficient development. That concludes my presentation. I will turn it back over to Maria.

Maria Barhams Sagoua:
Thank you, Andy. We now move into the stakeholder panel session and to keep the meeting moving forward on time, I will announce when there is one minute left. At the 10 minute mark I will ask you to conclude and introduce the next speaker. Our first panel provides consumer and patient perspective on BsUFA and three speakers in this panel are Monica Mallampalli from HealthyWomen , Anna Hyde from New York writers found a nation and Marjana Marinac. Monica, you are first and we welcome your comments now.

Monica Mallampalli:
Thank you. Good morning. Thank you for giving me this opportunity to present on this panel today. My name is Monica Mallampalli and I am the CEO science he pick achievement for HealthyWomen. For some of you who don't know about HealthyWomen , we are a national [Indiscernible] and been around for 30 years. We serve as information from a digital platform so our mission is to educate women ages 35 to 64 to make informed health choices. As you are all aware, since March 2015, FDA-approved 28 biosimilars in the space of oncology, rheumatology and blood disorders. And the chart on the right depicts this. According to the website of the FDA, biosimilars have the potential to have life altering benefits at reduced cost to the patient. So FDA has an important role in ensuring these medications are safe and effective and efficient regulatory standards. HealthyWomen understands the user fee program plays an important role in the review process and it supports FDA initiatives and activities to ensure timely and robust review. It encourages innovation a biosimilars that promotes initiatives that utilizes best science and deliver safe and effective treatments efficiently for women who need them. Regarding the reauthorization, we support the reauthorization of the biosimilar user fee act and we believe FDA can continue to address and improve upon the following things, provide general education on biosimilars, increase confidence on safety and efficacy of biosimilars, and ensure clarity of clinical data on biosimilars as part of their efficient review process. I will touch on these three points briefly to support these as well as also share some insights on why we think these are needed and what FDA can do. Now coming to providing general education on biosimilars. We want the FDA to look at women as consumers of biosimilars and in this pie chart in 2019, women made up a higher percentage of the population compared to men. If you look at the graph on the right and the age demographics that make up for the healthy women of ages 35 to 64, women are 19.3% of the population versus men so we believe there is still a target population that needs to be educated on biosimilars. Also midlife women bear the biggest burden of chronic health conditions as well such as arthritis, Crohn's disease, MLS and breast cancer. Last year, we did a science and policy forum and biosimilars with the angle of women's health. We did a quick survey and we found some interesting insights. 89% of women have never taken biosimilars. 91% have never discussed biosimilars with providers and 75% think biosimilars are not genetics. One-third don't think biosimilars are more affordable than biologics a 96% of women were concerned about medication costs. What was interesting is women did not understand the differences between biologics and biosimilars and the chart on the right shows that. Some of the insights we received were they did not show what they are, how closely they compare to biologics and some of them said it was the first time they had heard of it despite their interest in health and medicine. We found there was a need for education among specialty physicians and oncologists and these are papers I found. So due to the fact there seems to be a need for more education, here's one of the papers that shows that education helps raise awareness. If you look at the column of the gender population, and ones that are diagnosed for both biologics and biosimilars, education seems to help the awareness. The advocacy group are the people in support groups and working in educational materials and found the level of awareness was much higher compared to the general population. Interestingly most of the people who participated in the survey were again women all across these different subgroups. What can FDA do? With regard to gender education, I think FDA is doing a great job already creating stakeholders in the form of educational materials and we think the FDA should continue to do what they are doing as well as trying to do outreach specifically to women and healthcare providers with easily accessible and understandable materials and we encourage FDA to partner with HealthyWomen and also some specified organizations to create simple and deliverable messages that are easily accessible to the audience. Coming to my second point on consumer confidence on safety and efficacy of biosimilars, so the same paper I showed earlier, gaps continue to exist in knowledge of biosimilars especially safety and efficacy and if you compare on the left regarding biologics and biosimilars you see there's more of a knowledge gap on biosimilars. But if you compare the groups that knew about biosimilars and those unaware of biosimilars you continue to see a huge knowledge gap. Again coming back to some of

the consumer insights that we saw from our audience was like generic drugs, they were concerned about what was the real components of the biosimilars and not sure of the long-term benefits and also how would they react in the body and concerned they might not work well as well as concerns about safety. Again, what can FDA do? I think FDA can continue to help build confidence and help patients understand biosimilars have safety and there's consumer evidence and everyone thinks they're safe and effective to make a biologic and we think FDA should come up with a process on an initiative to ensure the information gets directly to the patient and providers hands informing them as well as instilling confidence in choosing a biosimilar. And finally, on my last point, to ensure clarity on clinical data as part of the review process, once again FDA has done a great job with the review process. Just to add to that regarding the clarity on clinical data, I want to point out that some diseases treated by biosimilars impact women disproportionately. Women tend to have a higher greater risk for developing adverse reaction due to sex-based differences in response to medications. We need to ensure the safety and efficacy data is analyzed and not just collected and reported by sex when appropriate. Finally, the FDA can ensure that that data related to safety and efficacy for biosimilars and is presented to consumers and healthcare providers on FDA websites in a simplifies manner. I want to plug in that perhaps if there is a need to [Indiscernible] to review the data by sex and race and ethnic city and doesn't have one assigned, they should make that a priority. Finally, I want to thank the FDA for giving me the opportunity to present here today and share our comments. Thank you.

Maria Barhams Sagoua:
Thank you, Monica. And Anna, your next. We welcome your comments now.

Anna Hyde:
Let me start my WebCam here. All right. I don't have slides today, but I will read my testimony. I want to thank the FDA for the opportunity to present today. Some things I will talk about are very similar to what Monica talked about and I will start with why BsUFA matters to the arthritis community. There are 12 biosimilars that have been approved for arthritis and three have, and market and the promise of biosimilars to a patient is more affordable and therefore increases access to medication. To us, understanding the factors contributing to by a similar uptake is essential to realize the promise. Many factors are market related and outside the scope of FDA, many other factors relate to patient and provider knowledge like trust and confidence in biosimilars in the scope of the FDA. When the FDA brought together stakeholders for BsUFA II five years ago there were no biosimilars on the market for arthritis and we just started surveying our patient community about them . A lot has happened since then and we learned a lot about those questions of trust, knowledge and confidence. Specifics I like to get into now from some surveys and focus groups we have done include from 2017 a survey we did of constituents and less than half of patients were familiar with biosimilars and 27% never had heard of the term. Confusion about the difference between biologic and biosimilar and half of the respondents said they would be confident using biosimilar that have been approved by the FDA and finally they care deeply about provider and patient relationship and what decisions about what medications they are taking whether biosimilar or another product be made at the provider level. And focus group since then we dug in further and we know that patients may not take a biosimilar if they don't know about them. If there Doctor hasn't talked about biosimilars as a treatment option and they fear they won't work as well or have concerns about interchangeability or they may not have easy access through their formulary for the cost is significantly lower. Information about biosimilars include healthcare provider which is the most popular and the preferred source of information. The FDA came up high as a highly trusted resource and then many patients learn about biosimilars from the Internet as 46% did so they said they use the Internet to learn about biosimilars. From that data we note that barriers to uptake include a lack of incentive, communication bias, inherent fear of new and formulary access challenges. The most relevant I would like to dig into here are around the communication and efforts to combat fear of the new. What are we doing to address barriers? We are enhancing patient education to normalize the term biosimilars and materials and outreach. We coordinate closely with provider groups and are working with the FDA on their patient education materials. And working with a broad group of stakeholders to address barriers to uptake generally. On the last point, you're ago we brought together patient and provider groups across therapeutic levels to level set on biosimilars and at that time the landscape changed rapidly in the previous couple of years and just the need to bring everyone together and learn about each other's activities and positions on biosimilars and identify areas of consensus. While we went into that meeting without any pretense of what would come out of it we were pleasantly surprised there was clear themes that came up that we were actually able to turn into principles defined by two doesn't patient and provider groups which are publicly available which I will share in written comments of the two principles most relevant for this purpose are visible one, patient trust and safety and efficacy of biosimilars and physician confidence in prescribing are crucial factors

for uptake and every stakeholder at the table said the FDA is a vital resource that patients, physicians and others turn to for trusted information and will continue to be so and another theme that came up was the importance of fostering peer to peer opportunities to learn from one another and we know biologics generally can be scary drugs for patients to begin taking. Learning what has worked well and what the experience has been for other patients goes a long way towards helping with that fear factor. And the second principle was language around stakeholders talking about biosimilars matters. Stakeholders use different terms to describe biosimilars that leads to confusion and bias. Using language from the FDA can avoid unintentional bias. On the last point, we collectively agreed on the importance of the FDA as a top resource for education and information about biosimilars and honed in on two key areas for moving forward. One is the need to identify or collect more data particularly about patient and provider preferences and being able to segment those between patients who are biologic naïve versus those stable on a medication and for what length of time, because confidence in switching to a biosimilar may change. And on the need for best practices on communicating unbiased information to patients and providers. On the last point we learned a lot about the nuance nature of talking about biosimilars. I use the word nuanced and biosimilars all the time these days because it's really how simple word choices can influence how patients feel about a biosimilar. Using a seemingly innocuous phrase like they are cheaper makes them think they are also lesser. And from there, we know there is data to suggest it has an impact on the placebo effect for example. With all that in mind we see a sense of urgency in addressing the issues and the goal is to turn the principles into practice. We'll the FDA shares a sense of urgency as we know over the course of the next round of BsUFA, more biosimilars will be approved and come to market including injectables which make these things more important. The FDA has been a tremendous partner in working with us and being readily available to partner on patient and provider education so far. We tremendously thanked the FDA for that and what we recommend now going forward correlates directly with our priorities for moving principles forward. Three things here and then I will wrap up. One is continuing to work with the patient and provider community on biosimilar education and in particular to work hand-in-hand with us to maximize reach. Data collection there are layers of information about patient preferences and concerns that need to be collected in ways we can collect the data that the FDA cannot and vice versa. On addressing bias it's a tremendous asset to have a set of best practices organizations can use to ensure material for developing biosimilar education to not include unintentional bias. One such best practice might be making a practice for organizations to that the language with FDA before publishing materials. Also practical best practices we can collectively implement over the next few years. Second, their specific needs around education and in particular there's a great deal of confusion about interchangeability, clearing up lingering points of confusion to help increase confidence in biosimilars and in particular biosimilars that are deemed interchangeable. And finally patient education should be a priority to the extent applicable and we encourage the FDA to carryover lessons from PDUFA and BsUFA and it could include versions of patient focused drug development and guidance on collecting and implementing real-world evidence and engaging patients through the approval and post-approval processes . Coming full circle to my points above, understanding what leads to patient trust and confidence requires talking to patients and learning from them and I learned every day from talking to patients. I learn something new every single day and don't take for granted how important patient engagement is within the organization and of course externally. We stand ready and willing to partner with the FDA through its patient engagement processes and I want to end by drinking you again for the opportunity to provide comment today.

Maria Barhams Sagoua:
Thank you so much, Anna. Now we will have Marjana and we welcome your comments.

Marjana Marinac:
Thank you. Good morning. My name is Marjana Marinac and I'm the senior director of regulatory affairs at JD RF international and it's our first time participating with the BsUFA process and we thank the FDA for the invitation to do so. What I thought I would do today since this is our first time as an organization being part of this process is talk a little bit about what we are as an organization and spend time talking about the importance of biosimilars in the diabetes space and share some thoughts on the BsUFA III process moving forward. A little bit about type one diabetes. About 5% of the 29 million Americans who have diabetes have type one diabetes. We see an increase in the incidence in the country and anticipating by 2050 that 5 million people will be affected by type 1 diabetes. 84% of people with type one diabetes are adults. This is a disease that often is diagnosed in childhood, but majority of those living with type one today are adults. And as you can see we are estimating that about 40,000 people will be diagnosed with type one diabetes each year and there are significant cost implications to the U.S. healthcare system. It's an autoimmune disease in which the beta cells are destroyed, insulin producing cells of the body, and we are also a disease in which there are

currently no disease modifying [Indiscernible] that are approved. Unmet needs for type 1 diabetes, what I'm sharing here is data that comes from the type 1 diabetes exchange which is an exchange of specialty centers across the United States that are specialty clinics with an expertise and diabetes. You see here that the recommendations for hemoglobin A1c targets in children of those less than 18 are less than 7.5% and recommended A1C target for adults is less than 7% and hear what this clinic data shows you is the majority of people with type one diabetes [Indiscernible] and we see that especially for younger populations which are in the 17% of 14% range and a little closer in the 27% to 28% range for adults. It's worth noting that this data is likely representing up better number than what is probably actually happening in the community as a whole as these are specialty centers so we still have a great unmet need in therapies that will lead to better outcomes for people with type one diabetes. In terms of helping those who live with type one diabetes with full lives, we are a community that needs advocacy to drive research advances to find cures and while being people healthy until cures are found. Ongoing research for cares and better treatments, educational information and support, and access to good health care coverage, also affordability and choices about therapies that work for people with type one diabetes. A little bit about JD RF as an organization, we were founded 50 years ago by parents of children who had type 1 diabetes and they saw a need for education and community support as well as a significant number needing research and type 1 diabetes. Our mission and vision is to have a world without type 1 diabetes and the mission is to improve lives of people living with type one until we can find cures for type 1 diabetes. We have committed since our founding in 1970 over $2.9 billion in research and currently supporting over 55 active human clinical trials. A little bit about how we do things in the work across the pipeline in order to get better therapies to our community. Obviously we fund research in both discovery and in the translational space. We work with the regulators across the world to ensure pathways that allow efficient review of therapies that people would type 1 diabetes need and we work with healthcare coverage providers and clinician communities to ensure ultimately what we have in therapies that get to patients as fast as they can and lead to better outcomes. A little bit about why biosimilars are important for the type 1 diabetes community. Insulin transition to being regulated as a biologic which means it a similar pathway is available for products. And in establishing that I listed here and I know there was much more that happened in terms of establishment of the pathway, but these are the areas in which we participated in public meetings and provided input. Our thanks to the FDA for from our perspective a very smooth and seamless transition and posting a public meeting in particular around insulin biosimilars and the patient community being brought to that forum to discuss the considerations that the patients would have in terms of biosimilar insulin. We don't have it today but they are coming, and with therapy of insulin which has such a narrow therapeutic index, we want to make sure that patients and providers understand options that they may have and the choices that they have moving forward. In terms of some thoughts for this round of the BsUFA process, we would encourage the FDA to continue to provide clarity and understanding around the biosimilar approval process and in particular around interchangeability requirements. We also encourage the FDA to consider the patient perspective and role and what it will be as it relates to bio similarity in interchangeable products. And as you heard from others here this morning as well, the continuation of clinician and patient education we feel is still going to be very important in garnering community alignment around what the key scientific points will be that will convey reliability of biosimilars. And how the patient community and organizations like JD RF can support educational efforts with providers and patients. While we don't have biosimilar insulins available today, when those options are here it's not something traditionally our community and patients would type 1 diabetes are used to seeing. In terms of ensuring there is education for continued safe use and to avoid potential medication errors in working with the community and stakeholders in the process we think will be incredibly important moving forward. Another aspect to consider and to think about is the application of real-world evidence and how that data or information in a postmarketing setting might be related to biosimilars and what information they can provide is more and more biosimilars come to the market and how it can continue to help inform and educate patients with those conditions and as always we would like to continue to see efforts that continue to improve hiring and retention of much-needed FDA review staff to continue to make these therapies available to our communities. With that, I thank you for the time today.

Maria Barhams Sagoua:
Thank you. Now we will move on to a session on healthcare professional perspectives. Our three speakers in this session are Angus Worthing for the American College of Rheumatology , Bhavesh Shah from the Boston Medical Center health system, and Lisa from -- we will break following the session and Angus as our first speaker you may begin.

Angus Worthing:

That's great. Thank you. As was said I'm Angus Worthing and a rheumatologist in here in the Washington D.C. area at arthritis and rheumatism associate private practice and also today representing American College of Rheumatology is a member of the Board of Directors and appreciate being welcomed back to this meeting and this is my third public meeting on biosimilars with BsUFA.

Pardon the interruption, Maria again, we can't see your video. If you wouldn't mind starting your WebCam. The second button. Thank you. Hello, everybody. I make at least one mistake with every audiovisual call so thank you for that. I wanted to mention I have no financial disclosures. Rheumatology, our perspective on biosimilars is mainly right now at the current time based on the two families of drugs that we have to treat for these things pictured here, the joints and spine with our [Indiscernible] family of biosimilars, rheumatoid arthritis and psoriatic arthritis and then also rituximab biosimilar family for vasculitis. Today we are representing people, mainly 6000 rheumatologists and a total in the ACR Association for rheumatology professionals of about 10,000 in the United States who are coming at this from the basic and clinical research standpoint, but mainly the majority of us as clinical prescribers and people like myself who are in a clinic that monitor on-site medication administration. Wanted to point out our position statement available at rheumatology.org website. Safe and effective treatment must be available to patients at the lowest possible cost and obviously biosimilars main reason for living is this bullet point and we appreciate the work. Approval decisions need to be driven by science and consider the greater scrutiny on the size and complexity and heterogeneity of biologics and biosimilars. And wanted to mention we are pointing out the importance of human clinical trials in this is mainly to establish homogenous city and especially important as we get into interchangeable biosimilars, so it's important for rheumatologists to know that the patient population has been tested for a biosimilar and future interchangeable molecules have been tested in a patient population for that purpose. BsUFA has been critical for essentially what I mentioned in the position statement to improve the issue of cost in excess. Currently the cost of biologics is debilitating and essentially it's necessary for patients to have adequate coverage, insurance coverage and often patient assistance programs in order to obtain biopharmaceuticals. And biologics and biosimilars provide better access to these life-changing medications because they are less expensive. The ACR supports BsUFA fees that are based on the complexity of the review . And regarding performance goals, we strongly support the goals that allow for prompt and thorough review of biosimilars submissions. So from the ACR perspective, what's going well and what could be better? In the next four years of the program, just a couple of sites on this. Before I close, BsUFA funding has been very successful allowing for a number of biosimilars to be approved and available. 17 approved biosimilars on the market and it has improved the FDA's capacity and manufacturer's ability to provide safe and effective biosimilars so we can get these medications more accessible to patients that need them by lowering costs. Overall rheumatologists have found it to be a very effective program. What could be a little better? A friendly reminder, the prescriber information, the label in biosimilars is extremely valuable. A couple of things we would recommend making more clear within this program on that label is to provide information about whether a medication is biosimilar and whether it is interchangeable or both. We would also suggest that the suffixes be more meaningful or somehow more memorable to eliminate confusion for patients and providers. We recommend that labels and patient inserts provide links since many of us are using access online to biosimilars analytical and clinical trial data. And essentially to make it clear that the data there is from the biosimilar and not the original reference product. I want to thank you again for including the American College of Rheumatology and I will pivot back now exiting and turning it back. Thanks a lot.

Maria Barhams Sagoua:
Thank you so much, Angus. So Bhavesh , you are next and we welcome your comments now.

Bhavesh Shah:
Great. Thank you so much for the opportunity and my name is Bhavesh Shah and I'm the senior director for hematology and oncology program at Boston Medical Center representing Boston Medical Center and heavily involved in adopting biosimilars in our system. I want to support what we are here for today and also shared the challenges in adoption that we face as a system and across the landscape with other providers. I really want to thank you for the opportunity to share this journey for biosimilar adoption and barriers to success. I think a few objectives here in terms of the challenges and economics and how we can improve biosimilar adoption as a system. There's a significant value we know we have, economic value, and also provides access and there is a lot of skill education that needs to happen. As a provider in a health system, we always think about how there is price inflation especially in times of COVID, you are fighting price inflations in every institution and looking at how to cut cost. There is a lot of price inflation without clinical justification and I did this analysis of eight price increases over one year and two drugs are responsible for

over $2 billion in price increase. They look to see if there's any new indications or new evidence to support this and there was no evidence to support this price inflation. Of course, how does that translate to patients? We know there is a significant abandonment rate because of these price increases. Data shows patients without co-pays have a higher abandonment rate. And being in a health system and coming across these types of cases and reading literature, it definitely is real. Where do we fit in compared to other markets? We look at the adoption rate for biosimilars in the U.S. versus Europe and there's significant discordance. I think in the current market with oncology we have seen a significant adoption in biosimilars. As you can see, there is a steep increase with uncommonly -- oncology biosimilars versus non-oncology biosimilars and in the European markets, they have been very aggressive in adoption. I think they also have favorability because they are a single-payer system. I think it tells you a picture about if there's work needing to be done but we are experiencing significant cost savings to the healthcare system because of biosimilars. Obviously I don't have time to go into every single biosimilar adoption challenge we have, but I think I would talk about a few of the challenges we experience. As you can see one biosimilar which has been approved for 4 years now has a competitor which is a reference part which has significant, over 80% market share because there is a lack of care coverage for the biosimilar in the market. So payers can be the biggest [Indiscernible] for adoption of biosimilars. Is a health system, we come across this all the time where we are ready to adopt the biosimilar into practice and find out our local payer markets are not covering the biosimilar. So of course that also has impact on providers who understand the economics of biosimilar, but they see there is a parody in coverage in biosimilars versus reference products and are confused how they should actually be prescribing a biosimilar which they know is a lower-cost option for patients but then the payers covering it at parity, I still feel like there is education that needs to be done around a lot of the bio similarity pathway because I do come across questions about extrapolation of indications where how is it this biosimilar was studied in one indication and extrapolated to seven indications? And there is still controversies around understanding interchangeability and nonmedical space and the definition of it. There is a lot of education that we can do for providers across the systems to support and improve biosimilar adoption. And we know that providers are so busy in the practices and need a lot of support. One of the biggest things I hear from providers is they would love to actually be adopting biosimilars but there is so much work involved in terms of educating the patients and other barriers that they come across with payers. There's a lot of administrative barriers which providers push off to adopting biosimilars. There's a lot of support that they need and need to be able to provide the support. And I think patients are key. Obviously, having understanding of insurance and covering both products, biosimilar versus a biologic, and then not seeing a difference in cost is confusing for a patient. They are thinking my insurances covering it so why should I switch? I think it puts the wrong message for the patients too. We know the way payers usually work is they are measuring PMPM and based on that it drives the cost of the drugs they are using. It drives the PMPM which strives deductibles and premiums that the patients will have.there's a lot of questions from patients about why they are switching and what is the benefit to them, so definitely things we can do around patient advocacy and disease foundation support in educating patients more about the benefits and clinical concerns they may have run biosimilars. One of the other challenges we face as we are adopting biosimilars is you see many institutions have multiple biosimilars, and then there is a lot of off label uses for Biologics which also you will see they are at 50% of conversion because there is some misunderstanding of how will the biosimilar work for off label uses too? That impedes biosimilar adoption where you will see less of an adoption if providers don't understand the implications on other indications that are not FDA approved. I think one of the other big issues that we also see is that some of the manufacturers with biosimilars have approved a skinny label which is a layman's term that means basically it's approved with some indications but not all the indications and here are examples. What is the impact on practice? Of course the providers may feel it's truly not a biosimilar because it doesn't have all of the indications, so some kind of misalignment about the benefits of a biosimilar because of this and we know it's related to patent infringement, where there might be an orphan drug or it's a faster path to get the biosimilar on the market. I think there is education around there that we can do. Interchangeability can be an issue where as I mentioned there is nonmedical switch and interchangeability where in an institutional setting we make these decisions along with the providers in terms of who is going to change to a biosimilar from a reference product and is it clinically appropriate? It's not that the institution is going in and changing every single patient to a biosimilar, but there is a collaboration with provider to make sure it's clinically appropriate. And there is a lot of infrastructure needed to adopt a biosimilar in terms of the I.T. lift, order sets we have to do, the payer coverage analysis, the PMP presentation and if you have a very large system you need buy in across every single specialty, so a huge lift from a system perspective that isn't considered into the process which could be a limitation that we need to support. I think what I want to share is we have been pretty successful having a pharmacist driven model where we are there to support providers and educate the patients and provide a lot of the financial and

efficacy that needs to happen. Also payer advocacy and contracting so all the barriers that providers may experience, we can help overcome a lot of these barriers, but not everyone has a pharmacist on their staff. So basically utilizing resources that you have that can champion the cause in your system. I think finally, one of the biggest accelerators of biosimilar adoption that we have noticed is actually having a process that accelerates it. Instead of going through the PNT committee for each biosimilar, having abbreviated pathway where building biosimilar pipeline intelligence before and then having the experience and engaging in contract negotiations to figure out peer communications which is key, because the payers don't know the health system is looking to adopt a biosimilar, they may be making changes to formulary without knowing that. And also, one thing we have always been successful with is communicating with European providers and getting their perspective, peer to peer connections has helped us adopt biosimilars into our system. I think the last thing is sharing real-world evidence. When TBO was approved, it came through a different pathway, but we have other biosimilars now. I think sharing real-world evidence is something that really helps increase biosimilar adoption, and this was more real-world evidence in the inflammatory field we published where we showed that biosimilar adoption, converting from reference to biosimilar, our experience was the same as what we saw in trials and what we see in Europe. There are no changes in clinical outcomes. There is a significant cost savings to the institution. I think there is definitely benefit of seeing more real-world evidence to help support biosimilar adoption. I think Mike takeaways as we know there are significant numbers of biosimilars and development. That means there's a significant cost savings to the healthcare system and this pathway is really important for the U.S.. I think we still have to do a lot to actually create educational activities, create more real-world evidence to realize this major cost savings in the healthcare system. And that is the end of this presentation for me. Thank you for the opportunity to do this.

[The event is on a recess. The session will reconvene at 10:50 AM EST. Captioner on standby.] a recess. The session will reconvene at 10:50 AM EST. Captioner on standby.]

Maria Barhams Sagoua:
All right. Welcome back to our public meeting. As a reminder, if if you experience technical issues during the webcast, type your issue into the technical issues box or email Emily Ewing at FDA.gov and keep in mind you can submit comments to the public docket open until December 19. We encourage everyone to submit their perspective to the public docket for FDA review. You can find a link to the public docket in the announcements box. Before we took our break we were going to hear from Lisa who comes to us from the Oncology Nursing Society. So we will go ahead and allow you to begin your comments. Thank you , Lisa.

Lisa Kennedy Sheldon:
Thank you, Maria. And thank you to the FDA for offering the Oncology Nursing Society to have a contribution to the BsUFA meeting today. As a review, cancer care in the United States, there are approximately 1.8 million new diagnoses anticipated in 2020 despite screening difficulties we have seen during the pandemic. Over 16 million cancer survivors are living in the United States, many living with chronic cancer. Treatment of cancer with biologic drugs is increasing, both because of high effectiveness and lower toxicity profile. We are also seeing shifting sites and modes of cancer care delivery including a shift to home care, oral agents and even different methodologies such as subcu injections for cancer treatment delivery. Changing the sites of care from the original infusion centers and care institutions. Today I will focus on two areas I think are of importance to the biosimilar discussion. One is the changing workforce demographics in oncology care which has developed over time to meet the needs of people with cancer, cancer survivors and even the cancer caregivers. The second is the increase in cost of care and out-of-pocket expenses for patients. The kind of discussions that nurses are often at the bedside or web side with their patients and see the toxicities that evolve because of that and the decrease in cancer treatment and adherence. In the United States, we are very fortunate to have almost 4 million registered nurses. Nursing is the most trusted profession in the United States 18 years in a row. According to the national state boards of nursing survey there are approximately 104,000 nurses to designate their specialty as oncology. And of those, 42,000 are certified in one of the oncology specialties. So a growing specialized area and as we know, unneeded area because of the increasing complexity of cancer care. In addition, there is estimated to be 5200 to 700,000 -- 7000 advanced practice providers and nurse practitioners picking up another 30% to 40% prescribing and reimbursable providers and radiation oncologists in the United States. There are nurse practitioners who have independent prescribing authority in 23 states with the remaining states have some degree of physician supervision. And nurse practitioners frequently prescribed growth factors like fill gas to men hemo total poetic agents like e-book 10 and renew treatments including monoclonal antibodies and I picked out these drugs in particular because they have biosimilars. What nurses do in cancer care delivery

and how it impacts the use of biosimilars in cancer treatment. Nurses spend most time with patients and do a lot of the education regarding different treatments, side effects, testing, survivorship care and administer anti-neoplastic treatments and supervise dosing and adherence of oral agents in this setting. They assess, triage, refer and report adverse events using Medwatch and also are active in using telehealth strategies for decades frankly to assess patient symptoms. Nurses and nurse practitioners serve on cancer committees for accreditation, process development and quality improvement and participate on formulary committees regarding selection of medications. They collaborate with pharmacists on prescribed drugs including interactions and adverse events. They consult with insurers for prior authorization, often an issue depending on the insurer, payer or lack of insurance and selection of medication that is both effective, safe and a patient can afford. They serve a national guidelines committees and develop different clinical pathways, and because of the proximity to the patient, they often hear financial concerns and have to refer people for counseling and supportive services so they can receive their treatment. We all know that the cost of care is growing globally and particularly cancer care. As you can see here, between 2015 and 2020 the cost of cancer care has grown almost 40%. This has led to an issue called financial toxicity which is recognized by many of us in literature and by the National Cancer Institute as a concern in the delivery of cancer treatment. There are lots of factors related to the financial toxicity of cancer care including the type of cancer, different treatments received, some social determinants of health like race, income and issues related to employment or unemployment and having health insurance are not having health insurance. Cancer survivors report higher out-of-pocket expenses that people who have never had cancer with some reporting as much as 20% of their annual income going to medical care. A concerning graph about the cumulative ability of a corpse he after you survive cancer so we are doing a better job treating patients with cancer and increasing the cure and survivorship and length of life and overall survival. If you look at these bars, you can see in dark blue at five years after diagnosis, 40% to 50% of patients have had to file for bankruptcy because of the high cost of treatment or to fill insurance coverage gaps with out-of-pocket expenses because of the loss of income and we don't anticipate it to get better during the current pandemic and unemployment. We are grateful the FDA has a regular policy for biosimilars to abbreviate the licensure pathway and provide more treatment options and potentially lowering the cost of healthcare and drugs through competition. As has been mentioned today we have 28 now FDA approved biosimilars the majority of which are for cancer care and you see the 18 agents in two new agents this year and of note is subcutaneous formulation that now can be given in the home setting. For cancer treatment and not just supportive agents, but the cancer treatment which may change care as well. So what is the oncology society want to say to the FDA regarding the BsUFA III comments? You have heard a lot about why biosimilars have been effective and some of the issues related to patients and organizations, but I would like to bring forward that oncology nurses support safe and effective treatments for people with cancer, and they want to see that reach as many people as possible, but that requires controlling costs and having heard many stories of not being able to afford cancer treatment or discontinuing treatment or not taking it in the way it should, it has great impact on cancer outcomes.
[Captioners transitioning]
Precision oncology. With more than 16 million survivors living in the United States, many with chronic cancer, seeing the rising cost of care over the last five years is alarming but does not project well into the future. We see that the treatment of cancer with biologic threats is increasing and it is highly effective and has a lower side effect profile. The cost of some of these newer drugs is really impeding the ability of patients in society to be able to afford these treatments there are expiring patents on some of the originators which offer opportunities to lower costs with biosimilars. Nurses and nurse practitioners in cancer care are trusted partners for patient and part of the oncology care team and they want to see safe and effective care for people with cancer that patients can afford. Thank you for allowing me the opportunity to share these perspectives.

Maria Barhams Sagoua:
Thank you, Lisa. Our next session is on the regulated industry perspective and we have four speakers in the session and we will begin with Megan Smith who was filling in for Julie Reed with biosimilars forum and we will transition to Cory Wohlbach , Association of special medicine, and then Cartier Esham and Lucy Vereshchagina from the pharmaceutical research and Manufacturers of America. Megan is our first speaker in the session and you may begin.

Meaghan Smith [for Julie Reed]:
I am Meaghan Smith , executive director of the biosimilars forum in my remarks represent the views of our 10 numbers to manufacture and market biosimilar products. The biosimilars forum is a nonprofit organization with a mission to promote biosimilar education and support advancement of policies that will

sustain a robust biosimilar market in the U.S. in order to lower cost. Our goal is to expand access and availability of biosimilars and improve healthcare treatment options. The forum appreciates the opportunity to provide our perspective on the progress FDA and industry have collectively achieved on the BsUFA II commitments and the exciting opportunities we hope to work with FDA on through the next iteration of the BsUFA program. We want to thank the FDA for their work toward meeting the goal laid out in the BsUFA II commitment letter to advance a robust biosimilars program. We appreciate how the COVID-19 work is necessarily taken priority in the last eight or so months I may have created challenges for FDA staff supporting biosimilars as staff were called away on COVID related assignments. Under BsUFA II much progress has been made in implementing a regulatory framework, evidentiary standard, and development programs for biosimilars. For example, FDA has been establishing dedicated staff capacity for key functions such as policy development, issuing guidance on topics listed in the commitment letter and we know there may be other in the pipeline and building publication campaigns around the benefits of biosimilars that reached a wide variety of clinicians, patients, employers, and key stakeholder groups. It is under our hope that under BsUFA III, even under the current challenging circumstances, we can continue to significantly advance biosimilar development and availability for patients. We must continue to advance the efficiency of the regulatory processes and ensure the regulatory guidance addresses key areas that will improve the stability and future growth of the biosimilars markets. Today I want to highlight several such areas for which the biosimilars forum and particularly is interested in working with the FDA to advance into BsUFA III. First we must continue the commitment to enhance the efficiency and utility of meeting and munication between FDA and industry. Active communication with the FDA during application review can heighten efficiency of the 350 1K BLA review process and contribute to higher for cycle approval rates. A transparent, protectable, and consistent review process is critically important to building successful biosimilar development programs. FDA guidance and advice received during development meetings helps biosimilar sponsors avoid studies and analysis that would not support regulatory approval and at the same time approve crucial information to strengthen other global development programs that sponsors will pursue. Increasing opportunities for industry to gain clarity on FDA's expectations about the process can minimize challenges that may emerge in later stages of development. Among the improvements we hope to work on with the FDA are to establish a new or otherwise modify existing pre-or early development meeting to help ensure the development programs are on the right track to start there by avoiding unnecessary delays. We also see value in creating right track -- mechanisms for industry to obtain clarifications advisor comments that occur during FDA sponsor meetings since we often need times to review. [Indiscernible] team. Further, we believe we must continue to work toward aligning the meeting processes or originator Biologics and biosimilars. If structured correctly, we believe modifications to meetings, management, and communication can result in a more efficient use of FDA resources and enhance agency staff productivity. We are committed to working with FDA on these concepts to bring them under BsUFA III. Next, well FDA has published several guidance documents related to biosimilars, industry continues to struggle with a lack of clarity regarding the agency's policy on certain aspects of interchangeability, as well as regulatory expectations for certain postapproval changes for biosimilar or interchangeable products. For example, the FDA has issued several biosimilar guidances that have explicitly excluded interchangeable Biologics. We appreciate that these exclusions may have been necessary at that time because the interchangeable guidance had not yet been issued. However, it is now an appropriate time to fill in these gaps. With respect to postapproval changes, in FDA's every 2020 guidance, the agency proposed to review supplements to a licensed 350 1K BLA within a eczema time period in separate guidance the agency addresses review time frames for safety and it would be helpful if FDA would take another look at the timeline in these guidances as we recommend the timelines be determined by the specific type of postapproval change. Additionally, as FDA stated in its biosimilars action plan, scientific and regulatory clarity is critical for biosimilars development. In the past decade, since the biosimilar pathway was established in the U.S., we have gained significant experience with biosimilars in the U.S. and elsewhere. Building on this knowledge, we want to work towards creating more streamlined processes and have guidance that keeps pace with regulatory science and provides patient, timely access to products. As we move into the third iteration of BsUFA, the form believes it is an appropriate time to establish a more streamlined and collaborative platform to examine scientific issues that could inform future changes to the program. We are hopeful to work with FDA to develop a regulatory science initiative that will capitalize on the current science on biosimilars and help advance public health by providing access to safe and effective biosimilar products. Last, in light of the postponement of most foreign inspections due to COVID-19, the form believes it would be important to discuss a more active implementation is a mutual recognition agreement with the EU for preapproval inspections. In this way we hope to alleviate any delays and work towards continued provision of affordable, lifesaving, biosimilar products to patients despite the challenges imposed by the COVID-19 pandemic. Again, thank you for the

opportunity to speak today and provide the perspective of the biosimilars forum. We are committed to working with the agency and other stakeholders to ensure that patients have high-quality, safe, effective, and more affordable medicines.

Maria Barhams Sagoua:
Thank you, Meaghan. Corey, you may begin.

Cory Wohlbach:
I'm speaking on behalf of the Association for accessible medicines, biosimilar counsel. I am grateful for the opportunity to look ahead to what we can achieve in BsUFA III building on many successes of BsUFA II as all of us attended this meeting today can agree, biologic medicines represent one of the great medical breakthroughs of our time, creating cancer, rheumatoid arthritis, Crohn's disease, and other previously untreated or poorly treated conditions. Similars hold the promise of making these important medicines more accessible to patients. Through science that is powerful, that is used to develop the reference product, biosimilar sponsors are able to bring products forward for FDA review that have no clinically meaningful differences in safety, purity, or potency, compared to the originator Biologics area biosimilars are projected save America tens of billions of dollars over the next decade, but only if patients can accept them. Since 2010, FDA has approved 20 biosimilars but only 18 are currently available to patients due to originator patent [Indiscernible]. Greater use of these medicines could generate more savings. The FDA [Indiscernible] created by the BPCII and implemented in BsUFA I and BsUFA II we believe more of these products will beach the market in the years of BsUFA III. When you look across the landscape of the user fee programs there is no question that it is a success. FDA has increased the rate of approval for biosimilars and there is a clear and predictable pathway to market with a substantial body of guidance for an industry as well as developed meeting structure. With that basic foundation in place, the FDA cannot build on its success to bring more biosimilars to market faster by focusing on regulatory science and enhancing, sponsor, communication. In particular, one aspect of the biosimilar program that can be strengthened in BsUFA III is creating more opportunities for biosimilar sponsors and FDA to interact early in the development process without the need for initial analytical data. Under BsUFA III we can create an additional meeting type that would help better inform product development. This could serve to minimize future meeting Wests and step development programs on the right path from the start. Specifically the biosimilars counsel believes an early meeting that occurs even before sponsor has initial analytical data could be useful to discuss early development in order to obtain FDA input on key issues such as clinical endpoints and study design, which are currently not as well supported by the meeting structure under BsUFA II. Industry could benefit from additional regulatory policies around postapproval changes to prepare high-quality amendments and biosimilars counsel believes there are many areas of opportunity to build out better structure around post-market regulatory actions, including postapproval CMC changes in labeling supplements. To add new indications for biosimilars that are licensed for subset of the reference products indication as well as labeling changes made in response with safety updates by the reference products sponsor. The Council also encourages FDA to consider whether there is an opportunity in BsUFA III to create a more formal regulatory science program for biosimilar products. Similar to the regulatory science program for generic drugs that are supported by good effect. In such a program they would consult with industry to create an annual list of initiatives the goal of these studies would be to help advance public health by further optimizing biosimilar development leading to more efficient programs and more effective first review cycles for biosimilars with overarching goal of increasing Actis to safe and effective biosimilar products. There could also be a research program or collaboration with external partners through grantmaking. We also hope that FDA will consider the regulatory environment in which we all operate with putting together the BsUFA III letter. Biosimilars are rarely developed for the U.S. market alone and this means that the global programs must take into account requirements for multiple regions to be successful. There has been a lot of press lately about the decision to tailor clinical science for biosimilar products authorized for marketing in the UK. Similar proposals have been developed developed and advocated by regulators. We believe there is an opportunity for global development programs for biosimilars with a clearly understood mechanism of action, a thorough analytical characterization and human pharmacokinetic and [Indiscernible] data without routinely requiring clinical efficacy studies. As the science around biosimilar and changeable products advances, health authorities must take into account the relevant of clinical studies to determine the overall safety and effectiveness of these products. Finally I would be remiss if I did not mention interchangeability in my remarks today. While we have not yet seen an exchangeable product like under BsUFA II, we would very likely see wondering the five years encompassed by BsUFA III. For company seeking interchangeability approval for their biosimilars, clear guidance on remaining issues will significantly

facilitate development and regulatory review leading to increased patient access and valuable therapies. Thanks again for your time today and I look forward to answering any questions.

Maria Barhams Sagoua:
Thank you for your comments and we will transition to Carter to begin her comments during the section.

Cartier Esham:
Thank you so much for allowing me to give this presentation today. I am Cartier Esham Executive Vice President of the emerging companies section and senior vice president of science and regulatory affairs at about technology innovation organization for bio. It is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the U.S. and more than 30 other nations. Our membership includes most of the large biosimilar pharmaceutical companies but the vast majority are pre-revenue small biotechnology companies. All are working to deliver the next generation of biomedical breakthroughs to improve the quality of patient care and find treatments for diseases where there are currently no therapeutic options. As Cory and Meaghan have highlighted bio is very supportive of the timely reauthorization of BsUFA. We recognize that the program is critical to promoting competition in the Biologics and biosimilar marketplace and in that same vein, BIO and its members support advancing policies to promote innovation and competition. We strongly support ensuring FDA has the resources and expertise needed to support timely and scientifically-based development and review processes for biosimilars. BIO believes that BsUFA can build off of the success of BsUFA I and BsUFA II which provided imported funding, hiring, and meeting management reforms. We will improve the efficiency of the program to better benefit patients and programs. Some of BIO's priorities for BsUFA III will build on the foundation established in BsUFA I of BsUFA II and we are committed to a patient-centered program. BIO believes that the reauthorization of BsUFA should strive to make targeted [Indiscernible] support product development, enhance the scientific dialogue between FDA and sponsors, and ensure hiring resource management accountability and provide modern data technology infrastructure at the FDA. In BsUFA II FDA committed to ensuring the effectiveness of the biosimilar dialogical product review program. BsUFA III offers an opportunity to develop an even more efficient and effective review and approval of biosimilars. We look forward to finding clarity around review timelines for sponsors prior approval supplements. In BsUFA III FDA committed to publishing draft guidance describing guidances [Indiscernible] biosimilar products. The current draft guidance provides information on the nature and type of information that a biosimilar sponsor should provide to support a postapproval manufacturing change for a license biosimilar project. There are opportunities to further clarify reporting categories for postapproval changes in chemistry manufacturing and controls. We have the continued goal of ensuring productive and effective communications as it is a cornerstone for advancing modern approaches to biosimilar development and the review processes. We continue to be committed to enabling early and effective engagement opportunities between sponsors and the FDA which is critical to ensuring the effectiveness and rigor of the biosimilar development program. BsUFA III provides the opportunity to continue to enable dialogue between sponsors in the FDA and processes that are iterative and effective. Specific considerations may include analyzing and establishing processes and best practices to improve efficiency and effectiveness of FDA-sponsor meetings. Establishing a Spencer -- mechanism for sponsors to receive more timely feedback to ensure clarity and improve efficiency. In closing I want to thank the FDA for the opportunity to give this presentation today on behalf of BIO and member companies and as it was previously stated BsUFA III can really help ensure the timely and science-based review of biosimilars which is critical to promoting innovation and competition in the Biologics and biosimilars marketplace. We look forward to working with FDA and other key state others to ensure a timely reauthorization of BsUFA III achieves these goals and maintains the high standards of the review program. Thank you very much.

Maria Barhams Sagoua:
Thank you, Cartier. We will conclude this section with Lucy. You may begin your comments now.

Lucy Vereshchagina:
Thank you. Good morning everyone. My main ebbs Lucy Vereshchagina. I am the vice president of science and regulatory advocacy. [Indiscernible] trade association [Indiscernible] biopharmaceutical research companies which are devoted to discovering and developing medicines that enable patients to live longer and more productive lives. [Indiscernible] companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone. Membership includes many pharmaceutical companies actively developing biosimilar [Indiscernible] and we appreciate the opportunity

to participate in today's public stakeholder meeting. [Indiscernible] is America's health care [Indiscernible] increasingly critical role in bringing new options to patients and decreasing prescription drug spending. [Indiscernible] projected by seniors would reduce planting of Biologics by 25 to $150 billion over the next 10 years. [Indiscernible] safe and approval biosimilars regulatory paradigm supports patients at a time review process and provides specific and regulatory sponsors. That is why PhMRA supports a strong fast and science based FDA [Indiscernible] appropriated funds and use fees from the regulated industries. [Indiscernible] has played a role [Indiscernible] for biosimilar products that supports innovation and is consistent with the agency standards for her and patient safety. PhMRA has been a strong supporter of -- 2012 as other speakers, BsUFA was provided to support the biosimilar approval pathway and promote greater consistency and flexibility with our products. BsUFA II was informed by [Indiscernible] and included an initiative [Indiscernible] promote more informative engagement in the FDA biosimilar [Indiscernible] and help ensure the long-term sustainability of BsUFA. BsUFA III offers an opportunity for stakeholders to work together to build on the successes of the first two cycles by strengthening foundational elements and enhancing regulatory review processes to provide increased efficient the instability to the program. In addition to BsUFA's specific enhancements there is an opportunity to support the approach to [Indiscernible] underpinning of human [Indiscernible] program. BsUFA users help ensure [Indiscernible] support the review and licensure [Indiscernible] high standards for biosimilars with regards to similarities as well as safety, purity, and potency, and helps facilitate future growth in the marketplace of biosimilar and interchangeable products. [Indiscernible] key variable such as including establishing independent structure, development [Indiscernible] function [Indiscernible] reporting. [Indiscernible] implementation and maturation of these improvements should continue in BsUFA III to support [Indiscernible] fronting levels and [Indiscernible] performance needs of the agency. BsUFA III, the FDA can adopt improvements to process reporting hiring, recruitment, and retention of staff and key experts to help ensure the agency has a strong workforce to advance its public health mission. FDA centralized administrative services, including its [Indiscernible] infrastructure helped enable all of the [Indiscernible] crucial functions supported by the multiple medical products user fee programs. Whether or not [Indiscernible] enhancing capabilities can help the agencies advanced [Indiscernible] to improve regulatory review processes such as the integration of [Indiscernible]. BsUFA III can help support the coordinated approach to enterprise-wide initiatives to build on efforts such as the action plan and lamenting [Indiscernible] modernization framework and strategy. While BsUFA II and BsUFA II BsUFA I laid the foundation for the biosimilar review process, select enhancements could further support biosimilar product development, and improve review efficiency by providing sponsors with more complete guidance related to interchangeable products. In addition, BsUFA III can further support patient safety by establishing review timelines and labeling updates so [Indiscernible] interchangeable products have a timely and transparent process for ensuring the applicable safety information [Indiscernible] matches that of the reference product. In summary, BsUFA III will help ensure the resources and structure to support science-based review by similar and interchangeable products which will help increase competition in the marketplace for the benefit of patients and healthcare system. PhMRA looks forward to working with the FDA and other stakeholders to enhance the existing program and make improvements where appropriate in BsUFA III. In conclusion, the timely reauthorization of the BsUFA program is important to maintain a high level of the biosimilar review program performance, while enhancing the verdict ability regulatory review framework needed to support future biosimilar investments. PhMRA supports the timely and efficient reauthorization process and expeditious approval by Congress to ensure there are no disruptions at any stages. Thank you.

Maria Barhams Sagoua:
Thank you. That concludes our session on regulated industry perspectives. Our final session is on scientific and academic expert perspectives. We will hear from Immaculata Hernandez from the University of Pittsburgh of pharmacy. We welcome your comments.

Inmaculada Hernandez:
My good morning and thank you for inviting me to participate in this important discussion. [Indiscernible] I think I will break the norm and not have the slides. I'm assistant professor at the University and I do research on pharmaceutical policy and I spent some time exploring [Indiscernible] and also the [Indiscernible] Biologics versus biosimilars. I want to provide some background on the focus of biosimilars [Indiscernible] in the U.S. [Indiscernible] regions [indiscernible - low volume]. As most of you know [Indiscernible] 40% [Indiscernible] and most of the increase [Indiscernible] are expected to continue to be the main drivers because most approvals and products [Indiscernible] biosimilars whole -- access to these important drugs. However [Indiscernible] has been minor today at least when we compare it to what we see

in Europe. In Europe as of 2020 [Indiscernible] approved for 16 reference unique [Indiscernible] and they have an important update. For example as of January 2020 FDA 70% of the market and 83%. Biosimilars have led to [Indiscernible] price reductions , 20 to 30% in one year in some cases [Indiscernible] have resulted in very significant savings for national healthcare systems. In comparison as you know, [Indiscernible] approved in the U.S. out of which 15 are marketed and those that are marketed have configurable market shares. Princeton biosimilars [Indiscernible] capture around 15 [Indiscernible] 29% of the U.S. market compared to 71 and 83% in Europe. I think that in order to have a [Indiscernible] biosimilars in the U.S. we need two things. The first is to have 25 biosimilars approved and the second is to have a structure that creates incentives for the use of biosimilars. The first condition subject to the FDA [Indiscernible] but the second is not and it's important knowledge here [Indiscernible] . I think this point is important [Indiscernible] biosimilars the scientific community somehow felt that the [Indiscernible] as opposed to [Indiscernible] delay the publication of guidance and I think now it is clear that the main [Indiscernible] widespread adoption in the U.S. is not related to regulatory approval but rather the structure [Indiscernible] . Unfortunately [Indiscernible] officials [Indiscernible] they could try to bring this [Indiscernible]. Having said that, I will argue that in order to remain only on the financial side or the reimbursement side we still need to have timely reviews of applications that ensure biosimilars are approved in a timely manner and I think [Indiscernible] have demonstrated it works well. Biosimilar use of [Indiscernible] provide resources for the review [Indiscernible] applications in a timely manner and I represent communities or unfortunately I do not have the specific feedback for performance revolt you goals and I understand the feedback is really important and in my job I do not have directions in this regard but again, I think it is very important [Indiscernible] have to say. In addition to supporting the review of biosimilars, biosimilar use of fee and has included funding for [Indiscernible] public outreach and I think this funding is important to be maintained because [Indiscernible] biosimilars continue to be key for their adoption. The first authorization of the biosimilar fee act did not include [Indiscernible] support such activities as was discussed earlier today and I think this is a major recommendation today. There is [Indiscernible] inclusion of research and the use of the accident think it is particularly important with biosimilars because it is a very narrow pathway and we don't have much [Indiscernible] approval for the U.S. [Indiscernible] included it would be very important to have a process that ensures there is a fair application for research funds and that this leads to the innovation of high-quality research products. I am thinking that biosimilar sponsors should come together in [Indiscernible] funding with these user fees. The FDA should probably [Indiscernible] applications the target [Captioner cannot get audio--unclear] sponsors and the FDA. Research applications would be reviewed and transparent for [Indiscernible] process similar to NIH context. Awarded institutions should be held accountable for producing [Indiscernible] frameworks. I think this process will be important in generating high-quality [Indiscernible] biosimilar pathways approval and [indiscernible - low volume]. Given that we [Indiscernible] many of these issues I think this research would be major contributions to the uptake of similars in the U.S. In closing biosimilar use [Indiscernible] applications in a timely and predictable matter and my solution for the implantation [Indiscernible] inclusion of a budget that supports high-quality research on the process and [Indiscernible] biosimilars. I think that this research would generate matching and domestic evidence that would support the adoption of biosimilars and hopefully the creation of a viable marketplace. Thank you for having me.

Maria Barhams Sagoua:
Thank you, Inma. We will now wrap up the panel presentation with remarks from Sarah Yim , director of FDA's therapeutics and Biologics similars.

Sarah Yim:
Again, I want to thank everyone who attended the meeting and provided input today. This is been very valuable so I'm going to take a few minutes to summarize the input that we have received so far starting with panel one, the consumer and patient perspectives, Monica Mallampalli from healthy women noted that women are important consumers or potential consumers of biosimilars and yet the vast majority of them have not taken biosimilars, have not discussed biosimilars and have a lot of information and education gaps that need to be addressed. She also noted that healthcare providers continue to need additional education on biosimilars and encouraged FDA to continue to support these activities. She also noted that increasing confidence on the safety and efficacy of biosimilars would be via these educational initiatives and it would be important for FDA to partner with external groups patient and healthcare provider groups like healthy women and she also mentioned needing clarity clinical data on biosimilars as part of the efficient review process and specifically safety and efficacy data which are analyzed and reported by [Indiscernible]. I think you can find that in the biosimilar reviews, by the way. Realizing people have to dig around for that. Then

Anna hide from the arthritis foundation also noted that there is communication bias, fear of new armillary barriers, the arthritis foundation is doing a lot to try to help address these barriers and we need to continue to work on improving patient trust in the safety and efficacy and physician confidence in biosimilars. Maybe work on fostering peer-to-peer opportunities to help patients and providers learn from each other, being clearer with our language and maybe not quite using so much regulatory speak. Providing more information on what data is available for biosimilars like from real-world experience. She also noted that the FDA should continue to partner with patient and provider communities and groups. And then it Marjana Marinac from JDRS noted biosimilars and type with diabetes that the majority of type I diabetics are not meeting their letter a 1 C targets and the importance of insulin and the fact that insulin was regulated as a biologic in March of 2020 and how that will hopefully bring additional biosimilars and interchangeable insulins as noted in the main 2019 [Indiscernible] meeting. JDRF place additional clarity and understanding is needed on interchangeability requirements and what that means and so also involving patient and provider communities and the efforts of continuing education and outreach efforts and also considering application of real-world evidence and how that can help inform and educate people. Panel to started off with Angus Worthing from the American College of rheumatology and the ACR has a published position statement on biosimilars, which encourages biosimilar use and that decision should be driven by science and there should be great scrutiny and regular rigorous analysis on the available data and include studies to assess [Indiscernible] especially for interchangeable's. The ACR sports fees based on complexity of review and performance goals that allow for prompt and thorough review and they believe that BsUFA allows for this and they would also like to see additional information and labeling that sort of improves the clarity and transparency of labeling and whether a product is a biosimilar or an interchangeable or both. He also thinks that we should try to make efforts to make the biosimilars data more obviously available for the public. And then Bhavesh Shah from Boston health system noted there was a great economic reason for biosimilar development, that there's increasing abandonment as cost exposure to Biologics increases. He noted the challenges with biosimilar adoptions within health systems, lack of a coverage is a significant barrier, provider buy-in is difficult to achieve with the economics and the continuing confusion about various biosimilar-related topics, and so we need to continue with our education efforts and also educating pairs regarding biosimilar product -- topics, especially interchangeability, but also things like partial or skinny labels. He noted how big of a lift it is to ensure smooth biosimilar adoption and pharmacists can help, so the agency should maybe consider partnering with pharmacists and helping to facilitate real-world evidence and then Lisa Kennedy Shelton noted that the increasing role of nurses, nurse practitioners and physician assistants as prescribers, members of cancer committees, formulary committees and national guideline development, and their acute awareness of the financial toxicity of cancer care, and that this is a significant burden for patients and biosimilars are an important part of the solution to that. In panel three from regulated industry we had Meaghan Smith from the biosimilars forum who noted that BsUFA has been a success so far and we do need to continue to advance efficiency of regulatory processes and guidance, enhance the efficiency and utility of meetings and communications between FDA and applicants, have a transparent and predictable and consistent review process, increase opportunities for industry to gain clarification on communications during review meetings, perhaps new early development meetings or new mechanisms for clarification and aligning the biosimilar meetings with the BsUFA related meetings of the innovators and they also suggested there is a real need for more clarity on interchangeability and postapproval changes. Also review timelines for supplements and updates for safety labeling and regulatory science initiatives, as well as more active mentation of mutual recognition agreements with the EU with respect to inspections. And then Cory Wohlbach from AAM, Association for accessible medicines, supports what was said by Meaghan in terms of thinking that BsUFA III could provide an opportunity for regulatory science and enhance sponsor communications, as well as more global alignment and clarity on interchangeability. Similarly, Maria Barhams Sagoua from BIO supported timely reauthorization of BsUFA , thought that we could make some improvements with respect to review timelines and prior approval supplements and clarifying categories for postapproval supplements and increasing FDA and sponsor interaction as well as hiring and resource management accountability and data technology infrastructure modernization. Lucy Vereshchagina from PhMRA also reiterated any of the same points that our other industry colleagues mentioned and supporting BsUFA but having an additional, finding additional opportunities in BsUFA III to improve the transparency of the program, communication, and done clarity regarding interchangeability and maybe establishing review timelines for biosimilar labeling updates and then finally Inmaculada Hernandez from the University of Pittsburg school of pharmacy noted that we are still behind in the U.S. compared to Europe and Europe is having more price reductions and savings for their healthcare systems so it should be motivation for us. She suggested that user fees do appear to help the timely review and approval of biosimilars but it would be important for us to continue to -- continue our education and outreach efforts and support a regulatory science program perhaps to address

research needs and information gaps that will facilitate uptake. And that is my summary from the previous speakers. I will turn it back over to Maria for the next segment of public comment.

Maria Barhams Sagoua:
Thank you, Sarah. Now we will move on to public comment and before this meeting FDA invited everyone who registered for this meeting before November fifth to respond to a survey indicating that they would like to provide public comment at the meeting and today we have for people who will provide comments and I would invite them to speak one by one. First we have David Balto from the coalition to protect patient choice.

David Balto:
Thank you so much and thank you for inviting me to speak. I am David Balto, public antitrust lawyer and in the Clinton administration I was policy director of the Federal Trade Commission and I was instrumental in starting the FTC's pharmaceutical enforcement program. I represent the coalition to protect patient choice but many other unions customer groups have great concerns about biosimilar competition, most recently in the investigation of the [Indiscernible] merger and these groups include public citizens, FDA you ask me and others, they're largely concerned that biosimilars offer tremendous promise but it is a promise that just is not been met in the current marketplace and I think we have some attention to that and some of the earlier speakers. That is because of the lack of attention to competition issues and I'm going to talk about one competition issue in particular here today and that is the issue of rebate -- again many people [Indiscernible] springtime, the biosimilars have offered great savings and tremendous savings that have been missed. If Americans could buy FDA approved biosimilars in the [Indiscernible] they could've saved over 9 billion dollars, just a small share of which are actually sharing. I'm here to talk about rebate woes, [Indiscernible] manufacturers use to keep rival biosimilars off the market and the two drugs, they were identified by Dr. Shaw in his presentation and that accounts for 80% of the price increases. And those are two drugs in which rebates are currently being used and when we look at what goes on in Europe with those drugs we see a significant price decrease, not increase, and that is because of the availability of the biosimilars, and those price decreases not only cost consumers more the cost payers more but they mean that these drugs are less available and the promise of biosimilars are not being achieved. What is a rebate wall? This was described in our earlier comments and other things you will see we have a whole page on our coalition website that deals with rebate walls and we made walls that were dominant manufacturing [Indiscernible] says to a your or insurance company, if you want rebates on this one therapeutic category you have got to restrict competition in these other therapeutic categories, basically leveraging their market power from one therapeutic category to another category [Indiscernible] rebate walls he argued for [Indiscernible] stop branded drug companies from using rebates to squelch competition from biosimilars. If there is one situation where rebates are anticompetitive it is when they are used to block competition from a lower-cost biosimilar generic drug. Let's have some perspective of when we are talking about rebates. We are not talking about discounts to consumers. One of the important things about the administration's efforts to go and regulate rebates was the recognition that rebates don't necessarily benefit consumers. They end up in the pockets of the insurance companies and they don't really lower drug costs and that is why the administration sought to eliminate the kickback harbor in an effort that many consumers and unions supported. So what is the solution here to help improve rebate competition? I'm sorry, biosimilar competition. By the way I should mention one thing we talked about the effect of rebate walls often times rebate walls don't completely exclude a drug but require that the competitive drug go through a complex set of patients, the competitive drug goes through a complex step therapy program. Those step therapy programs are particularly difficult for consumers when you deal with the kinds of illnesses that they have to, that they need biosimilars with. That is why [Indiscernible] doctors decided that contractors use rebate walls and traps, [Indiscernible] competition, increase costs, and decrease patient access to wider and more effective range of treatments. These step therapy programs force consumers to use a less efficacious drug and go through a painful process before they can go to the drug that is really more efficacious. Either way, when we are talking about a loss of competition, something important to keep in mind. We're not only talking about consumers and payers paying higher prices, we are also talking about they are not receiving the most efficacious drug. Having to suffer through a drug that is less efficacious and both the Remicade and the Humira situation, drugs that are more efficacious, better for consumers, that they have kept off the market. One solution here in a written comments we will come up with three solutions. The experience is the FDA and FTC must intensify their coordination and a lot of things have been accomplished through FDC and FDA coordination in the past and Commissioner Godley has talked about the need for the FDA to work closely on identifying anticompetitive practices. Second, there should be a stronger coordination and a formal process to allay competition concerns, access and coverage

concerns, from the FDA throughout the FTC and the [Indiscernible] the FDA should collaborate with the FTC and CMF to improve each agency's understanding of how rebate walls affect the availability of biosimilars, especially in the Medicare part D program where the government is effectively paying much greater amount because of these rebate walls. Thirdly, it would suggest that the FTC and FDA and CMF hold another joint workshop focusing specifically on these access issues. Caused by rebate walls. Documenting the lack of access consumers have, bringing in many stakeholders, and demonstrating and providing greater attention to both lower-cost medication and more effective medication that is being kept off the market. We applaud with the FDA is doing on biosimilars and we hope it can work with these other agencies to pay greater attention to the anticompetitive effect of rebate walls and how they harm both payers and consumers. Thank you very much.

Maria Barhams Sagoua:
Thank you, David. Our next speaker is Sundar Ramanan from Biocon Biologics. Please feel free to unmute yourself.

Sundar Ramanan:
Good morning. My name is Sundar Ramanan, [indiscernible - low volume]. The basic premise in the practice of medicine is [Indiscernible] needless to say we continue to accumulate [Indiscernible] safety, efficacy, [Indiscernible] American patients and it is time to consider [Indiscernible] regulatory processes. [Captioner cannot get audio--unclear] regulatory process enhancing therapy frameworks, expectation via guidance, timelines and communications. Sends BsUFA I absolutely BsUFA II the agency has evolved regular processes enhancing the clarity and regulatory framework expectations via guidance as well as the timelines and medications and we applaud the agency for evolving requirements with emerging evidence and in BsUFA III requesting agency to further evolve regulatory framework based on ongoing cumulative evidence and consider the following recommendations which could further facilitate efficiency to regulatory processes. Our first comment is on the review timelines. Specifically currently they are fixed regardless of quantity of data being reviewed or B the reference product and lack of biosimilars.
[Captioners transitioning]
The review board is likely to be substantially lower than for a product every safety. Therefore, we request the agency to consider the differences in the review board and timelines. I.e., create an adaptive timeline as opposed to the current fixed timeline, more specifically lower timeline. Second, not all originator Biologics have biosimilars. They have demonstrated value to the society, and it's important to broaden the value back to society and eliminate the inefficiencies. To spur further competition, we request the agency with a lower review time, much like in the accelerator review process for drugs, and there is -- our second comment is on the incremental evidence required for interchangeability. For every originator antibody for which biosimilars have been approved, specifically in the U.S., there have been four biosimilars each, approximately, for one product in the U.S. and in the you. With the robust evidence on lack of safety, not only between the reference product in the bio similar but between biosimilars, we urge the agency to take this scientific and clinical evidence into consideration for the need for an incremental clinical evidence as is currently required for biosimilars. Our last comment is on naming. We urge the agency to look at the need for suffix. During the early days of biosimilars, a private based systems and electronic systems are present. With mainly electronic systems nowadays, there are adequate safety for track and trace for safety and pharmacologic services. We asked them to reconsider the need for something in the naming and nomenclature. Thank you for the opportunity to present today, and back to you.

Maria Barhams Sagoua:
Thank you, Sundar . Next is Arlene Wally from Sandoz. Arlene, you may begin. Arlene, you may need to unmute your phone for us to hear you.

Arlene Wolny:
Okay. Thank you. Hello. My name is Arlene Wolny, and I work at Sandoz, and I would like to thank you for the opportunity to speak on the BsUFA II meeting . BsUFA II is a step toward affordable healthcare, as Biologics are the fastest-growing class of medicines and are a substantial portion of healthcare costs today. Although the BsUFA program with Sandoz would like to highlight four areas were further enhancements of the potential to further optimize drug element for efficient and effective review cycles. These are meetings, foreign expansions, interchangeability and regulatory science initiatives. The first consideration is meetings and submission enhancements. This could allow industry time to refine and substantiate development strategies, thereby providing efficiencies for everyone. At first, to allow biosimilar initial advisory meetings

to occur without the requirement of technical data. These meetings provide invaluable advice for early product development and feasibility. They allow for refinement of global development plans, creating value in future interactions with the FDA. However, extensive technical data is required for these meetings. When one considers the complexity of manufacturing processes to create a biosimilar, requiring significant development permutations and clinical trial timelines that require long lead times often after a year when one considers operational initiatives, health authority approvals for trials conducted worldwide. Early advice to discuss clinical trial design, PK safety before technical data could provide additional time for development and input from other regions. Second, along with the other procedural goals, specifically the -- needing that at the ready as part of the meeting leads to length and development timelines. For pre-submission meetings, everyone must be done in sequence rather than in a parallel approach. Responses are able to discuss without the book and had more time to generate further data and refine development strategies. Third is the importance of our timely meeting minutes, as companies are often waiting for final confirmation before pulling the trigger on critical next steps in manufacturing. Protocols or other development activities. Finally, although not related to meetings or FDA information requests, responding to information requests requires personnel from programming, clinical and other areas to be at the ready. If there was a way that FDA could indicate that further information is not needed at this time would be so helpful to companies. Second consideration is inspection enhancements. Can we consider ways to optimize resources, deal with COVID-19 and reduce waste? It is well-established that biosimilars provide access to life-saving or life altering medications, but how can we best ensure that there is timely foreign expections? Although preapproval inspections are different than other agents, can we utilize existing agreements? Possibly utilizing trusted agencies for foreign expections, utilizing mutual recognition agreements or perhaps virtual inspections. Is it possible to harmonize preapproval inspection dates or a window with other health authorities for the following reasons? Biosimilars need to be in production at the time of inspection. Many manufacturing plants produce more than one product with back-to-back productions, making it difficult for inspections. Therefore, multiple agency inspections at different time points occupy the valuable production time for other life-saving products. Finally, please consider that an approval does not translate to an immediate lunch due to patent complexity. A launch could be years later. Would PMR be an option? The third consideration that I would like to talk about is interchangeability enhancements. Closing the gap of understanding regulatory requirements is essential to reduce development risks for our products. Interchangeable Biologics have been carved out of several biosimilar guidances. Certainty is needed to encourage development of future interchangeable Biologics. Better understanding of FDA requirements to specific interchangeable guidances will lead to higher quality books and meeting interactions for intended interchangeable products, global development plans ultimately submissions that make those FDA requirements. Specific interchangeable guidances that are needed are included are promotional and advertising, labeling, product presentations and categories of postapproval process changes. The final consideration is regulatory science initiatives. The collaboration on scientific issues related to biosimilar development. Can we build on the successful regulatory science initiatives in PdUFA ? It provides topics of mutual interest to FDA and industry and has a potential to advance development and use of biosimilars in the U.S. They build trust for the quality and rigor of biosimilar evaluation approvals. Build the patient and prescriber confidence of the benefit of biosimilars. I would like to thank the FDA for the opportunity to share these perspectives. Thank you.

Maria Barhams Sagoua:
Thank you, Arlene. Unfortunately, Ajay Singh wasn't able to join us today . I think our public comments section, thank you to all. The public docket to provide written comments is open until December 19th. If you would like to provide a comment, please do so via the public docket link in the announcement box. That concludes our meeting for today thank you to all the speakers who took the time to share comments with us. Thank you to everyone who logged in to listen to this meeting today and we hope you enjoy the rest of your day. Thank you.