Transcript for Public Workshop - Medical Device User Fee Program Public Meeting, March 28, 2012

UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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MEDICAL DEVICE USER FEE PROGRAM PUBLIC MEETING

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March 28, 2012

9:00 a.m.

Hubert H. Humphrey Building

200 Independence Avenue, S.W.

Washington , DC 20201

PRESENT:

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KAREN MIDTHUN, M.D.

Director, Center for Biologics Evaluation and Research (CBER)

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Diana Zuckerman, Ph.D.

Eric Gascho

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Peter Beckerman, J.D.

M E E T I N G

(9:00 a.m.)

MR. BECKERMAN: Good morning. Welcome to this public meeting on the reauthorization of the Medical Device User Fee Act, which you, I assume, know as MDUFA. Thank you for joining us today. I'm Peter Beckerman. I'm a Senior Policy Advisor in FDA's Office Of Policy in the Office of the Commissioner, and I'm going to be your moderator for today.

As I expect you all know, MDUFA authorizes FDA to collect fees from regulated industry to help offset the cost of reviewing applications to market safe and effective medical devices. The current legislative authority for MDUFA, which was reauthorized in 2007 by the FDA Amendments Act, will expire on October 1, 2012.

FDA began the process to reauthorize MDUFA for the coming five-year period by holding a public meeting and opening a public comment period in September of 2010. Following that, FDA began regular concurrent discussions with industry and public stakeholders, including patient advocates, consumer advocates, healthcare professionals, and scientific and academic experts. These discussions lasted from January 2010 [sic] through February of 2012, and after

administration clearance, the package of proposed recommendations that resulted from these discussions was posted on FDA's website on March 15th.

The purpose of today's meeting is to discuss these proposed recommendations and offer the public the opportunity to present views on the recommendations. This meeting is being webcast, and the slide presentation from today will be available on FDA's website in a few days. Additionally, a transcript of this meeting will be posted on FDA's website within a few weeks, when it's been prepared.

The public also has the opportunity to provide written comments to the Agency via the public docket. Instructions on how to submit comments to the public docket can be found at the end of your agenda handout. Those were on the seats when you walked in. The deadline for these submissions is April 16, 2012. FDA will consider all comments promptly, make any edits necessary, and transmit final recommendations for MDUFA III to Congress shortly thereafter.

Now, I'd like to briefly explain the format we're going to use today in order to listen to and take your comments. As you can see from the agenda, we've got ample time to hear what you have to say. We're going to begin with remarks by Dr. Jeff Shuren, the Director of the Center for Devices. Then, we're going to hear from Dr. Karen Midthun, the Director for the Center of Biologics. Following these remarks from the Center directors, Malcolm Bertoni, the Assistant Commissioner for Planning and FDA's Lead Device User Fee negotiator, is going to present an overview and explanation of the proposed recommendations for MDUFA III. We're then going to allow some time for clarifying questions regarding FDA's presentation, but I'm going to ask that any commentary be reserved for the open comment period in the afternoon.

I should note that today's meeting is being webcast. The webcast is in transmission mode only, so questions to FDA on the overview will be from the room only.

The FDA presentation will be followed by a panel of stakeholder representatives and a panel of industry representatives. Each panelist has been asked to provide their comments on the proposed recommendations in 10 minutes or less, and I'm going to do my best to keep to the schedule.

At the end of each panel, FDA may ask clarifying questions of the panelists. After the panels, we're going to proceed to the open public comment session, where I believe four people have currently registered a desire to speak. If you decide you would like to say something during the open public comment period, please let Cindy Garris or another member of the FDA team know, and we're going to add you to the schedule for that session. Cindy, can you identify yourself? Is Cindy in the room? Okay, well, we will point her out to you when she appears. In the meantime, if you are going to present during open public comment, if you would let one of the other FDA representatives know, that would be helpful.

We know that we've got some press attending today's meeting as well. We ask, as we have with the other user fee meetings, that any reporters with questions, please talk to our representative from the press office, that's Karen Riley, who is standing at the back. So rather than using the time allocated for public comment, please address your questions to Karen and she can get you in touch with the right person.

Last, we have one short break planned for the morning. The break will be an opportunity to stretch your legs and use the facilities, which are just on the left outside of the door; you passed them as you came in. You are not able to leave this floor. We don't plan to take a lunch break since the agenda calls for us to adjourn by approximately 1 p.m., and we like to try to stick that schedule. If you need to leave the meeting room at any time, please find somebody from FDA to escort you downstairs. It's important that you keep your wristband on for the entire meeting. The wristband I think gets you access to the public meeting, not the waterslide or the planetarium show.

(Laughter.)

MR. BECKERMAN: But maybe future meetings. Due to security in the building, all visitors have to be escorted when they are not in the meeting area. So with that, I'd like to invite Dr. Shuren to the podium for some introductory remarks and to give CDRH's perspective.

DR. SHUREN: Good morning and welcome. It has now been one and half years since the initial public meeting to kick off the MDUFA III reauthorization process. This has been a long process, certainly longer than we expected it to be, but thanks to the perseverance of all involved, FDA and industry reached a negotiated agreement which the Commissioner and I believe is a win for everyone.

The first user fee program for the review of medical devices was passed in 2002 following the enactment of the Medical Device User Fee and Modernization Act. This was prompted by growing concerns about the medical device review program's capacity and performance. Under MDUFA I, industry paid user fees for the review of marketing applications, and FDA's performance was evaluated in terms of review days per cycle and final decisions. These additional resources enabled FDA to make its reviews more timely, predictable, and transparent to applicants.

The medical device user fee program has produced benefits for public health. A better-resourced premarket device review program has enhanced FDA's ability to help bring more safe and effective medical devices to market, while keeping pace with the increasing complexity of technology and changes in clinical practice.

Since MDUFA II was reauthorized in 2007, FDA has approved 106 original PMAs and cleared more than 13,000 devices under the 510(k) program. However, neither the FDA nor industry believe that the user fee program has reached the level of performance or produced the extent of benefits we all want to see.

Over the past couple of years, CDRH has been working to improve our internal systems. Our goal has been to assure that safety and effectiveness and innovation are complementary, mutually supporting aspects of our mission to protect and promote the public health. Through reaching out to stakeholders and through program assessments, we identified that the number one problem was insufficient predictability in our premarket programs, which can create inefficiencies, increase costs for industry and FDA, and delay bringing safe and effective products to market. Several root causes were identified, including very high reviewer and manager turnover at CDRH, insufficient training for staff and industry, extremely high ratios of employees to front-line supervisors, insufficient oversight by managers, growing workload caused by the increasing complexity and number of devices and the overall number of submissions we review, unnecessary and/or inconsistent data requirements imposed on

device sponsors, insufficient guidance for industry and FDA staff, and submissions from applicants that were not meeting FDA's expectations for completeness and quality.

While it is true that providing more user fee resources alone won't solve the problems with our premarket programs, insufficient funding is at the root of or a contributing factor to several of these problems. Adequate and stable funding is one key component to ours and industry's success in incentivizing device innovation and bringing safe and effective medical devices to market quickly and efficiently. We have numerous ongoing efforts to improve the premarket review programs at CDRH, and we believe that these efforts, in combination with the MDUFA III reauthorization, will have a positive impact on the medical device review program.

The reauthorization process for the MDUFA program has been different than those in the past, as it has included a broader array of stakeholders throughout the process. We began with a public meeting and open public comment period in September 2010, during which we obtained input from stakeholders on what they would like to see in the program. We continued monthly meetings with registered stakeholders, including representatives of patient and consumer groups, throughout the negotiation process, keeping them abreast of negotiations with industry and obtaining their feedback. Minutes of these meetings were made available to the public along with minutes of the discussions we had with representatives of the medical device industry. Some elements of the proposed commitment letter were influenced by the discussion with stakeholders. Those of you who have participated have added value to the outcome, and we thank you for your time and your thoughtful comments throughout the process.

The proposed agreement, which would authorize FDA to collect $595 million in user fees over five years, plus increases based on inflation, strikes a careful balance between what industry agreed to pay and what FDA can accomplish with that amount of funding proposed. This increased funding would allow FDA to hire over 200 additional full-time equivalent employees by the end of the five-year program, about 195 of which would be with CDRH.

While the goal structure has evolved throughout the MDUFA program and continues to do so under the proposed MDUFA III program, the concept of fee for performance remains. We believe that a program that enables us to shorten our review times, while maintaining U.S. review standards, is truly a win for public health, as it allows safe and effective devices to reach the patients who need them, more quickly. That's what this user fee program does.

We believe this program will result in greater predictability, consistency, and transparency through a number of improvements to the review process. This will contribute to a manufacturer's ability to bring devices to market in a timely manner.

This agreement was not easy to reach. Nobody got everything they wanted. Yet the careful balance that we achieved represents an important step forward in the ongoing improvement of the program. FDA is committed to achieving the improvements reflected in the agreement, and we look forward to working with industry and other stakeholders to achieve better outcomes for public health. We also hope that the recommendations we send to Congress after the public comment period successfully make it through the legislative process intact and are enacted in a timely manner. We hope to avoid the unintended consequences that might occur if contradictory or burdensome requirements are placed on FDA, which could divert attention and resources away from our implementation of the agreement.

I must thank all participants - stakeholders, industry trade associations, and the FDA team - for working through many challenging issues, taking the time to understand each other's positions, and developing a creative program to address the broad array of issues and, most importantly, that we believe will improve public health.

We think we've been very careful at considering everything, but this is our chance to make sure we haven't missed any issue that should be considered within the scope of this program.

So, again, thank you for coming and thank you again for participating in the process.

MR. BECKERMAN: Thank you, Dr. Shuren.

I'd like to ask Dr. Karen Midthun to come and give CBER's perspective on the Medical Advice User Fee Act.

DR. MIDTHUN: Good morning and welcome. I'm happy to have this opportunity to greet you all today and to say that after over a year of hard work by representatives of stakeholder groups, industry, FDA, we have negotiated this user fee agreement. And as the Director for the Center of Biologics, I want to say that our center supports this, together with the Commissioner and CDRH. This is very important to all of us.

I want to thank the negotiators who worked tirelessly to bridge a gulf that a year ago seemed to be very wide. I think this is really a testament to the commitment that we all share to really have a device regulatory program that provides consistency, transparency, predictability, and efficiency and that provides timely access to safe and effective devices.

I also want to thank the representatives of patient and consumer advocacy groups, who met monthly with the FDA negotiating team to discuss their views on the reauthorization and their suggestions for changes the user fee program. The negotiated agreement recognizes the importance of understanding patient needs and expectations. And as part of that, FDA has committed as a part of this user fee program to issue final guidance on assessing patient tolerance for risk and the magnitude of patient benefit, particularly when other treatments or diagnostic options are available. In addition, FDA has committed to meeting with patient groups to better understand and characterize the patient perspective on disease severity or unmet medical need.

Thus, we look forward to hearing your comments today and also reading any written comments that are submitted to the docket.

I want to thank everyone for their efforts. I know that this has been a very, very rigorous process, and we look to it to really continue to build a very strong device program, so thank you very much.

MR. BECKERMAN: Thank you, Dr. Midthun. At this point, I'd like to ask Malcolm Bertoni, who is FDA's MDUFA lead negotiator, to come and present an overview of the recommended reauthorization package. And then we'll have a chance for some clarifying questions.

And for speakers coming up, I'd like to point out, we've got cables around on the floor, so please be careful as you come up, and hopefully you can avoid tripping over them. Thanks.

MR. BERTONI: Thank you, Pete, and good morning. We're going to take a moment here to get the telephone a little closer, much closer, so we hope that the sound on the webcast is a little better for those of you. Well, it's my pleasure to present to you this morning an overview of the agreement that we've posted on our website and that was described in the *Federal Register* Notice recently. And I'll also take a moment here before going further while we get the slides up on the screen, hopefully both within the room and for the folks on the webcast. I do want to -- well, there we go. So, let's go ahead and we'll move on to the overview slide. The presentation today is really rather simple. We'll talk a little bit about the process that we have conducted since we had the last public meeting a year and a half ago. And then we'll spend the bulk of the time -- I'll talk through the key features of the draft recommendations, and then we'll reserve some time for any clarifying questions with regard to the draft recommendations. And as Pete had said, we would appreciate it if commentary would be reserved for the public comment period, but if there are clarifying questions that have to do with the user fee agreement, I'll be happy to answer those questions.

So, first a few words about the process that we use to develop these recommendations. The slide that I'm showing here, slide 4, that shows basically four different stages of a process that was laid out in the statute, in the Federal Food, Drug and Cosmetic Act. And the four stages are really an initial public input period that began in September of 2010; then the development of the recommendations, which occurred from January of 2011 to February 2012 -- and I'll say, I did hear when Pete was talking initially, he said January 2010, and I think that was just a typo or something because we did start the negotiations in January of 2011. It seemed like a long time, but not quite that long.

(Laughter.)

MR. BERTONI: And then we're currently in the public review stage, and once we get through with this as was noted before, we will be evaluating the comments, making any edits to the recommendations, and transmitting final recommendations through the Secretary of Health and Human Services to Congress. The bullets at the lower half of this slide really represent the individual milestones that are statutorily required for this process, and they are the same steps that the Prescription Drug User Fee Act program had to go through.

As we mentioned, we had the initial public meeting. There was a 30-day comment period at the very outset. We posted the comments on the FDA website. We have been involved in negotiations with the regulated industry over the past year or so. And we did publish the meeting minutes on a regular basis, and not only those meetings but also the meeting minutes from the discussions that we had with patient and consumer advocacy groups. We did get through -- we got to an agreement. We got through review within the administration, at the Department of Health and Human Services and the Office of Management and Budget, and that is the agreement that was posted to the website. We have had some briefings with congressional staff and with committee staff. There will probably be some more for not just the authorizing committees but the appropriation committees soon, and we did publish the draft *Federal Register* Notice and we've already put a check mark on this public meeting, because once begun is half done, right?

And we -- the next step, as we noted, will be that we will complete the 30-day comment period. We do encourage people, if you are able to get your comments in as early as possible because we will be reviewing the comments that are posted to the docket on a rolling basis to try to identify any analysis or discussions or considerations that we need to do. And it's

always better if we have a little bit more time to consider your comments because we are under some time pressure to get the final recommendations up to Congress, given their schedule for getting the bills marked up and passed this summer and signed in to law before everybody goes off to do other things before a certain date in November.

So why don't we move along a little bit and talk a little bit more about the details of the development of the draft recommendations. The industry representatives that we have been negotiating with and who are represented here today on a panel are the Advanced Medical Technology Association or AdvaMed, the Medical Device Manufacturers Association or MDMA, the Medical Imaging Technology Alliance or MITA, which is a subsidiary of the National Electronics Manufacturing Association, and the American Clinical Laboratory Association. So we met frequently with those associations and some of their members who also joined the discussions. And we also met monthly with patient and consumer advocacy representatives during that period to give them an update on the progress of the negotiations and get some of their feedback and input. I've already noted that the detailed minutes are available on the FDA website.

This slide shows you a listing of the broad array of different patient, healthcare, and consumer advocacy representatives that participated throughout the process, some of them in the initial public meeting and many of them along through in the monthly meetings that we held. And, again, we very much appreciate your participation. I think it was a helpful part of this process. And it was good to be able to get different perspectives and to be able to bring those perspectives to the table.

I want to also give you just a little bit of a narrative of how the negotiations went, and I have a representation of a calendar, a 16-month calendar here because that brings us from the beginning of negotiations up to where the phase that we are now. We did start off in January, and for the next couple months afterward to really dig in to a lot of data analysis of the program and how the program was performing and what some of the contributing factors to the performance were, trying to get at the root causes of some of the concerns that specifically relate to the user fee aspects of the program.

Dr. Shuren mentioned a number of different aspects of the program that the Center has been trying to improve over time, and a good many of those really fall within the boundaries of the user fee program which is really, you know, additional resources for improvements in performance. And those discussions at times were spirited. There were different perspectives, and I think it was, I would say a healthy exchange of different perspectives on the program. And it led us to a point where in late April, FDA presented what we would call a comprehensive set of proposals, and then we followed up just the following month on May 4th with an estimate of the resources required to support this package of lots of different changes to the program.

Industry's first response was not one that FDA was able to support because they had suggested that the timing wasn't right for a complete five-year agreement, and they had a suggestion for allowing uncertainties to resolve themselves before going for a full reauthorization. FDA was very concerned about that plan, and yet we also recognized that there were some issues about the uncertainties in changes to the program, so we developed a plan for trying to mitigate and address some of those uncertainties. I think as it turned out, because the negotiations took as long as they did, some of those uncertainties resolved

themselves because of just the timing of some of the program changes that were under consideration.

And so when we got some resolution of the plan for mitigating the potential changes to the program that could potentially affect performance and workload, industry did come back with a very comprehensive set of proposals in late July. And that really kicked off a vigorous period of back and forth counter offers, counter proposals primarily on the technical aspects of the performance goals and other features of what we call the commitment letter, which is really the statement, document that the Secretary transmits to Congress that reflects the bulk of the performance commitments that the Agency makes in return for the user fees.

And then by the end of October, we had reached I think a very comprehensive redesign of the commitment letter that both sides had sort of provisionally said, yes, this is worth taking to the next stage of negotiations to talk about coming to some agreement on the financial resources required to accomplish that initial draft of the goal through the commitment letter. And it took a fair bit of time to try to bridge the gap there because FDA's estimates of what that was going to take were much higher than industry was willing to pay, and then of course, again, the time it took to resolve the negotiations meant that some new information became available in terms of say inflation and the actual cost that the Agency was incurring, and so that allowed us to sharpen our pencil a little bit. And we just worked together and worked hard at trying to find ways to make the program more efficient and try to save costs where we could, given industry's concerns about the potential increases in resources.

And then by the end of January, we had reached an agreement in principle that balanced the commitment letter and the total resources over five years. Then it took us a few more weeks to get the fee structures and a few remaining details nailed down, but by about mid-February we were able to reach a final agreement on the commitment letter and the draft legislative language that represents the total of the draft recommendations that we're going to go over in some detail in just a minute. And so that leaves us to the public comment period where we are today, and we note that the public comment, the docket, does end on Monday, April 16th, and we do not anticipate extending that period, so we do encourage people, as I said before, to get your comments in, in a timely way, and the earlier the better.

So we do think that we achieved a successful result. As

Dr. Shuren emphasized, you will hear this a lot from us; we think it is a careful balance between what we were able to commit to accomplish within the fee amounts that industry is willing to pay. And it is, I think an important -- we very much appreciate the fact that industry has increased their investment in this program to $595 million plus an inflation adjustment over those five years. And we think that the commitment letter really represents some important improvements that enhance the transparency, consistency, predictability, and I think the productivity of the program as well.

And I think throughout this, we've been very careful to emphasize that there's some fundamental principles to which we all agree, and that is that the standards that we have for safe and effective devices are preserved, but it's important to public health that we also think about making sure that we have timely access to those safe and effective devices. And in that regard, we have improved the FDA review goals as part of this and made a number of other process improvements that we think are going to lead to an improved outcome of shorter

times for the total average to a final decision through this review process for premarket approval applications, or PMAs, and for the premarket notifications, or the 510(k)s.

Now, what I'll do is talk through some details for some time here, bulk of the time, regarding the two components of the draft recommendations: the draft commitment letter from the Secretary to Congress and the proposed legislative language that contains a few other details of the agreement.

And with regard to the key features of the draft commitment letter, I think it's important to start off by emphasizing to everyone that there are some important principles that are laid out in this commitment letter that are just as important as the details. And I'm going to read to you verbatim the second paragraph of this commitment letter because all parties think this is very important.

"FDA and industry are committed to protecting and promoting public health by providing timely access to safe and effective medical devices. Nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of the safety and effectiveness of medical devices. Both FDA and industry are committed to the spirit and intent of the goals described in this letter."

Now, I think we've done a good job of trying to put together details that adhere to those general principles. The general categories of the features of the letter are laid out here. There's a number of process improvements. There are some review performance goals that are really about FDA review time. There are shared outcome goals about the total average time to a decision, and there are a number of other provisions, what we've dubbed infrastructure and other aspects, and we'll go over those now.

So one of the process improvements is an important way of assuring that the requirements for submissions, to allow FDA to evaluate substantial equivalence or safety and effectiveness, is making sure that if applicants have questions, that they can be addressed ahead of time, before they invest in tests or studies, and those requirements are clear. So we spent some time talking about how to make that pre-submission process more clear and more structured and more predictable.

So, in particular, the investigational device exemption, IDE, which is sort of the clinical phase, and making sure that the process there is working well, the 510(k)s and PMAs, and making sure that when people have questions, that in essence we're doing that efficiently and predictably. So there's a new pre-submission tag that we're putting on a type of submission. There's documentation and guidelines that we will be producing to improve the predictability and consistency. When we considered a range of options for this, including some specific timelines for how to manage this process, in the end we decided that there was a substantial amount of resources already being devoted to some of these kinds of submissions and that the types of improvements that we were agreeing to in the commitment letter could be implemented within the current level of resources on the program. So we think that there will be some important improvements and clarifications of how this should run, and we believe that we'll be able to handle this if our assumptions about the number of submissions are correct and if that process works the way we intend it to work.

Another set of improvements have to do with clarifying the acceptance criteria when we initially review submissions. FDA currently has the authority to refuse to accept submissions,

but the way it had been implemented did not really give FDA much advantage to refusing to accept, particularly on a 510(k) submission, because the way we were handling the clock around the submissions. And what we did was -- we had some concerns about the completeness and quality of many of the submissions, and it seemed to us that there were a number of different things we were doing to try to improve the clarity of what we were needing, such as the pre-submissions, but also clarify our requirements and to kind of hold applicants more accountable to submitting all the information that we needed to be efficient, can start a complete review. So we had some discussions about what that would look like. And we have all agreed that putting out a guidance document about a more clear objective set of criteria that will allow the Agency to quickly review, kind of a checklist basis, and make sure that that application or submission is ready to be reviewed. And if it isn't, kick it back and really don't start the clock until a complete submission has been presented to FDA. We think that that will help reduce some of the review cycles that have kind of plagued the program and led to less efficiency than it could be.

There is a continuing provision with regard to interactive review, and that's something that we are reaffirming our commitment, and it's sort of baked into the process improvements that we have, particularly with respect to how we're going to accomplish the FDA review goals.

There's also a provision on improving the process for guidance document development. We've got some additional resources, a small amount, to help with managing this process and taking some of the burden away from some of the technical experts, so that project managers and editors can try to take some of that sort of work away from them, and then they only need to worry about applying their technical expertise to the development of these guidance documents. And also making sure that it's clear what are the priority topics that we're going to be addressing in the coming year. And making sure that if there are guidance documents out there and maybe our thinking about that particular device area has evolved and there's some aspects of those documents that are no longer current, that we're being more clear about what situations are in that or what documents are in that situation so that it's more transparent as to what the latest thinking is and which documents are currently under review and might be revised.

We're also reaffirming our support for reauthorization of the third party review program. And this is another area where there was a lot of discussion about some, you know, very good ideas about possible ways of improving the program. In the end it was decided that we would try to make most of the changes that we are able to under our current level of resources. So we look forward to working with industry to make some improvements to that program to assure that it's more efficient and maintaining the levels of quality and timeliness that it should.

We've also included provision on patient safety and risk tolerance. We have just come out with guidance on factors and considering when making benefit/risk determinations, and we're committing to, you know, full implementation of that and making sure that we're systematically incorporating patient representation as we move forward on this and similar initiatives.

We've also agreed to do a follow-on on I think a successful aspect of the current MDUFA II, where we're going to -- as we normally would through the course of the evolution of the program, as we gain experience with devices and learn what their risk and benefit profiles are, that we can look at down-classifying certain devices to be exempt from the premarket

notification requirements. And so we've got -- we have a plan for adding to that list and moving forward on implementing that. And there's also a provision there, well, we will work with industry to develop a transitional In Vitro Diagnostics approach for the regulation of emerging diagnostics and see if we can come to some consensus on that approach.

I'd like to spend some time now talking about the quantitative review performance goals because that is at the heart of the user fee agreement. One of the important changes that we've made this time is that we've simplified the goal structure. The current structure has sort of a different strategy for dealing with the bulk of the submissions and then what we would maybe think of the tail end of the distribution or the, not necessarily outliers, but the ones that take a little longer.

In the current approach that we're proposing under MDUFA III, we'll have a single-tiered structure with a high percentage target for that particular set of submissions, we call them a cohort, that is all the submissions that are submitted to FDA of that particular type within a fiscal year. And we're going to incorporate some best practices that we found throughout the Agency. Really, that is putting some interim milestones on the review process so that roughly at a midpoint of the review, that the reviewer would have completed the entire review and would then have a substantive interaction with the applicant to let them know, gee, are things on track, does it look like we're just about ready to make a decision, or do I need just a little bit of information that we can resolve interactively, or are there some questions and issues that may require us to place the submission on hold while the company goes and gathers some additional information and comes back and submits that information to FDA. But that will happen at a time when there's still a reasonable amount of time left on the clock, if you will. And we think that it just gets us in a place where we will be moving much more of the bulk of the reviews into a more predictable and consistent profile for timeliness.

There's also an important feature, which our colleagues on the industry side have dubbed "no submission left behind" that has stuck as the informal name. And that is in those cases, presumably a very small percentage of cases, when we miss the target timeline, if we don't get it done within a small grace period, just within 10 days for a PMA -- or excuse me, for a 510(k) that has a 90-day clock, or within 20 days of the PMA that has either 180- or 320-day clock depending on whether it goes to an advisory panel. If we don't get it done within that grace period, we owe the applicant a plan and a conversation about how we're going to resolve the remaining issues. And I think that's an important provision. It makes sure that nothing has kind of fallen through the cracks and that there's still some attention and focus on resolving the outstanding issues in a timely way. We think that this overall approach really will improve the predictability and, you know, reduce the number of submissions that become outliers and are taking a much longer time to get resolved.

Let's talk a bit about the shared outcome goals. This is a new feature. This was sort of an important threshold that we crossed in these negotiations. We saw when we were doing the analysis of the program that even though FDA was meeting not all but most of our review goals, the total time to a decision was creeping up particularly with respect to 510(k)s, which are the mechanism by which we clear for marketing most of the devices that go through the Center. And that was troublesome because as long as we're maintaining our standards for safety and effectiveness, taking longer to go to market is not in the best interest of public health as well as not in the best interest of the company trying to get their product to market.

So we looked at a lot of issues, and we acknowledged that if we were making all of the process improvements that we're talking about elsewhere in the commitment letter, that that should result in a reduction in the total time to a decision, and that it would be, I think, an important statement for the Agency and for industry to commit to setting some very specific targets for reversing that trend and bringing these goals down. Of course, the Agency was faced with the challenge of committing to a goal that we don't control because part of the total time is taken up when a submission is put on hold while Agency is responding to requests for additional information. And we tried to think of how we could try to balance these issues and make an acceptable proposal to both sides. And we did come up with a solution.

First of all, it needs to be emphasized that this is a shared outcome goal, that it is something that not only the Agency but industry has agreed to. And I think one of the telling moments in the negotiations, if I can open the door a little bit to it, was when the other side -- and somebody, who I won't name by name, but somebody who works for one of the companies said, look, you need to understand, if we agree to this, this goal is going to be on my performance review. These CEOs are going to be holding us accountable for doing our part of meeting this goal. And I trust that he's right and he's accurate because certainly FDA is going to be looking to make sure that industry is doing its part, and we'll absolutely be doing our part to try to bring this down.

But let me talk a little bit about the specifics of this goal and how we try to deal with the problem of shared accountability when the Agency is not fully controlling this. And the big concern was the fact that there are some submissions that just take a lot of time for some valid reasons. And we wanted to make sure that, you know, both sides who are committing to this aren't really penalized for that. Yet industry was understandably concerned that we look at an average, because that way kind of all the submissions that were going to be considered would be having an impact. And in some sense, when you're trying to compute an average, then when you do things quicker, that helps you. And so you get credit and there's an incentive for doing things faster.

So we agreed to an average with the following caveat. It's going to be what we would call a trimmed mean, meaning we're going to take the two percent highest and two percent lowest for 510(k)s which have a lot of submissions, and we're just going to kind of leave them out of the calculation of the average. And we're also not going to wait until the very last one in a year is done. We're going to wait until we've got 99 percent of them decided upon, and that way we don't have to wait too long before we know whether or not we met the goal. And we think that that's sort of a reasonable compromise where you're making a decision about whether you met a goal based on the vast majority of the submissions and not kind of holding the whole process hostage to the outliers.

The percentages are slightly different for the PMAs because they're a smaller number of submissions so there we're taking the five percent highest and five percent lowest, leaving those out of the calculations and closing the cohort and doing the assessment after 95 percent of the submission cohort has been decided upon.

So we think that this is a good provision, that it's going to be challenging in some respects for us to accomplish, but it's really something that we're going to accomplish through the other portions of the agreement, by making the process improvements and clarifying the pre-submission requirements, by making sure that we're not accepting applications that aren't

ready to be reviewed, making sure that we're really getting the review done sooner and resolving these issues in a more timely and systematic way. And, thankfully, for the additional resources, that we'll have to have more reviewers and more managers who are able to manage effectively and make sure that we're on track. I have a slide that you can't read --

(Laughter.)

But I'm just putting it up here. I know that's a no-no for PowerPoint, but these slides will be part of the -- they will be available on the web, and I just wanted to point out that there is kind of a handy-dandy cheat sheet on all the goals and how they relate to the previous goal. So when these are posted or if you nudge somebody from FDA and get your hands on a copy now, there's nothing secretive about it. This is just a convenient way of seeing all the different goals.

And the one thing I'll note about them is the stringency -- or essentially some of the improvements in the percentages of submissions that will achieve the different timelines, they ramp up over the first three years or so of the program. And that's because the resources are ramping up over the first three years of the program. So we're trying to put in place targets here that we can commit to achieving, we'll work our best to achieve, and that's how we've structured this so that the high percentages that we've sort of agreed to is the end-state or all by the time you get to the last year or two of the program, and presumably going forward, if this is successful. And we've also included in the purple line when you get your copy, that we've included the average total time goals as well, which for the 510(k)s started at 135 days in 2013 and reduced down to 124 days by 2017. And for the PMAs, I'll also note that those are three-year rolling averages, just to provide a little bit more stability in the average numbers, that start at 395 days in fiscal year 2013, and reduced to 385 in fiscal year 2017.

So let's move on to some other features of the commitment letter. Something we've dubbed infrastructure, it really addresses some important aspects of the resources and underlying structure of the program. A section on scientific and regulatory review capacity really just states what we're trying to do with the additional resources that we have is to increase the number of reviewers, as well as increase the number of managers, so that we can reduce the ratio of reviewers to managers because currently they're -- the managers aren't really able to provide the kind of oversight and mentoring to the reviewers that's necessary to really have a well-functioning program of this type. We've done a lot of analysis of that and benchmarked it against other similar kinds of organizations, and we think that this agreement is going to put us into the right range in that respect.

We also have acknowledged that one of the big problems and root causes of some of the issues has been high reviewer turnover. So we are going to be looking at what are some of the other best practices around the Federal Government and other organizations for employee retention and see how we can improve that.

Training was another issue, area of concern that had been expressed. We've committed to making sure we have adequate management training. There is a new reviewer certification program that we will continue to implement. And, importantly, because there are some changes to the goals that all of the reviewers and managers need to understand well, we have MDUFA III training as part of this program to make sure that everyone knows how to handle the transition to the new approach.

And we will continue to try to improve our information, technology systems. We're hoping that at some point we will have the kind of, you know, fully electronic environment that we're not quite there yet on and that will enable other things to happen in the future, including the ability to, you know, check the status of submissions in real time, although I think the provisions that we have established for the early review of -- on the review to accept, as well as the substantive interaction after just a fairly short period of time, and then, you know, the no submission left behind, those kinds of features are important improvements to transparency and interaction with the sponsor, so hopefully that will address some of the concerns around tracking where submissions are.

There are a number of other provisions in the commitment letter. Importantly, there's an independent assessment of the review process where FDA has committed to hire a consultant to conduct an evaluation of the device review process and make recommendations, to see are we on track to meet the new goals, are there ways that we can improve the productivity and timeliness? And we're going to look at those recommendations and develop a corrective action and implementation plan and incorporate the findings and do some guidance on good review management practices. This is very similar to what the pharmaceutical side of FDA has done. Interestingly, it's sort of on the same kind of timeline. PDUFA is 10 years older as a program than the device program is, and they're just now sort of getting to that stage where they're feeling that they're, at least on the Center for Drugs side, that they've got the 21st century review process implemented throughout their program. And I know that Center for Biologics has had a managed review process for some time because of the many different review pathways that they have to manage. And so this quality management systems approach to the review process is a trend across the Agency, and it's one that we're serious about taking on in the device program as well, and I think this provision and all the other provisions of this commitment letter are putting us on a good track forward in that regard.

Performance Reports is another area that has changed, in that we have agreed to some more detailed reporting. And we're going to continue to meet on a quarterly basis with industry to discuss the performance, and for those of you who follow these things, those quarterly reports are posted to the FDA website, so they're available to the public as a whole. So all of this information I think improves transparency but also the diagnostic value of this because really -- the principal concern here is that we view this review ecosystem in a way where we're trying to understand how things are going and what needs to be done to make sure that the program is moving along and operating effectively.

There is a new feature we'll talk about a little bit more when we talk about the legislative language, that there is a new discretionary waiver that is at the sole discretion of the Secretary. And as we talk a little bit more about -- we will make clear why the commitment letter states that any submissions that are granted this waiver are not part of the cohort that's used for calculating the goal, although the overall trend we would emphasize is that we are managing this program in sort of a quality management systems kind of approach where all the managers manage these goals regardless of whether it's a MDUFA goal or not a MDUFA goal or what have you, that there is an interest from a public health standpoint to be predictable and consistent and timely. This provision, as the statute states, is expiring at the end of MDUFA III, and while you can argue that everything expires at the end of MDUFA III if it's not reauthorized, this is a provision that explicitly, you know, stated that the intent here is that that would sunset; of course, everything is re-negotiated, but that's what we all agreed to at this stage.

Let's talk now about the second big piece of the draft recommendations, and that is the proposed legislative language. Anybody who's looked at actual draft bills knows that some of that can get rather complicated and arcane, so we've just tried to highlight in hopefully plain language some of the changes to the statute that are relevant to the user fee program here.

And the first one, of course, is that the actual fee structure is part of the statute, and we've certainly gone through and looked at all the dates in there and updated them to reflect the new reauthorized period for five years. We note that there's a similar approach here where essentially there are two actual fee numbers in the statute explicitly, the premarket approval application fee, which in 2013 will be $248,000 and then there's the establishment registration fee. I don't recall that number off the top of my head, but it's in the sort of less than $3,000 range, and somebody can probably look that up for me.

But the important thing, though, is that all the other submission types are sort of a percentage of the PMA fee. And the percentages stay the same, except for the 510(k) submissions where that went up slightly from 1.84 percent to 2 percent as part of this agreement. So they're carrying a little bit heavier portion of the financial load. The total revenue amount that we mentioned before is about $595 million dollars is also in the statute. We have had some important changes in the technical details of how this has worked out. The annual fee setting provision is updated to have an adjustment to the total revenue amount that's based on the inflation adjustment.

So rather than try to guess what inflation is going to be over the course of five years, we have a formula that's based on objective numbers that are available to us before it's time to set fees. And basically what it is, is it's 60 percent actual pay from FDA and about 40 -- well, it is 40 percent of on the non-pay portion of the costs, which is really the consumer price index for the Washington, D.C. urban area, and this is essentially very, very similar to what the Prescription Drug User Fee Act approach is as well. And so that inflation adjustment will be applied to the total revenue target for the given year. And the year-by-year targets before the inflation adjustment are spelled out in the statute.

But there's also an adjustment to the registration fees if we find that there's a big difference in what our assumptions were on say the quantities of establishments, or some other quantity. Generally speaking, the submission quantities have been relatively stable, but if we see something change drastically, then we'll be able to adjust the registration fee to try to avoid any over-collection or under-collection of fees. And both over-collections and under-collections present problems. Under-collections certainly present a problem for the Agency if we don't have the resources needed to do the program, but over-collections are a problem as well, just because of the arcane rules of the budget world and how the congressional Budget Office scores amounts and it ends up we collect money that we can't spend and industry's fees aren't going to the purpose to which they were intended. So we think that these are some important technical changes that will improve that.

We do have a change in the approach for the establishment registrations in that we've simplified the definition here, and now if you are required to register, then you will be paying a registration fee. And that will increase the base of establishments that are paying the fees. We have an estimate. We think it will go from approximately 16,000 to maybe in the neighborhood of 22,000, but that remains to be seen as we implement these changes. So it's a level playing field now on the side of the establishment fees.

Here is the provision with respect to the discretionary fee waiver. This is not something that is an entitlement or it is not something that anyone can apply for. It is really at the Secretary's sole discretion to grant a waiver or reduction of fees if the Secretary finds that such a waiver reduction is in the interest of public health. There is a fee waiver provision in the prescription side, drug side, that's slightly different however, and it's for different purposes. This was quite frankly negotiated as part of trying to wrestle with an issue again of uncertainty, because as has been made public before, FDA has been considering a modification to its current policy of enforcement discretion with regard to laboratory developed tests, which the Agency's position that these are medical devices in terms of In Vitro Diagnostic devices, and if we do end up implementing a change in this policy that results in additional laboratory developed tests being called in to submit an application or other submission, and therefore the applicant would also need to register, that we intend to grant a waiver, and that would apply only to those that we would call in as a result of this revised policy. We would not be granting this waiver for current LDT manufacturers who have already submitted and registered or for any that may voluntarily decide to register and submit.

And, again, this is a provision that sunsets by the end of MDUFA III. We know that this is an area of policy that is still unresolved, and so this is one of our ways of sort of managing the uncertainty by taking that particular aspect kind of off the table. And, fortunately, all of the industry associations, including the American Clinical Laboratory Association, are able to hopefully tell you later on have agreed to the overall package that includes this.

So moving on, there are some other technical changes in terms of updating what we call, you know, the triggers, and that is, you know, as you well know, the medical product user fee programs for FDA are somewhat unique programs in that the taxpayers, through the budget authority appropriations that Congress provides, still provide a base of funding, and the user fees are additive on top of that. And so as part of the overall deal, these appropriation triggers as well as some other spending triggers have been part of the package. And what that assures is to the greatest degree possible is that the user fees won't be used to just offset reductions in our budget authority appropriations. So, in essence, Congress needs to continue to appropriate for the device program, the taxpayer dollars, if you will, at a certain level. And because of some increases that have occurred in recent years to FDA's overall budget as well as to the device line budget that applies to this program, it no longer provides a lot of protection. In other words, Congress could cut the device program budget way too much before hitting the previous triggers or the current level of triggers. So what we've done is we've set this at a level that's essentially equivalent to the appropriation level from fiscal year 2009. That still allows us to be cut a little bit and absorb that if that happens in today's environment without bumping up against a problem, because if Congress fails to appropriate sufficient amounts to meet these triggers, we are no longer authorized to collect user fees. So it's kind of a very careful balance there that we have to make sure that our budget is protected but that we don't try to cut it too close and run the risk of losing these fees; they are such an important addition to the program.

There are some other technical aspects of this that are going to reduce the chance that we'll have excess collections that created problems I mentioned a minute ago, and some technical amendments just regarding the relationships between appropriations and user fee collections, and particularly things that could potentially happen in a year where we might have a continuing resolution or even a government shutdown and things of that nature, but some technical things that the Office of Management and Budget wanted all these programs to incorporate that we have addressed in this recommended package.

There's another provision here that we think is an important nod to the future, and that is an electronic copy provision, that we are asking Congress to give us the authority to require an electronic copy accompany, their submissions. And this requirement would only kick in once we've issued final guidance providing the standards for this, and this is a voluntary program right now, but in essence it's a portable document format copy that is loaded into the systems that the reviewers use at the Agency, and it provides a savings of time, and as you can imagine, you know, searching for things in an electronic version is much easier than searching for things in a paper version. So this helps us quite a bit, and it's something that industry agreed to, which we appreciate very much because we think this is a win/win in terms of making sure that we can be more productive when we do receive the submissions.

And, finally, there is a provision on streamlined hiring authority, and it's no secret that the procedures for hiring people in the Federal Government, because there are many different policy objectives that are trying to be achieved in them, slow the process down, and sometimes there are more efficient ways of doing it, at least on a short-term basis that we've resorted to in the past when we've had to ramp up a lot of hiring.

And if you look at, you know, well over 200 FTE that we're talking about over the course of really the first three years of this, plus whatever normal hiring we need to do through the course of just normal turnover, will place quite a burden on the routine system for recruiting and hiring people. So this provision would give us the ability for essential managers to make offers, and then there are other procedures to assure that all the other provisions of Title IV and other aspects of the hiring rules and regulations and statutes are followed, but it does streamline the process quite a bit. And we've successfully used this in the past as an Agency, and we hope to get this authority to be able to help us meet the hiring requirements so we get the best quality people in a timely way, so that we can effectively achieve these goals on a schedule that we've set forth here.

So that is the end of my prepared remarks here. And I'm going to open it up a bit for questions. I haven't been paying attention to the clock, so I don't know how close to the agenda timeline we are. But I'm not sure how we're supposed to handle --

MR. BECKERMAN: Let me --

MR. BERTONI: -- the questions here.

MR. BECKERMAN: I think we've got time for questions. I would like to just caution the group again that if you're a member of the press, please defer your question and direct it through Karen Riley. And, again, this is a session intended for clarifying questions for Malcolm. And if you've got comments, if you could reserve those for the open public comment period.

The room is a bit awkward, and given that we've moved the speakerphone, what -- I don't think we've got a microphone for the audience. Do we have a microphone for the audience? But if folks would simply raise their hand, would indicate they've got a question, I think Toby can get to you with a microphone.

Well, I will let you know that this group had precisely the same number of questions that we had clarifying questions in the Generic Drug --

(Laughter.)

MR. BECKERMAN: -- User Fee public meeting. So congratulations, everybody is being very consistent. And thank you, Malcolm.

MR. BERTONI: Well, thank you for politeness, because I'm sure it wasn't as clear as I'd hoped it to be, but in any event, thank you for your attention, and again, we're pleased to have reached this agreement. We know it was hard won but I think it was a really good agreement, and I'm really looking forward to working with industry and with the rest of the Agency in helping to implement it. And I will look forward to hearing your comments on the agreement in the panels and in the public comment period.

Thank you very much.

MR. BECKERMAN: And I was just asked to reiterate a couple points. For those of you who are watching from the web, that was the only presentation for which you got slides, so don't expect to see any other slides. And we also, as I indicated before, are in transmission only mode, so we don't -- we can't take comments through the web transmission. You will still have the ability, of course, to submit comments to the docket, and we encourage that.

We were at the point where we are going to bring up panelists for a stakeholder panel. I'm actually going to divert from our plan a little bit given the structure of the room and see if we can have each of the three industry panelists come up one by one to the podium and give a presentation. And then when they're done, if I could ask them to take a seat at the table, and that will allow FDA to ask the entire panel clarifying questions, and then we will take our break after that.

So our first industry stakeholder panelist is Lana Keeton, who is the Founder and President for Truth in Medicine, Incorporated. We'll be moving -- I'm sorry -- to the industry panel second, and so we'll deal with the stakeholder panel first. I apologize for misspeaking. That's two between that and 2010 as opposed to 2011. So if Lana Keeton is here, I could ask her to come to the podium.

MS. KEETON: Thank you. Good morning. So, my name is Lana Keeton, and I am the President and Founder of Truth in Medicine. My comments today are first to thank Dr. Jeffrey Shuren for his leadership as the Director of the CDRH in tough political and economic times.

I want to thank Dr. William Maisel for taking a leadership position at the CDRH to continue his fight for medical device safety. I'd like to thank the team members of the synthetic surgical mesh investigative team who do their very best every day to keep patients' safety first. They have done an exemplary job within the current framework at the FDA.

All the well-deserved comments aside, the FDA regulatory framework they must work under is completely inadequate. Americans are not safe. Industry is here to preserve and protect the profit of their companies for their stockholders. It is their day job. I am here to speak for patient stakeholders who do not have a voice, who are sick and injured and disabled, some who are already dead and some who would welcome death not to be in pain anymore.

Patients don't sign up for the greater good. They go to their doctors to be well. What happens to them is despicable. The FDA doesn't have the resources or the manpower or the regulatory authority to protect the public health. $595 million is a ridiculously small amount of money for one of the most important institutions in the American government.

While we as Americans spend countless billions around the world in lives and treasure and aid to disaster victims, the House of Representatives, the Senate, and the President of the country fund the FDA with only a few hundred million per year. There never really should have been a MDUFA I. The FDA and the CDRH should be a wholly funded government entity, not the hybrid government-private sector funded entity it is today.

Much has been made of late that the FDA is stifling jobs and innovation. I have to ask what is innovative about a copycat piece of mesh that has been used for over 50 years? As for the FDA being a job creator, the jobs are not moving overseas because of the FDA's speed or lack thereof in the approval process. These are international companies producing products overseas. These medical advisors are and have been overseas for years now by choice. The laws are less stringent overseas. Device companies produce their products in the most favorable legislative climate in other countries and then ask the FDA for U.S. approval to having their approval in other countries. It's a shell game, a well-played shell game.

Not only does the medical device industry produce products internationally, it produces harm internationally. Lorraine Evans, who's the U.K. Director of Truth in Medicine and founder of TVT Mum charity in Bristol, United Kingdom, recently received a response from the Department of Health after raising concerns to David Cameron, Prime Minister of England, and Andrew Lansley, the Secretary of State for Health, of the severe ongoing harm from synthetic surgical mesh.

In a letter to Dr. Shuren and Dr. Hamburg in May 2011, Gayle Graham of South Africa wrote, "The reason for this letter is to educate and plead to the FDA on their decisions, the repercussions of those decisions, and procrastination to action in rectifying those decisions, and how this affects individuals beyond U.S. borders even as far as South Africa." South Africa has no public health agency.

Robyn Ribarits and other women have traveled from Australia to Los Angeles, California to have surgical mesh removed by Dr. Shlomo Raz at UCLA because they were unable to find a surgeon in Australia to help them.

What we need are stronger laws here in the U.S. so the innovation would become safe and effective medical devices, not we tried this in animals and we think it might work in humans. As Janet Holt Regulatory Affairs Director of Truth in Medicine says, "We must mandate patient labeling and clinical trials for implanted medical devices and not wait for MDUFA IV before patient registries are created."

Instead, industry will pay $595 million over the next five years to the FDA, a drop in the bucket to what device companies spend every single year to get their products to market knowing they will enter patients who they will only compensate through product liability litigation.

They spend money influencing medical students at the university level. They pay money to support professional medical associations. They pay money to individual doctors and

surgeons designated as key thought leaders. They pay money to medical consultants, medical advisors and speakers. They pay money to foundations. They sometimes pay ghostwriters. They pay money to lobbyists. They pay millions of dollars to defense attorneys. They pay millions of dollars in settlements to device injured plaintiffs.

They even pay money to the Department of Justice. Pharmaceutical and device companies have paid over $19.2 billion since 1992 in criminal fines, and they still have multi billions of dollars of profit almost every year from the medical devices that continue to harm unknowing, innocent people who simply wanted to be well.

So here's the big picture. The international medical device industry has sales of approximately $350 billion per year. You only need to look at the annual reports from these medical device companies to see they're a worldwide structure. These companies are not shipping jobs overseas because of the FDA's performance as a regulatory authority. These companies already have major worldwide holdings.

For instance, in approximately 2000 Johnson & Johnson bought Medscand AB, a Swedish company producing the metal hooks used to implant their trademark Prolene mesh. The Gynecare TVT Prolene mesh has been assembled in Switzerland, shipped to Scotland for sterilization, returned to Switzerland for distribution through a Johnson & Johnson plant there. Ethicon U.S. just distributes the product here in the U.S. This is not a USA-manufactured product.

Then there's the Bard Avaulta originally designed and produced in France where the CEO of the company, Dr. Michel Therin, is a veterinarian, not a medical doctor. A pilot study on the product by Dr. Jim Ross here in the U.S. was on four sheep for 45 days, which referred to studies on mice and rabbits and pigs. Was it ever studied in humans? Who knows. But it is implanted in thousands of women, hundreds of whom who are now suing Davol Bard.

When I was fighting for my life following emergency surgery to remove a flesh eating bacteria on Christmas morning 2001, I had no idea I had a piece of polypropylene implanted in me a few days before by my doctor, a piece of petroleum waste byproduct they won't put in a gas tank, an untested, unsafe medical device cleared by the FDA.

The next four days in the hospital with a million units of a cocktail of antibiotics dripping into my body every two hours, I was terrified. What had happened to me? Was I going to live? A small card given to me upon discharge, patient labeling from the initial surgery, would have told the surgeon to remove the 3-inch diameter portion of the skin of my stomach. There was a foreign body inside of me that was potentiating the infection.

It was almost four years after the first surgery when the tenth doctor I'd seen for complications told me Ethicon, a division of Johnson & Johnson, was being sued for a bad product. Until that moment I believed all of my health issues were caused by the initial surgery, a bad doctor, and a life-threatening infection. Until then there was no way to deal with the complications because I didn't know the cause of them.

From that day in August of 2005 until today I've been trying to get a ½-inch by about 8-inch piece of Prolene mesh out of me. I have had repeated surgical procedures, and I'm now waiting till June when I will be eligible for Medicare to hopefully have the last surgery to

remove the last 4 inches of petroleum waste by product that has ruled my life for over 10 years.

Here are two tiny pieces of mesh, one the size of a flea and the other the size of a tick. They required a cystoscopy without anesthesia and $1200 to remove it from me. Erosion they call it, a minor in-office procedure. Of course, they don't have mesh inside of them or they would never call it a minor problem. I won't bore you with the details, but my bladder is now worth about a million dollars from medical treatment and lawsuits, a stark contrast to the approximately $1200 the hospital paid to purchase the device from Ethicon in 2001.

The sad result of the flawed 510(k) system is hundreds of thousands of permanently disabled patients, millions of recalled devices, thousands of lawsuits, and billions of wasted taxpayer dollars. The remedy for this? Safe medical devices.

To make Americans safe, we must properly fund and properly man and give the best regulatory authority possible to one of the most important institutions in the American government, the FDA. The House of Representatives and the Senate and the President of the United States have to stop using the FDA as a political football. They have to come together in unity to do their most important job: protect the public health.

Thank you.

MR. BECKERMAN: Thank you. Are you willing to sit here for --

MS. KEETON: Sure.

MR. BECKERMAN: Thank you. Thank you very much, Ms. Keeton.

I'd like to ask Kate Ryan, the Program Coordinator at the National Women's Health Network to come up and address the group next. And if I could remind panelists, if it's possible to keep your remarks to 10 minutes, that would be great. We'll do questions in a panel form.

MS. RYAN: Hello. My name is Kate Ryan, and I'm with the National Women's Health Network. It's nonprofit advocacy organization that works to improve the health of all women. Our goal is to bring the voices of women consumers to policy and regulatory decision making bodies. It's also important to note we're supported by our members and do not take financial contributions from drug companies, medical device manufacturers, insurance companies, or any other entity with a financial stake in women's health decision making.

I appreciate the opportunity to speak with you today about the third reauthorization of MDUFA and the ways in which the medical device program can and must be strengthened to ensure the safety and effectiveness of devices for women. As some of you surely know, the Network has a long history of working with the FDA, and while we often play the role of critic, we're staunch advocates of the critically important contribution the Agency makes to the health and well-being of women specifically and all patients and consumers in this country.

When we're critical of the Agency, it's driven by our commitment to improving FDA's ability and expanding its capacity to protect the public from exposure to unnecessary medical risks caused by unsafe drugs and devices. I offer my comments today in that spirit. I'd like to begin

by addressing the reauthorization process itself, specifically the parts of the process established by Congress in MDUFA III -- sorry -- MDUFA II to make the negotiation of the MDUFA agreement more transparent and to provide opportunities for patient and consumer advocacy groups to engage in the discussions earlier in the process.

We greatly appreciate CDRH's proactive and transparent approach to the stakeholder meetings, specifically its consistent solicitation of our input and frank discussions about the negotiation process. We thank Malcolm Bertoni and his team. You all are sitting here, and you know who you are, and we really do appreciate all of those monthly conversations.

With that said, as we reflect on the outcome of the negotiations, it's clear that the agreement reached by CDRH and industry reflects almost none of our comments and priorities. Therefore, while we did find the meetings useful, we've concluded that they did not enable us to have a meaningful impact on the negotiations. And we will continue to advocate for Congress to establish seats at the negotiating table for patients and consumers so that the concerns of these important stakeholders will be addressed in future reauthorizations.

The proposed recommendations don't address the concerns that we had raised about protecting and promoting the health of patients and consumers by strengthening the FDA's capacity to ensure the safety and efficacy of medical devices throughout the device life cycle. The agreement does not propose allocating user fees to support the development of more rigorous premarket review standards or the expansion of postmarket safety surveillance. Instead it focuses primarily on proposals to streamline and speed up premarket reviews.

While we understand that can have benefit to patients as well, it's also clearly a priority of the device industry, which is currently the only non-Agency stakeholder at the negotiating table. We're not therefore surprised at this outcome, but we are disappointed to see the opportunity to improve the FDA's ability to meet the needs of patients and consumers go by.

We shared specific proposals with CDRH during the negotiation process for improvements to both pre- and post-market regulation of devices. While some of those were policy based and we'll continue to advocate for those, some were user fee allocations to programs we believe deserve user fees. We firmly believe that our proposals would strengthen the Center's capacity to make sure patients and consumers have access to safe and effective devices by giving it the tools necessary to identify problems earlier and to take action to protect our health and safety.

I won't revisit all of those proposals today but will briefly outline two ways we believe the work at CDRH could be significantly improved with additional support for safety initiatives that are already in place. One way focuses on the passive surveillance system of medical devices, which is outdated and in need of modernization. The second relates to the need to put infrastructure in place to allow CDRH to take part in FDA's newer and exciting active surveillance efforts.

Postmarket surveillance is necessary because the adverse reactions that a woman or provider experiences while using medical devices may be the first indication of a safety problem. This is particularly true for medical devices because clinical trials are rarely required, and even in the cases when a study is conducted, as is the case with all studies, safety problems are less likely to emerge in carefully strained study populations.

Regarding passive surveillance, we believe the MedWatch program can serve as an important early warning function in the successful operation of a larger postmarket safety surveillance system. But if the system is going to work, the Agency must support active participation by consumers and health professionals to improve timely and accurate reporting of problems.

While the Network is part of the working group developing a new user friendly MedWatch forum, which is great, that won't address several other important problems, including shortcomings in IT capabilities of MAUDE, the device tracking system database, which limits the usefulness of the data and the ability of the Agency to respond quickly to safety signals.

Despite our advocacy the current agreement allocates no user fees for improvements to the MedWatch program. And while we know the Agency has plans to continue its work to improve it as resources permit, we all know that that's difficult.

It's also important to note the limitations of a larger postmarket surveillance system with regard to devices. For prescription drugs, passive surveillance is just one piece. It also includes active surveillance of the surveillance system, but also the Sentinel Initiative specifically.

However, active surveillance of medical devices is incredibly difficult because devices do not yet have a standard unique device identifier system. To fully ensure patient and consumer safety, it's essential that all devices have a unique device identifier. Currently when there's a safety problem with the device, the FDA often has trouble informing the affected consumers, patients, and healthcare providers because there isn't a tracking system. People often don't know the model or manufacturer of the device implanted in their bodies, which is what you just heard from Lana. A UDI system would allow for active surveillance of devices as part of the Sentinel Initiative. Again, however, the agreement reached allocates no user fees to implement this UDI system nor develop a plan to integrate devices into the Sentinel Initiative.

In addition to talking about the missed opportunities in the negotiated agreement, I'd like to address some of the proposals that were included, both those we support and those we're concerned about.

And to start with a positive, we do appreciate that the proposed recommendations allocate user fees for CDRH infrastructure and capacity building initiatives. We believe that hiring additional review staff, providing enhanced training for new reviewers, and providing professional and technical expertise development for experienced reviewers is essential. And it's because we support these initiatives that we're concerned about the impact of the demanding review timelines outlined in the agreement.

Although there will be additional reviewers, the timelines on which those reviewers will be required to work are shorter. And, additionally, we saw with pre-submission meetings and interactive reviews that there will be a lot of work on those reviewers. We can do the math, and we're concerned with what we see. Doubled fees are significantly less useful if the workload is tripled.

Regarding premarket review standards, we have consistently expressed concerns regarding a third party review program. According to CDRH's own presentation during the negotiations,

there are serious problems with the program. Nearly 60% of third party reviews have quality issues, and third party reviewers only correctly identified as not substantially equivalent 2 of 14 510(k) submissions in 2010. Given the cost of the program and the acknowledgement that CDRH generally has to re-review the work of third party reviewers, this program clearly does not accomplish its intended purpose: to better allocate FDA resources and reach decisions more quickly, thus ensuring the Agency is able to meet MDUFA performance goals. Despite these problems, the proposed recommendations support reauthorization of a third party review program. Again, we understand that the Agency is already trying to improve the program, but again, it's as resources come in. We believe user fees should be allocated to improve this program.

Finally, I would be remiss not to mention concerns the Network has been raising for many years about how medical device review process exposes women to unnecessary risks, in particular the fact that devices are subject to a lower safety and effectiveness standard. Most PMA applications typically only provide a single study, and most 510(k) submissions provide no clinical data. While we recognize the standards for devices will be different than those for drugs, they don't have to be lower. Congress must address the underlying problem, which is the lower standard of approval in the statute, and we understand that. However, we believe the Agency should have the authority and resources to significantly strengthen the medical device program, both the premarket review standards and the postmarket surveillance capabilities. And we will continue to advocate for this in Congress.

In conclusion, we believe that the proposed recommendations must do more to ensure that patients and consumers have access to safe and effective medical devices. We sincerely appreciate the efforts of the Agency to work toward that end, and we know how much you also care about these safety and effectiveness standards. But as long as patients and consumers are excluded from the MDUFA negotiations, the concerns and priorities of these stakeholders will get less attention than they deserve. We will continue to advocate for these interests and improve the proposed recommendations for MDUFA III by supporting the proposals I just discussed today and by ensuring that the Agency is provided with sufficient resources to carry out these initiatives.

Thank you very much.

MR. BECKERMAN: Great. Thank you very much, Ms. Ryan. If you could stay up for here for the potential for questions as well.

MS. RYAN: Sure.

MR. BECKERMAN: Our final stakeholder panelist is Paul Brown, the Government Relations Manager at the National Research Center for Women & Families. Paul.

MR. BROWN: Good morning. Good morning. Thank you for the opportunity to speak. I'm Paul Brown speaking on behalf of the National Research Center for Women & Families, which is a think tank that uses scientific and medical research to develop strategies to improve the health of adults and children. I'm also speaking on behalf of our Cancer Prevention and Treatment Fund, which analyzes research results that can improve the prevention, diagnosis, and treatment of cancer. Our center does not accept financial interests in the medical products. We do not accept money from medical device pharmaceutical companies, so we have no financial interests in the medial products and policies we examine.

For more than a year, I think, I have participated in just about every MDUFA meeting, and there's a phrase that familiarity breeds contempt. That is not true in this case. I have a great deal of respect for the FDA staff and also for my patient and consumer colleagues.

I'm going to cover three topics: fees, the adequacy of the fees, and then a couple of smaller items -- actually a little more than three topics --

pre-submissions and third parties.

We are not enthusiastic about user fees. Matter of fact, most of our comments will echo the comments that Kate made. But in today's budgetary climate, they are necessary, user fees are necessary, especially since the FDA has been under-funded for so many years. The Center for Devices and Radiological Health is struggling to manage an expanded demand for more complex devices with inadequate appropriations, so user fees are needed.

User fees, however, were never intended to replace public funding to meet FDA's mission and statutory responsibilities. We continue to advocate with Congress for increased funding for the FDA to ensure the Agency has the resources it needs to carry out its mission of protecting and the promoting the public health. Our center is a member of the Alliance for a Stronger FDA, and that alliance has helped increase FDA's appropriations in recent years.

In the *Federal Register* Notice about this meeting, it states, "FDA policy issues are beyond the scope of the user fee program. Public comments should focus on MDUFA III draft recommendations." I will try my best to do that.

A 2009 GAO report stated, "Federal FDA officials said that this growing dependence on user fees has seriously limited the Agency's ability to fulfill its oversight responsibilities in some areas, particularly those not funded with user fees."

In a discussion draft, FDA states -- and I think Malcolm referenced this earlier this morning -- "nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of safety and effectiveness of medical devices."

Unfortunately, nothing is also the amount of funding from user fees dedicated to specific safety proposals. For example, no user fees are allocated for postmarket surveillance, as Kate noted, to determine if there are problems with devices. If the U.K. hadn't studied metal-on-metal hips and determined their risk, it's unlikely the FDA would have known they should have recalled the product.

And the MDUFA agreement includes no funding to pay for de novo reviews. It includes no funding to improve MAUDE analysis to improve the recall system to make sure, for example, that a patient is informed the heart valve that's in his body has been recalled, or in Lana's case the mesh product.

It is clear from the *Federal Register* Notice that the main purpose of user fees is to speed up medical device clearances and approvals. Ensuring patients' safety regarding devices on the market or being considered for the market is not the role of user fees. I have some specific concerns with those recommendations. Most of them are around fees.

Although the total amount of device user fees will increase substantially in this agreement over five years, it is starting from such a low point that the fees will still pay a small percentage of what these reviews actually cost. Unless CDRH receives a substantial increase in appropriations, the Center will not be able to do a better job of ensuring safety and also reduce review times. User fees, there has been a great deal made about them doubling, but as Kate noted, if the workload triples, then CDRH is actually losing ground.

We think medical device user fees have been, and with this new agreement still are, too low. That is especially true for the largest companies and for all 510(k) fees. PMA user fees for the larger medical device companies should be comparable to those for INDs for pharmaceutical companies of similar size. The largest device companies such as Johnson & Johnson currently pay user fees of $220,050 for a PMA and $4,049 for a 510(k) application. This is 12% and just 1% respectively of the same company user fees for a prescription drug application and about 20% of what the device review actually costs the FDA.

There's been a lot of talk about the doubling of the fees, but the actual increase for an application fee for a PMA has gone up about 12.5% for 2013. And as Malcolm pointed out, the 510(k) fees are based on the PMA fee, and that has gone up slightly too.

Fees for small manufacturers are much lower. They pay half of a 510(k) application, they pay nothing for their first PMA, and they pay one-quarter for subsequent PMAs. So these fees are not burdens on small manufacturers, which I believe are defined as revenues of a hundred million dollars.

Other regulatory entities' received user fees are sufficient to actually prevent disasters from happening. CDRH user fees do not. The Nuclear Regulatory Commission gets 90% of its $1 billion funding from user fees paid by the industry. The FAA gets almost all of its $10 billion budget from user fees paid by customers. The Pipeline and Hazardous Material Safety Administration gets almost its entire $200 million from oil company user fees. The FDA's Center for Drugs gets the majority of its budget from pharma user fees.

Even with the proposed increases, device companies would be paying only a fraction of the cost of device reviews and none of the cost of postmarket surveillance. In short, they're getting a very sweet deal.

Are user fees adequate to meet performance goals? We're not sure. We're very concerned that the total amount of user fees is not enough to meet the performance goals. Under Section (c), Shared Outcome Goals, of the *Federal Register* Notice, the FDA states that "improvements outlined in the draft commitment letter should reduce the average total time of decisions provided that total funding of the device review program adheres to assumptions underlying the agreement."

In the January 31st, 2012 minutes from negotiation meetings on MDUFA III, the Agency stated, "They had some concerns about how solid a financial footing this agreement establishes, given that there are a lot of uncertainties about how much effort will be required to meet the goals, and that in order to bring the proposal to a level the industry could agree to, FDA had to take away any margin of error."

I want to shift gears here a little bit and talk about pre-submissions and third party reviews. We think that FDA rightly rejects the industry proposed -- we're calling unfunded mandates.

The industry wanted the FDA to meet what amounts to performance goals on pre-submissions and third party reviews, yet industry did not want user fees applied to these programs.

We support the FDA's position that they will manage pre-submissions and third party reviews as resources permit. And I'm glad that Kate said and noted the same thing. However, we think the third party review program should be scrapped altogether. It is the FDA's job to review safety and effectiveness of devices. Third parties have inherent conflicts of interest; they know that device makers can shop around to find the most lenient reviewer. Also with the current third party review, the FDA often finds the reviews are scientifically inadequate, which slows down the clearance process.

Will user fees be sufficient for interactive reviews and patient safety and risk tolerance meetings? We're not sure. These meetings will take up a lot of the staff's time, but user fees are unlikely to be sufficient. And if Congress agrees to industry's additional demands, the gap between resources and required CDRH meeting and negotiations with industry will be even greater. And industry lobbying of Congress also raises important questions about whether the industry negotiated with CDRH staff in good faith.

In the final draft document, FDA should explicitly state next to any performance goal that is not funded with user fees that FDA will meet the goal only as resources permit.

In conclusion, we support applying user fees for additional CDRH staff, including training and guidance and for guidance documents development. And we'd like to see additional user fees in the future for additional work. For example, if a device is approved or cleared, the company should pay an additional user fee to help support the FDA's postmarket surveillance. If a device is recalled, that should have another user fee for FDA to help manage the recall.

As I stated earlier, we are not fans of user fees, but with today's budget restraints, they are necessary, especially since CDRH has been under-funded for years. However, the user fees that CDRH would receive in this agreement are much too low to support the additional performance goals and work that the industry has demanded.

Thank you.

MR. BECKERMAN: Thank you, Paul. I'd like to thank each of our stakeholder panelists for their thoughtful and carefully considered statements. And at this point we'd like to see if any of the FDA personnel have clarifying questions for our stakeholder panel.

MR. BERTONI: They've been very clear. I really don't have any questions.

MS. RYAN: We've spent a lot of time with you guys, so I wasn't really expecting a lot of questions.

MR. BERTONI: Okay. And thank you very much for your time.

MR. BECKERMAN: Wonderful. Thank you very much to all three of you. At this point we're actually a tiny bit ahead of schedule, so given that I've got -- it's 10 minutes to 11. I'm going to suggest that we come back actually at 10 minutes after the hour rather than quarter

after. We can get started a few minutes early or at least stay right on track for our remaining panel and then have a meeting and continue.

Okay. So let's take a little break, and we will see you at 10 minutes after the hour.

(Off the record at 10:50 a.m.)

(On the record at 11:10 a.m.)

MR. BECKERMAN: Very good. Well, we're ready to start up again, so I would like to welcome the panelists for the industry panel. And, again, rather than have them come up to the front table, what I'm going to do is ask folks to come up one by one, and then when they're done with their presentations, have a seat so the FDA can ask the panel clarifying questions, if indeed there are any.

Our first industry panelist is Janet Trunzo, who is the Executive Vice President of Technology & Regulatory Affairs at AdvaMed.

MS. TRUNZO: Good morning, and thank you very much. I wish to thank FDA for this opportunity to comment on the recent agreement that we negotiated between the Agency and the medical technology industry to reauthorize a medical device user fees program. I'm Janet Trunzo with AdvaMed.

As I began to prepare these remarks, I had to think about the past and starting with a meeting back in September of 2010, just as Malcolm did. And I looked back at my presentation for that meeting to help prepare for my comments. And in looking at that presentation, it made me recall what we had said, of course. And at that meeting my presentation talked about the guiding principles that we should use as we move forward with a successful user fee agreement and for the negotiation that was about to commence.

And we talked about negotiating in good faith and looking at performance metrics that were based on data, all the things that we actually did during the negotiations, as was previously mentioned. But foremost among those guiding principles was the recognition of our common goal, which was timely patient access to safe and effective medical technology.

And with that goal in mind, the negotiators embarked on a series of meetings that lasted over a 12-month period, but that goal was our guiding principle. And as a result, the commitment to the goal was placed in the agreement, up front in the first section of the agreement. I noticed that Malcolm had it on his slide and I have it my prepared remarks, so I believe that that goal has major significance.

And that is the goal or the comment that said the FDA and the industry are committed to protecting and promoting public health by providing timely patient access to safe and effective medical devices. And nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of safety and effectiveness.

Both FDA and the industry are committed to the spirit and intent of the goals described in this letter. I'm stating it again because I think it's an important point to make. As we

embarked on these negotiations, we had the goal in mind, and we followed through on it, and we are both committed to this agreement.

AdvaMed believes that the negotiated user fee agreement represents a balanced agreement. It is good for FDA and for the medical technology industry, but most importantly the ultimate beneficiaries of this agreement are the American patients who will benefit from timely decisions on submissions for the innovative devices and diagnostics that save and enhance lives.

With looking at the agreement and its enhancing FDA's performance, we further believe that the MDUFA III user fee agreement has the potential to enhance the efficiency and accountability of FDA's medical device review process through much needed process improvements in exchange for additional resources, which will allow the Agency to meet the commitments in the agreement.

Each of the provisions in the agreement has the potential to make a difference in improving FDA's performance. But in this case the whole is truly greater than the sum of its parts. Each of the elements of the agreement reinforces the others. As we work toward developing goals that address areas for improvement in the review process, the negotiators looked at the overall review process systematically. And I believe that the goals represent that systematic approach.

Beginning with the process improvements for the pre-submission process, the refuse to file and accept procedure for applications missing information, substantive interactions midway in the review process, improved FDA day goals, FDA's reviewers' attention to submissions that do not meet the goal, the no submission left behind concept, all coupled with the shared common goal of improving the average total time to decision should naturally as a whole result in improvement in the overall process.

The agreement also provides the improved transparency and greater accountability. New reporting tools will provide key data to track FDA performance, and the independent analysis of the management of the review process will highlight any inefficiencies in the review process, make recommendations for improvement, and provide the basis for corrective action.

The additional resources are also significant. Additional reviewers, lower manager to reviewer ratios, enhanced reviewer training, and other resources provided by the agreement will give FDA what it needs to improve performance. However, no agreement is self-executing. Successful implementation of the agreement will depend on consistent and efficient administration of the program by FDA and the industry. And the industry pledges to work with the Agency to make sure that the goals of the agreement are achieved.

We are strongly committed to the user fee agreement as negotiated and do not support any proposals that would change the terms of the agreement or undermine its goals. The medical technology industry, AdvaMed, is committed to working with Congress and FDA and other stakeholders to help make sure the agreement wins approval before the current user fee program expires on September 30th of this year.

Thank you again for the opportunity to make this statement.

MR. BECKERMAN: Thank you, Janet.

Our next industry panelist is Mark Leahey, the President and CEO of Medical Device Manufacturers Association.

MR. LEAHEY: Thanks very much. Good morning. My name is Mark Leahey, again with Medical Device Manufacturers Association. We're a trade group here in Washington, D.C. that represents approximately 280 primarily small to mid-sized medical technology companies who work day in and day out to try to improve the human condition through innovative medical technologies.

I want to begin by thanking Dr. Shuren, Malcolm, the negotiating team at FDA, my industry colleagues, and those other stakeholders who have spent countless hours over the past year and a half to try to strike that delicate balance to ensure that moving forward patients will be better served through enhancements to the user fee program.

This is, like Janet, my third time involved in this reauthorization process, and I think with each time we learn a little bit more of some enhancements that can be made in recognizing that this truly is a partnership between multiple parties and trying to work together to learn how we can improve this, ultimately to again provide patients with timely access to safe and effective products. And I think, again, we've struck that balance here through this agreement.

For example, you know, I think going into this there were some goals that perhaps we identified in MDUFA II that for various reasons were having difficulty being met, so we talked about how we can simplify the structure, maybe provide modified timelines to help provide predictability for both the FDA and industry.

And I also want to just touch on a couple points, you know, starting first with the resources. I think when you look back to MDUFA I every -- you know, from MDUFA I and MDUFA II, there's a doubling of fees. From MDUFA II to MDUFA III, there's been a doubling. I will say that, you know, at least from our members' perspective, this trajectory -- you know, we view each negotiation on its own, but this is a significant investment on behalf of the industry.

And over that period of time, we're also part of the coalition to strengthen FDA, and I think we've been successful in lobbying for significant enhancements to appropriations. And we want to make sure, again, that the intent of this user fee program, where user fees are supplemental to congressional appropriations and not become the primary source, because I think when that happens, you know, the public often complains, and rightly so, that there could be an influence there that is -- at least the perception is not one we want to go down the road.

So, again, I think we struck the right balance here as it relates to industry's contribution, but certainly want to make sure that Congress -- Republicans, Democrats, and the Congress and the Administration understand the critical importance of making sure that there's a solid base of appropriations moving forward. With that said, you know, this $595 million is not insignificant.

In fact, as it was stated earlier, this will provide 208 additional FTEs under MDUFA III that will enhance FDA's scientific expertise, help with the reviewer to manager ratio as well. And what's also stated in the public meeting minutes is that this agreement being reached allows the FDA to use some additional collections they have under MDUFA II to bring on 32 new

FTEs right now. And those folks are going to help bring that reviewer/manager ratio into better alignment to help manage the process.

So, again, I think our ability to reach agreement here with FDA and the other stakeholders and then ultimately get across the finish line up on Capitol Hill should actually start realizing some of the benefits here, particularly as it relates to the manager to reviewer ratios prior to the inception of MDUFA III, which I think is an important benefit.

I also just want to take a few moments to talk about -- and again, Malcolm did a great job about going through each of the provisions and the highlights here, but I think there are a couple that are worth calling out. And really I want to focus on the process improvements because I think while there are some areas on the quantitative goal side that certainly show improvement from current performance, maybe not where we wanted it from MDUFA II goals, but again from current performance, that's really the end result, I think.

Our members looked at this as how do we make the process more predictable, transparent from the inception of when the reviewer and the submitter come together throughout the process. And if you can do that, make it more effective for both FDA and industry, the net result is a more efficient review process. And part of that I think stems from the pre-submission process and recognizing that, you know, FDA stated they're putting a new guidance document out about this pre-submission process.

To the extent there's more structure around that, I think that will help both FDA and industry in moving forward, and the incorporation, I think, of meeting minutes here to help memorialize discussions so that both parties are clear about what the expectations are, again, is something that should help both industry and FDA.

We also heard briefly about the submission acceptance criteria. Again, anything that we can do to ensure that when these submissions come in, that they're complete, have all the elements, should certainly I think be a net positive for both FDA and industry.

And just a couple others I'll touch on as well, and I think was in large part driven by the discussions in the parallel stakeholder discussions, there is a provision that incorporates patient safety and risk tolerance and talking about implementing guidance in risk/benefit and to meet with patient groups to understand tolerance for risk. Again, this was something quite frankly that the industry and FDA didn't have in our initial discussions, but through the insight and the input from the parallel group, I think this was an important provision that would hopefully, again, help achieve the objectives.

So, in conclusion, let me just state that while it not maybe the perfect agreement, again, I think it represents -- and I think industry had some things in there that we would have liked to have seen, but given the dynamics in place related to resources, capacity, et cetera, I think we came to a place where we can confidently say that MDUFA III is structurally set up to provide those enhancements both to FDA, to industry, to patients, beyond MDUFA II. And we look forward to working with FDA to ensure that the package that was agreed to here is maintained and preserved up on Capitol Hill.

And ultimately I think when we're here five years from now, we can confidently say that patients were better served because of this agreement. And ultimately this is what it's all about, so thank you very much.

MR. BECKERMAN: Thank you, Mark.

MR. LEAHEY: So many questions, right?

MR. BECKERMAN: Our third industry panelist is Elisabeth George, the Industry Chair of the Technical and Regulatory Committee in the Medical Imaging and Technology Alliance, and a Vice President for Global Government Affairs, Regulations and Standards at Philips Healthcare.

MS. GEORGE: That's a mouthful. Good morning.
Thank you for this opportunity to be here today. And, first, I would like to thank Dr. Shuren, Dr. Midthun, Malcolm and all the FDA staff that helped us get here today and helped us work together for the MDUFA reauthorization.

As was stated, I'm the Vice President of Global Government Affairs, Regulations and Standards at Philips. Over the last 25 years I've worked in medical device regulation. Unlike my colleagues I didn't have the fun of participating in MDUFA I and II, but I did have the pleasure of participating in MDUFA III, and it was pleasurable. We did work towards understanding a partnership and an alignment on what was necessary to ensure safe and effective medical devices for all.

I think over those 25 years, change has been one of the things that is a given and, therefore, accountability and transparency are imperative. My colleagues did speak about a number of different aspects. I'm really going to focus on transparency, on performance reporting, and on accountability because those are really three areas that I just want to point out specifically.

In transparency, clear and current guidance documents are really key to manufacturers for understanding what the FDA's expectations are and the processes necessary for safe and effective devices. Having things that are nebulous and out-of-date complicates this process and makes it difficult for both manufacturers and the FDA staff to address timely and effective release of products.

In the MDUFA III draft commitment letter, the FDA commits to improve all parts of this process: the development, the review, the issuance, and the updating of documents that don't reflect current thinking.

The FDA is making a commitment to delete documents that don't reflect current Agency thinking, which helps to ensure manufacturers don't waste time and resources following a guidance that is out of date. And it also helps the FDA to ensure that they are able to effectively review our products in a timely manner to ensure timely release for patients.

This process will encourage stakeholders to provide thoughtful comments to the Agency when those documents are sent out for draft. And as these perspectives are all being collected and heard early on in the process, we can ensure effective and timely release of those guidances.

With regards to performance reporting, MDUFA II has always required formal quarterly reporting that provided visibility to the Agency's performance. Unfortunately some of the metrics in this report and a lack of granularity prevented reporting from reaching its potential in terms of helpfulness to both the industry and the Agency. For instance, OIVD reports a

single set of metrics even though it handles both radiological products and diagnostics. In the draft commitment letter, FDA has agreed to provide a fuller picture of its performance. Instead of just an average, FDA will report many metrics by quintiles -- sorry, Barbara. FDA will identify key areas that are noteworthy because of a potential effect on performance, such as significant additional information, letter rates. This reporting will allow stakeholders to work with the FDA to solve problems during MDUFA rather than having to wait until the next negotiation. FDA will also report the greater granularity to ensure performance issues can be more easily solved.

With regards to accountability, unfortunately under MDUFA II, FDA missed several of their performance goals. At the same time, total calendar days to reach a decision have increased even in areas where the FDA has met its established goals. The Agency and outside stakeholders have expressed the issue they believe are the root causes for these trends, but there has been a lack of independent, unbiased analysis based on the information within FDA. This agreement should fix that problem. In the commitment letter, FDA commits to hiring an independent, private third party organization to review its processes and management to help identify root causes and potential solutions. In response to the recommendations reported by this contractor, FDA will publish a corrective action plan, the implementation of which will be reported on independently. This assessment has the potential to provide the FDA with invaluable feedback on how to improve efficiency and get to the bottom of consistently difficult problems. It will also allow outside stakeholders to hold FDA accountable for improving the Agency and providing even greater benefits to patients.

And as Malcolm said, those total time goals, as regulatory management in my company, I and my staff will be held accountable to those metrics as well. So thanks, Malcolm, for that support.

MR. BECKERMAN: Thank you very much. Our final industry panelist is Jen Bowman, Vice President for Policy and Regulatory Affairs at the American Clinical Laboratories Association.

MS. BOWMAN: Hi, everyone. I am Jen Bowman, and I'm VP for Policy at the American Clinical Laboratories Association and had the pleasure for the past, gosh, three or four months to be ACLA's representative to the MDUFA III negotiations following my predecessor at our organization, David Mongillo.

So first of all I would like to thank FDA, Dr. Shuren, Dr. Midthun, and Malcolm for all of the many hours that they've spent in this process and for allowing us to participate in the process, which I think was something that was -- you know, it was beneficial to both parties to have the dialogue.

So, to tell you a little bit about ACLA, the American Clinical Laboratories Association is a nonprofit organization created in 1971. We offer representation, education, information, and research to our members, and advocate for the laws and regulations that benefit the laboratory industry and patients. We promote public awareness about the value of laboratory testing and laboratory services in preventing illness, diagnosing disease, and monitoring medical treatment. In fact, 70% of treatment decisions are influenced by laboratory tests.

ACLA's members include 44 organizations that represent the diversity of the clinical laboratory industry. Those include independent clinical laboratories focused on genetic and

molecular testing services, end-state renal disease laboratory testing, and regional and national full-service labs, as well as anatomic pathology and hospital laboratories, all of those providing services in clinical laboratory testing. I should also note that all ACLA members do perform laboratory developed tests.

To address ACLA's participation overall in these negotiations, I have to say that participation by ACLA and our members in these negotiations, including any agreement that are reached by the parties as a result of the negotiations and any subsequent support of any such agreement through the legislative process, shall not constitute a waiver of any legal or equitable argument or relief to which ACLA and its members may be entitled with respect to the issue of potential FDA regulatory oversights of LDTs or clinical laboratories by FDA.

With that said, after a year and some months of negotiations, we are very pleased to say that the FDA did propose legislative language that gives the Secretary the authority to grant, at the Secretary's sole discretion, a waiver from or a reduction of fees if the Secretary finds that such a waiver or reduction is in the interest of public health.

And in the minutes to the MDUFA meeting, which are found online on FDA's website, FDA also stated its intent to exercise that authority to ensure that no additional laboratory developed tests or laboratories would be subject to user fees during the MDUFA III period due to changes in policy on laboratory developed tests.

And with that important piece of the legislative language in place, ACLA does fully support the final agreement. We support the commitment letter, the legislative language, and we will certainly also be working with our members on the Hill to advocate for support of the overall agreement and its hopefully consideration and passage by the Congress this summer.

Thank you very much.

MR. BECKERMAN: Thank you very much to each of our industry panelists. I could tell by -- I could tell by mixing things up that instead of having a panel up here to start, I've created mass confusion, so I apologize.

So does the FDA team have any clarifying questions for the industry panel?

MR. BERTONI: I have just one clarifying question for Elisabeth.

MS. GEORGE: Oh, no.

MR. BERTONI: Will you submit to me your 2013 individual performance plan so that I can see that you're being held accountable? And I'm just joking, of course.

MS. GEORGE: Of course I will, Malcolm. No problem.

MR. BERTONI: As long as that doesn't violate any confidentiality -- but thank you very much for your comment. No other questions.

MR. BECKERMAN: Okay. In that case I'd like to ask our industry presenters to return to the audience. We're going to proceed with the open comment period. And congratulations all of you on your nimbleness in avoiding the cords that we've got strewn around.

At this point, for the FDA panel, would it be more helpful to have you at the table or should we maintain the same -- well, let's keep the same structure.

For the audience and for folks on the phone, we've got several members of the FDA panel, Malcolm Bertoni from the Office of the Commissioner, Nathan Brown from the Office of Chief Counsel, Barbara Zimmerman from CDRH, and Kate Cook from CBER who are FDA panel. And rather than have them come up, given the layout of the room, I'm going to have them continue to sit in the front row.

We've got several people who registered for the open comment session. First up we have Andrew Sperling from the National Alliance on Mental Illness. And is Andrew around?

MR. SPERLING: Yes.

MR. BECKERMAN: Great. Andrew, you can go ahead and come up to the podium.

MR. SPERLING: Okay.

MR. BECKERMAN: I'd like to once again caution our speakers that you keep your remarks brief. We would appreciate it. We've got a 5-minute timeframe on the agenda, and so that's what we'd like to --

MR. SPERLING: I'll consume nowhere close to 5 minutes. I'll be very brief. Thank you.

MR. BECKERMAN: Thank you.

MR. SPERLING: Good morning. My name is Andrew Sperling. I'm the Director of Legislative Advocacy for NAMI, the National Alliance on Mental Illness. NAMI is the nation's largest organization advocating on behalf of people living with severe mental illness in their families.

We have an enormous stake in MDUFA. There are a number of devices, innovative devices and existing devices, that are used to treat conditions, serious mental illness conditions. Most notably, for treatment-resistant depression, they have nerve stimulation, deep brain stimulation, and for many patients with treatment-resistant depression, ECT is still an effective intervention that can help them cope with even suicidal depression.

So this is a very important issue for NAMI, and we want to express thanks to Malcolm and all the team at the FDA for engaging me and the patient organizations in the stakeholder meetings that we had. They were very informative. We learned a lot about how FDA does business, how CDRH does business, and we were very fortunate to be a part of that. And maybe in a few years, look forward to participating in the next MDUFA agreement and helping in monitoring the process of negotiations.

NAMI would like to express its support for the MDUFA agreement. We believe it's a big step forward in getting the FDA the resources it needs. We support the improved performance goals, the better methods for measuring progress and the quantitative goals both once an application is submitted and the information that comes prior to submission. We think this is a step in the right direction.

We are especially supportive of the provisions related to patient tolerance for risk. This is certainly a big issue for people that experience treatment-resistant depression. Their tolerance for risk is dramatically higher than people who have mild, episodic depression. And we believe it's critical that this is a part of the agreement and stays a part of the agreement when it goes through Congress.

And we are very encouraged with the provision that specifically required FDA to engage in significant consultations with patient and patient advocacy organizations. And it orders the FDA, you know, once this passes Congress, hopefully passes Congress, to engage patient advocacy organizations that represent not just individual patients, but patients across the spectrum of a disease. And so we encourage FDA to do that, and we look forward to working with FDA to implement MDUFA after it passes Congress.

Thank you.

MR. BERTONI: Thank you very much. No questions.

MR. BECKERMAN: Okay.

MR. SPERLING: Thank you. Appreciate that.

MR. BECKERMAN: And for each of our public commenters, if you'd be willing to wait until we just make sure there are no clarifying questions that would be great, but I think we're --

Thank you. Good. Next up is Jolene Chambers from the Failed Implant Device Alliance. Is Jolene here? Okay.

We also have registered Diana Zuckerman from the National Research Center for Women and Families?

DR. ZUCKERMAN: I'm Dr. Diana Zuckerman, President of the National Research Center for Women and Families. I'm very happy to have the opportunity to be here today. Thank you.

I'm speaking on behalf of myself, but also we are a very active member of the Patient, Consumer, and Public Health Coalition. Many of the nonprofit organizations that belong to that coalition have been actively engaged and concerned about MDUFA but are not able to be here today partly because of what's going on with the Supreme Court and partly because of legislative efforts on Capitol Hill and other pressing business.

So I can't speak for everybody in the coalition, but I do want to reflect the concerns that they've had, one of which is an article in *Consumer Reports* that is in the May issue but just was released this morning, so the title is "Dangerous Devices." And Consumers Union, which publishes *Consumer Reports*, has been active and concerned about the regulatory process and the role of MDUFA and the inadequacy of resources coming out of MDUFA.

So I want to spend a little bit of my 5 minutes talking about that. It was pretty clear to me that the industry panel is very happy, and a lot of the consumer groups are not feeling so good about this agreement. And our main concern really is the adequacy of resources under this agreement. And we understand that negotiation and compromise is necessary, but we are

particularly concerned because lobbying continues to go on in Capitol Hill, efforts are being made on Capitol Hill to add more work and pressure on CDRH as part of MDUFA legislation. And we don't see how the resources available under the slightly increased user fees will be adequate to handle all that additional work.

We agree that it's important for CDRH to provide useful, helpful information throughout the approval process and throughout the review process, but somebody has to pay for those resources. In comparison, as Paul Brown mentioned earlier, if you think of other regulatory agencies whose job it is to prevent disaster -- and the Nuclear Regulatory is one of those, the FAA is another -- their user fees are basically paying for the entire agencies. And those have no negotiation.

The user fees pay the salaries and all the resources needed by those agencies and the agencies do their job. In the ideal world, appropriations would pay for them, but if appropriations aren't going to pay, then the user fees have to be sufficient to pay.

And this actually reminds me -- I think an easy analogy are all-you-can-eat restaurants. It's very helpful for the FDA to know how much money they're going to get so that they can hire staff. We understand the importance of having a predictable amount of money coming in. An all-you-can-eat restaurant can do the same thing. They can have, you know, one price for whatever you eat. But there aren't very many all-you-can-eat restaurants that survive because people eat a lot at an all-you-can-eat restaurant.

So if you think of what the FDA does in their work, some applications are a lot more work than others. And when a product is cleared or approved and you then have to do postmarket, that's additional work. So if you have a lot of meetings before approval, a lot of meetings during the review process, and then additional work after, whether it's postmarket surveillance or managing a recall, we believe there needs to be additional user fees to pay for that additional work.

And we also think that -- we're very sympathetic to the fact that many device companies are small. And we think that under this agreement, the small device companies are paying more than their fair share and that the larger device companies are not paying their fair share. So we think that, you know, it would have made more sense to have larger increases, particularly in the PMA user fees. We think the 510(k) user fees are very small and that even the smallest companies can afford to pay more than that. And we're particularly concerned that the de novo review process only comes with a 510(k) user fee, it's my understanding. And yet a de novo review will be much more work, if done appropriately, much more work than a 510(k). So we're going to keep urging the FDA in the future to think more about the individual user fees instead of just the aggregate amount of money, to think about whether the companies that are requiring the most work both in terms of number of applications and complexity of work are paying their fair share.

And we will continue to work with Congress to try to improve the situation because we believe that all of our lives depend on the safety of medical products. And that means that our lives depend on CDRH having adequate resources to do their job the best way they can. Thank you.

MR. BECKERMAN: Thank you, Dr. Zuckerman. Are there any clarifying questions from FDA?

MR. BERTONI: Thank you for the comments.

MR. BECKERMAN: Okay. And our final registered open commenter is Eric Gascho from the National Health Council. Is Eric here?

MR. GASCHO: Yes.

MR. BECKERMAN: Would you like to come to the podium?

MR. GASCHO: Good morning. I'm Eric Gascho. I'm the Director of Government Affairs with the National Health Council. The National Health Council is a membership organization where we bring together stakeholders from across the healthcare community to help us meet our mission, which is to provide a united voice for patients with chronic diseases and disabilities and the family caregivers.

First, I'd like to thank you, Malcolm, and your team here at FDA for not only the opportunity to comment today, but all the other opportunities that we've had over the last year and a half or so to discuss this very important topic.

I will say that the NHC would like to express our support for the user fee program and for the current commitment letter and the current agreement. We believe that it will enhance efficiency, predictability, and timeliness, which will help us meet a shared goal, which is to bring safe and effective products to patients who need them.

I will spend the time here to discuss two provisions of the agreement that we're in support of. The first is with emerging diagnostics. We feel that this new field will help us get the right treatments to the right patients at the right time. And we look forward to seeing what the FDA plans to do with this program and working with you as it -- will become developed.

The second is with the benefit/risk. We thank you for not only the work that you've put into the agreement but also the work that you've been doing on it. The guidance that came out yesterday, we feel that this will help in increased transparency of the process and really help us better balance the benefits and risks for the different patients depending on where they are in the spectrum of conditions.

I will say that we are also looking forward to working with you. We appreciate that there is a part in there that talks about how you'll be working with the patient community to develop this program. I look forward to seeing how exactly that's going to happen, and we look forward to working with you. That's all.

MR. BERTONI: Thank you. No questions, but thank you very much for your comments here.

MR. BECKERMAN: Thank you, Eric. Are there any other comments from the room at this time? Okay. Seeing or hearing none, does the FDA team have any additional questions for the stakeholders? All right.

In that case I'm going to turn the podium to Malcolm Bertoni for some closing remarks.

MR. BERTONI: This will be brief. I do want to thank everyone again for taking time out of your busy schedules to come here today to offer your comments and to hear the comments of

others. This is an important program clearly that's been discussed here. We certainly appreciate your comments, and we appreciate that there is a diversity of opinions in some aspects of this. I was pleased to see that there is a consensus around some aspects of the draft recommendations as well.

And we certainly look forward to receiving your written comments to the docket as soon as possible, but no later than Monday, April 16th. And we will certainly be giving those careful consideration and then working as swiftly as we can to get the recommendations, the final recommendations up to Congress so that they can continue their important work.

I think it's great to hear so many people talk about the importance of timely access to safe and effective medical devices and technology and diagnostics to patients because patient safety and health and the public health is really what this program is all about.

Thank you very much for your participation.

MR. BECKERMAN: I'm glad I didn't have to enforce the 5-minute limit on that one. I'd just like to, in closing, echo Malcolm's thanks to everyone for coming or for tuning into the webcast. Thanks especially to our panelists and speakers for their thoughtful comments and also to the MDUFA team for planning this meeting, especial Cindy Garris and Toby Love.

One final reminder: the *Federal Register* Notice that announced this meeting included instructions for how to submit your comments to the docket. Those instructions, as I indicated, are at the bottom of the agenda, the handouts. So you've got until April 16th, 2012, to submit your comments. The FDA is going to consider all comments either received through the docket or made during this meeting.

And with that, I would like to thank you once again for your valuable feedback and interest in the program and adjourn the meeting. Thank you.

(Whereupon, at 11:51 a.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

MEDICAL DEVICE USER FEE PROGRAM PUBLIC MEETING

March 28, 2012

Washington , D.C.

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health.

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TIMOTHY J. ATKINSON, JR. Official Reporter

Source: Dear Colleague:

The transcript from the March 28th MDUFA public meeting and the presentation that was given by Mr. Malcolm Bertoni, Assistant Commissioner for Planning, can now be viewed on the MDUFA meeting webpage at:

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm299822.htm

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