

UNITED STATES FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE AND USER FEE UTILIZATION ACT  
PUBLIC MEETING

Monday, April 30, 2007  
Silver Spring, Maryland

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Commission

20 PUBLIC SPEAKERS:

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1 P R O C E E D I N G S

2 (12:04 p.m.)

3 DR. SHUREN: Go ahead and get  
4 started. Good afternoon. I'm Jeff Shuren,  
5 the Assistant Commissioner for Policy at the  
6 Food and Drug Administration, and I'd like  
7 to invite you to the Medical Device User Fee  
8 and Modernization Act public meeting. On  
9 behalf of the FDA, we look forward to a very  
10 informative and constructive meeting.

11 Before I begin, I'd like to review  
12 a few housekeeping issues. We have our FDA  
13 panel here at the front of the room. We've  
14 also set aside some seats for our registered  
15 speakers in the front as well. Each speaker  
16 will give presentations during the afternoon  
17 session. These presentations will last no  
18 longer than 15 minutes.

19 For efficiency, we're just asking  
20 that folks hold any of their questions until  
21 the public session, and we'll address them  
22 at that time. We also ask that those who do

1 wish to speak sign up by 1:30 for the open  
2 public session. And lastly, I want to remind  
3 everyone that the docket will remain open  
4 until May 18th, and you can submit written  
5 comments on the issues discussed today until  
6 that date.

7           Let me ask, are folks hearing an  
8 echo in the room or is the sound okay? The  
9 sound is okay? Okay. All right. There will  
10 be a transcript available, and copies of the  
11 presentation will be posted up on our website  
12 on the dockets website. Bear with us. It  
13 will be certainly a few days before the  
14 transcript gets posted.

15           Now I'd to introduce our FDA panel.  
16 Working down from the end is Anne Kirchner,  
17 Don St. Pierre, Donna-Bea Tillman, Linda  
18 Kahan, Dan Schultz, Diane Maloney, and Martha  
19 Louviere, all from the FDA. The registered  
20 speakers for today are Andrew Whitman from  
21 the Medical Imaging and Technology Alliance,  
22 a division of NEMA; Sibylle Zitko, Delegation

1 of the European Commission; Fred Freedman  
2 from the Dental Trade Alliance; Kelly Slone  
3 from National Venture Capital Association;  
4 Mark Leahey from the Medical Device  
5 Manufacturers Association; and Janet Trunzo  
6 from the Advanced Medical Technology  
7 Association.

8 I'd like to begin our meeting now  
9 by introducing the director of the Center  
10 for Devices and Radiological Health at FDA,  
11 Dr. Daniel Schultz. Dr. Schultz will be  
12 giving the opening remarks. Following that,  
13 I will come back up to the podium and walk  
14 you through the legislative recommendations  
15 that we have presented to Congress.  
16 Dr. Shultz?

17 DR. SCHULTZ: A little tight  
18 quarters up here. Not so tight out there.  
19 I mean, you're lucky.

20 (Laughter)

21 DR. SCHULTZ: Good afternoon. It's  
22 my pleasure to be here and my goal today is

1 basically to say thank you. I want to say  
2 thank you to all the people that worked so  
3 hard in getting this proposal together for  
4 what we hope will be a smooth and rapid  
5 reauthorization of the MDUFMA legislation,  
6 and I also want to say thank you to the  
7 people that implemented this legislation,  
8 namely those in the Center for Devices and  
9 Radiological Health, as well as those in the  
10 Center for Biologics.

11 I can say, at least from my vantage  
12 point, that this legislation has been an  
13 unqualified success. And let me tell you why  
14 I say that. Number one, we met almost all  
15 of the goals. The 77 goals that were put  
16 forward have all been met during the first  
17 part of this legislation. And number two,  
18 and perhaps even more importantly, we managed  
19 to keep the financial part of this separate  
20 from the review part. So the agency  
21 continues to carry out its mission of  
22 ensuring safe and effective medical products,

1 as well getting the resources necessary to  
2 accomplish those goals.

3           But more importantly, I think that  
4 there are certain things that have happened  
5 that may not be quite so obvious, and I'd  
6 like to touch on a few of those. I believe  
7 that this legislation has really allowed us  
8 to set the groundwork for what this center,  
9 what the two centers, and what the agency  
10 are going to look like in the years to come  
11 in terms of being able to deal with the  
12 increasingly complex and diverse technology  
13 that we're going to be looking at. A big  
14 part of this is our ability to hire experts  
15 throughout the Center in all areas of the  
16 scientific enterprise and at all different  
17 levels. That has been critical to making the  
18 program a success thus far and will continue  
19 to be critical to fulfilling our mission in  
20 the future.

21           The second aspect is our ability  
22 to bring expertise in from outside the

1 Center. This was something that a number of  
2 constituents expressed a lot of interest in.  
3 And using the resources provided by MDUFMA,  
4 we've created a medical device fellowship  
5 which continues to thrive, and I believe  
6 will be a model for how this type of use of  
7 outside expertise will be done by the entire  
8 agency and perhaps even beyond the FDA. This  
9 fellowship has allowed us to bring in a  
10 number of experts again at various levels and  
11 various area of scientific expertise that  
12 we may not have in house that will allow us  
13 to address specific scientific problems and  
14 regulatory problems and questions.

15 The other thing that I think again  
16 goes a little bit unnoticed is the fact that  
17 we have made incredible progress in terms of  
18 shoring up our IT infrastructure. A couple  
19 of examples: We've begun to address the  
20 issue of electronic submissions through our  
21 Turbo 510(k) program. We have created a  
22 tracking system, which has allowed us to

1 track submissions when they come in the door  
2 to the time then they're acted upon. And  
3 this tracking system not only has allowed us  
4 to do a more efficient job in terms of device  
5 review, but it has also served as a model for  
6 other tracking systems throughout the Center.  
7 Again, the idea is that we build something  
8 that can be useful for one enterprise and  
9 then be able to use that model for other  
10 things as well.

11 Another area that we've made  
12 significant progress is in the area of  
13 communication. Communication involves a  
14 number of different aspects. One of those is  
15 providing adequate guidance to the industry.  
16 We've put into place a guidance priority  
17 system which is working, which is allowing  
18 us to put out more guidances and provide the  
19 information necessary for people to submit  
20 the right information so that we don't have  
21 to go multiple rounds on every submission.  
22 That's of critical importance. We've also

1 upgraded our website to the extent that we  
2 now have a much more user-friendly website,  
3 and will continue to have a much more  
4 user-friendly website to provide information  
5 to industry as well as to the general public.

6           So that's what we've done so far.  
7 But I think a large part of what this meeting  
8 is about is to talk about the future, and,  
9 again, I want to thank those who have worked  
10 terribly hard over the last few months to  
11 put this proposal together, and a couple of  
12 things again from my perspective as to why we  
13 can look forward to building on what we've  
14 done through the first five years into the  
15 second phase of this program.

16           Number one, the fee structure.  
17 The fee structure is more stable and more  
18 equitable. And I think this will allow all  
19 of us to do the kind of planning that we need  
20 to be able to do moving forward, both from  
21 the industry side as well as from the agency  
22 side.

1                   Number two, the performance goals.  
2     The performance goals that were constructed  
3     the first time around, while I think well  
4     intentioned, I think were overly complex. I  
5     think one of the things that we've learned  
6     is that simple is probably better, and the  
7     goals that we've put forward for the second  
8     proposal are much simpler, and I think really  
9     get to the core of what we're all about,  
10    which is to get safe and effective new  
11    technologies to the marketplace as quickly  
12    as possible.

13                   What about third-party inspections?

14    Well, I think again we learned a lot from  
15    the first five years of this program, and  
16    I think the proposals that are being put  
17    forth now will simplify this, make it more  
18    user-friendly, and still allow FDA to do  
19    those inspections which it needs to do to  
20    ensure the safety and effectiveness of  
21    medical devices.

22                   You're going to be hearing a lot

1 this afternoon about the details of the  
2 legislation, so I'm certainly not going to do  
3 that. But I wanted to give you a little bit  
4 of perspective again from where I sit as  
5 director of the Center for Devices and  
6 Radiological Health, and to tell you a little  
7 bit about what we've done and what we plan  
8 to do. As I see it, the future for medical  
9 devices and medical device regulation is  
10 extremely bright, and this legislation has  
11 helped us to ensure that it will be bright  
12 moving forward, and I just want to say thank  
13 you to all of those who've worked so hard to  
14 make this happen. Thanks very much.

15 DR. SHUREN: Thanks, Dan. Clearly,  
16 Dan and I need more rehearsal time together.

17 (Laughter)

18 DR. SCHULTZ: Get rid of the pole.

19 DR. SHUREN: That's right. Well,  
20 again, welcome everyone. What I'd like to  
21 do is to give you a little bit of background  
22 on MDUFMA, walk you through the proposed

1 legislative recommendations we put out in a  
2 Federal Register notice, and then talk to you  
3 about the next steps we'll take to finalize  
4 those recommendations before we send the  
5 final package over to Congress for their  
6 consideration.

7           So, MDUFMA I, the goals here were  
8 to develop a sustainable review program to  
9 increase predictability in review times and  
10 increase timeliness in the review process.  
11 And the overall goal was to get safe and  
12 effective medical devices to patients and  
13 practitioners more quickly.

14           Critical here is that the FDA  
15 standards do not change. What MDUFMA is  
16 about is providing additional resources to  
17 the agency to make improvements in its review  
18 process. But the review standards do not  
19 change. Now MDUFMA I was amended, a big  
20 amendment in 2005 called MDUFSA, another  
21 acronym. But what I want to do is just give  
22 you the basic mechanics of what the law looks

1 like today and then tell you about some of  
2 the challenges we've encountered and what  
3 our recommendations are to address those  
4 challenges.

5           So first off, what MDUFMA does is  
6 it gives the agency additional resources  
7 through appropriations and user fees. And  
8 right now, about 83 percent of the costs of  
9 our device review program are covered by  
10 appropriations, and 17 percent of it comes  
11 from user fees. The historical experience in  
12 our appropriations has been that they've gone  
13 up for the device program at an annual rate  
14 of about 3-1/2 percent each year. And  
15 user fees under MDUFSA got locked in at an  
16 increasing rate of 8-1/2 percent for 2006  
17 and 2007. MDUFMA provided a variety of  
18 fee waivers and fee discounts for small  
19 businesses, and we'll come back to that in  
20 a few minutes. There were also some other  
21 waivers that anyone can take advantage of,  
22 such as if you are manufacturing a device

1 for a pediatric indication.

2           There are triggers that actually  
3 require that the agency receive a certain  
4 amount of money and that the agency spend a  
5 certain amount of money on device review and  
6 inspection to keep the program going. There  
7 are many performance goals. As you heard  
8 from Dr. Schultz, it was fairly complex.  
9 We had 77 quantitative goals and eight  
10 qualitative goals. MDUFMA created a  
11 third-party inspection program for  
12 surveillance inspections for good  
13 manufacturing practices. There were a  
14 number of provisions that pertain to the  
15 reprocessing of single-use devices, and it  
16 created an Office of Combination Products.

17           You can think about MDUFMA I as  
18 ramping up the program. Essentially it was  
19 about increasing the size of the review  
20 program through an increasing amount of  
21 resources, funding provided to the agency,  
22 and in return there would be improved

1 timeliness of review. And, in fact, the  
2 goals for MDUFMA I got progressively more  
3 challenging.

4 In MDUFMA II, now that we've built  
5 up that critical mass, the plan for MDUFMA II  
6 is to maintain a stable program, ensure there  
7 are adequate resources to keep the program  
8 that we have today in 2007. We would  
9 continue to have improved performance, and  
10 we would essentially fine tune the user fee  
11 program.

12 The key challenge from FDA's  
13 perspective is that the performance goals  
14 have been complex, and they've had some  
15 unintended consequences. And I'll walk you  
16 through that in just a minute. The  
17 third-party inspection program has not been  
18 the success we would like for it to have  
19 been. And the agency currently lacks  
20 predictable and stable user fee funding. So  
21 to address that, the goals that the agency  
22 had walking into reconsideration of MDUFMA

1 were to simplify the performance goal  
2 structure, to make the third-party program  
3 workable, and to provide adequate and  
4 predictable funding for FDA to maintain  
5 a stable device review program.

6           So our recommendations for  
7 legislation, as you'll see in the Federal  
8 Register notice we put out just about two  
9 weeks ago, cover performance goals. They're  
10 broken out into quantitative and qualitative.  
11 We address funding through user fee revenues,  
12 the amount we get, and the user fee  
13 structure, how those fees are actually  
14 apportioned. There are some additional  
15 small business fee reductions, and there  
16 are some recommendations for changes in the  
17 third-party inspection program.

18           We think MDUFMA II will have some  
19 very important benefits to the public health.  
20 First off, patients and practitioners will  
21 have access to safe and effective medical  
22 devices more quickly. And we'll get there

1 through continued improvement in device  
2 review times, as well as greater transparency  
3 in the review process. We plan to be a lot  
4 more open about what we are doing, to the  
5 entire public, not just to industry.

6 MDUFMA II will also give the  
7 agency the resources it needs to maintain  
8 cutting-edge scientific expertise necessary  
9 to provide the timely review, and to ensure  
10 the safety of increasingly complex devices of  
11 tomorrow, because also the funding we talk  
12 about of an appropriations does not just go  
13 for device review. It's also for device  
14 safety. It goes for the whole program. In  
15 fact, the scope of MDUFMA covers a variety of  
16 device safety activities. So we'll get there  
17 through adequate and stable funding for the  
18 agency.

19 And then lastly, MDUFMA II  
20 would allow the FDA to better focus its  
21 inspectional resources on the higher-risk  
22 devices, and we would get there by enhancing

1 our third-party inspection program.

2           So let me first turn to the  
3 performance goals. This chart is just to  
4 give you a flavor of what we've been dealing  
5 with. Current performance goals fall into  
6 two buckets. There are decision goals.  
7 That's what we decide at the very end of the  
8 day. For example, are we going to approve  
9 an application or not approve it? And then  
10 there are cycle goals. Those are sort of  
11 interim steps along the way. For example,  
12 if we send out a formal request for more  
13 information, if it's for a pre-market  
14 approval application, those are the  
15 applications for the higher-risk, more  
16 complex devices, we would send out a major  
17 deficiency letter. So there's actually a  
18 goal for when we would send out that letter.  
19 That's a cycle goal.

20           And the problem we ran into with  
21 these is that by focusing on trying to meet  
22 the cycle goals, sometimes that interfered

1 with our ability to have a back and forth, an  
2 interaction, with the sponsor, try to work  
3 out some of the information requests we  
4 needed, some of the additional analysis we  
5 may need, in a more informal way. And in an  
6 effort to meet those cycle goals, we really  
7 cut down on that interaction. We don't think  
8 that that was very productive -- something we  
9 want to change in MDUFMA II. Also because  
10 there are so many goals we're trying to focus  
11 on, we're really missing the big picture,  
12 which is ultimately the decision goals,  
13 because that's what makes the difference  
14 for timely review.

15 So what we are proposing is  
16 the following: First off is continued  
17 improvements with current staffing. How  
18 do we get there? Well, MDUFMA I, as I  
19 mentioned, was about building up the program,  
20 bringing on more people. Well now those  
21 people have been on board, they have been  
22 trained, and so we now have a very well

1 tailored, very expert set of staff, and we  
2 expect to see now return on the investments  
3 we've made in MDUFMA I. We'll also continue  
4 to put in place efficiencies through  
5 investments in our IT systems and other  
6 actions we would take.

7           For the goals themselves, first  
8 off, we'd eliminate the cycle goals.  
9 Secondly, we're going to create two-tiered  
10 decision goals, one goal that's earlier on,  
11 meaning that we'll make a decision within a  
12 certain number of days on a certain percent  
13 of those applications, and then a later goal,  
14 which is that we'll make a decision on a  
15 greater number of those applications at a  
16 later time. And lastly, there are some new  
17 goals for application types for which they  
18 weren't goals in the past.

19           What I've put up here, this is  
20 actually up on our website, so I'm not going  
21 to walk you through all the goals. I just  
22 want to highlight a few things. There's a

1 comparison between MDUFMA I and MDUFMA II,  
2 and you'll see, some of these there were no  
3 goals in MDUFMA I and now there are new ones  
4 in MDUFMA II. But I just want to point out  
5 on the right side here, for example, you'll  
6 see some of these are a lot tougher than we  
7 had before. Three lines down you'll see for  
8 expedited PMAs that we would make a decision  
9 50 percent of the time in 180 days. This  
10 goal wasn't there before. Before, we treated  
11 all PMAs the same.

12 Expedited PMAs are the ones for  
13 the most innovative devices. They're also  
14 often the most complex devices. But because  
15 they're the ones we know the least amount,  
16 they often take the most amount of work. But  
17 we're still going to try to make a decision  
18 in 180 days 50 percent of the time, and for  
19 the later goal, we're actually moving that  
20 down from 90 percent and 300 days to 90  
21 percent and 280 days. And as you start to  
22 shave off more time, it becomes more and more

1 challenging to get there, but we do think  
2 with the staff we have on board we can do  
3 that.

4           The other thing I want to point out  
5 on the goal here on 180 day PMA supplements,  
6 it may look a little confusing. The FDA is  
7 going from 90 percent making a decision 180  
8 days to 85 percent? Doesn't it look like  
9 performance is getting worse? Well, the  
10 original goal was actually a combination of  
11 a decision goal and a cycle goal, and we're  
12 changing this so that the goal right now is  
13 only a decision goal. There's nothing really  
14 interim about it.

15           So in the past, if we would sort  
16 of ask for more information, we'd have to do  
17 that by essentially, if the supplement was  
18 incomplete, by making it not approvable.  
19 And in essence, we're resolving that issue  
20 now. We will go out and now put out a major  
21 deficiency letter, so the process would  
22 continue along, and the only thing we get

1 credit for is making that final decision  
2 based on all the information. So we do think  
3 it is a more challenging goal.

4 For the qualitative goals, they  
5 break down as I've listed them here on the  
6 slide, and I'll just walk you through them  
7 very quickly. I talked a minute before about  
8 how in MDUFMA I, it was much more challenging  
9 to have informal interactions with the  
10 sponsor. And we think it is important to  
11 have that kind of dialogue because there may  
12 be a number of issues we can work out with a  
13 phone call or an e-mail rather than having to  
14 send a formal request for information. And  
15 that's what interactive review is. In fact,  
16 we'll put a guidance to lay out our thoughts  
17 in terms of how interactive review would  
18 actually be conducted.

19 Maintenance of performance means  
20 that for those activities where we don't  
21 have a goal, we will continue to at least  
22 maintain our current performance. Certainly,

1 no one's going to be upset if we do better.

2           Guidance document development.

3 Well, right now we have a fairly established  
4 process for getting input from the public on  
5 our guidance documents, but what we do is we  
6 put the guidance document out when drafting  
7 it for comment. What we're going to do now  
8 is actually put out a list of the guidances  
9 we think we may work on in the next year  
10 or so and ask for comment on that, namely  
11 does it makes sense to be working on these  
12 guidances? Is there another guidance  
13 we should work on, and do you have any  
14 preliminary thoughts on what the guidance  
15 would cover? And we'll take that into  
16 account. We'll still keep the same process  
17 we currently have in place, which is we'll  
18 develop a draft and we'll put that out for  
19 public comment before we go to a final. So  
20 this is in addition.

21           Quarterly updates. We will  
22 provide to the public a report card on our

1 performance every quarter. We're also going  
2 to track our performance in total days, so  
3 not just how much time it took FDA for its  
4 review, but the total time for when the  
5 application came in to when, in fact, we made  
6 a final decision. So that also includes  
7 industry's time. It will be a better measure  
8 on how long it may be taking for products  
9 coming into the agency to actually to get  
10 the nod to go forward and go on the market.

11 For meetings, we find that meetings  
12 are incredibly helpful for working things  
13 out with sponsors. Industry finds it very  
14 helpful as well. When they're developing a  
15 product, what kind of information do they  
16 need to collect and other activities? What  
17 this simply is is a commitment to continue to  
18 try to schedule meetings in a timely fashion,  
19 because we're finding the number meetings  
20 were increasing due to what we industry find  
21 a valuable interaction.

22 And lastly, for reviewer training

1 we will use user fees, if appropriate, and we  
2 have the funding to do it, to invest in  
3 training of our reviewers, because we think  
4 it's important and industry thinks it  
5 important that we maintain our reviewers  
6 with cutting-edge expertise.

7           We have a goal that pertains to  
8 imaging devices. A number of these will use  
9 a radiopharmaceutical or a contrast agent.  
10 We call these concomitant products, because  
11 it's one product being used with another  
12 product, and we are going to develop a  
13 guidance that sort of clarifies that process  
14 and the procedures that we use, including  
15 data for the review of those imaging  
16 devices when used with contrast agents  
17 or radiopharmaceuticals.

18           There are a number of goals that  
19 pertain to in vitro diagnostics, essentially  
20 lab tests. And why the focus? Well, you've  
21 heard a lot about personalized medicine,  
22 about being able to target treatments to

1 individuals. But really the pathway to get  
2 there is that you need safe and effective  
3 tests to identify who are the people who are  
4 going to be high responders for treatment,  
5 who are the people who may be at greatest  
6 risk for adverse events. So there's a little  
7 bit more of a focus on qualitative goals for  
8 in vitro diagnostics this go around.

9           And the agency plans to put out a  
10 variety of guidances or revise some existing  
11 guidances in some important areas, including  
12 ones that address bio threats and pandemic  
13 influenza, and emerging infectious diseases.  
14 In addition, if you have a lab test in a  
15 laboratory, they're subject to two regulatory  
16 regimes, one by FDA, and we actually focus  
17 on the device and the manufacturing of the  
18 device, the test. And then there's the  
19 Clinical Laboratory Improvements Act that  
20 CMS, the Centers for Medicare and Medicaid  
21 Services oversees, and that actually goes  
22 to the quality of the lab itself and the

1     laboratorium. Well, FDA has a function here  
2     in CLIA. We actually categorize the devices.  
3     We determine are they waived, are they  
4     moderate complexity or high complexity, and a  
5     variety of requirements are imposed depending  
6     on that categorization. Right now, when we  
7     make the determination, we do it after we've  
8     looked at the application. And so if we're  
9     going to do a waiver, and these tend to be  
10    when there's a 510(k), the devices that are  
11    of lower risk, we first want to know a lot  
12    more about that device before we make a  
13    decision. So we'll do the 510(k) and then  
14    we'll do the look at the waiver request.  
15    We're now going to conduct a pilot program  
16    to see if we can perform those activities  
17    simultaneously.

18                 We will look at a number of  
19    low-risk IVDs to see if they might be  
20    exempted from pre-market review. This is  
21    pretty standard operating procedure for  
22    devices. But, you know, when something is

1 brand new and comes on the market, we don't  
2 know a lot about it. It might be high risk.  
3 It may be a class III device. A lot of  
4 requirements go to it. As we gain more  
5 experience with it, we may downclassify it  
6 to class II. And for some devices where we  
7 have a lot of experience and it's very, very  
8 low risk, they wind up being exempted from  
9 pre-market review, although they still have  
10 to follow a variety of other requirements  
11 under the Act.

12           And then lastly, we're going  
13 to actually review our pre-IDE program,  
14 essentially where we are working with  
15 sponsors during the development of in vitro  
16 diagnostic, and we're going to look at that  
17 program in terms of its effectiveness and  
18 efficiency.

19           Third-party inspection program.  
20 Under third-party inspection, the agency  
21 can accredit a third party -- what we call  
22 an accredited person -- and they can conduct

1 one of these surveillance good manufacturing  
2 practice inspections. Essentially, this is  
3 where there isn't necessarily a problem,  
4 but the law actually says we're supposed to  
5 conduct these inspections every other year,  
6 just to see if people are, in fact, compliant  
7 with GMPs.

8           The law right now provides very  
9 strong protections against conflict of  
10 interest. The only firms who can participate  
11 are really the good players, those who have a  
12 good track record. And FDA still retains the  
13 ability to go in and inspect that firm for  
14 cause, if there is a need. And the value of  
15 third-party inspection is that it allows the  
16 agency to focus on those devices that are  
17 higher risk or the ones we may have the most  
18 concern about. So we think that there can  
19 be tremendous value if the program works out  
20 right. However, our experience to date has  
21 not been so positive. There's been limited  
22 industry participation. So far, only 14

1 medical device firms have petitioned FDA to  
2 use an accredited person, and 3 of those  
3 inspections have been conducted so far.

4           There's a cost involved to the  
5 agency. We've spent just shy of \$3 million  
6 to actually set it up, to do the training,  
7 and of course there's also an auditing  
8 function here as well. Once an accredited  
9 person is out there, we're still going to do  
10 followup to make sure they're doing a good  
11 job.

12           And the reason we think there are  
13 problems is because there are number of  
14 disincentives currently built into the  
15 program. It's a fairly cumbersome process  
16 to go through. And the ability to use an  
17 accredited person is fairly limited. So we  
18 want to address those in MDUFMA II. And what  
19 we have proposed is first off to streamline  
20 the administrative burdens. Right now, if  
21 you want to use an accredited person, you  
22 have to ask the FDA, and we wind up having to

1 clear that individual, even though there may  
2 not be an issue. What we're going to do  
3 instead is we're recommending that you notify  
4 the agency. If we have an issue, we may come  
5 back. But if no issue, certainly by 30 days,  
6 you could proceed and use that accredited  
7 person. You don't need to then wait for FDA  
8 to clear that petition.

9           Secondly, we would expand  
10 participation. Right now, you can only have  
11 two consecutive inspections by an accredited  
12 person. After that, you have to wait on FDA.  
13 We think we can provide a greater incentive  
14 if we allow an unlimited number of  
15 inspections as long as you continue to be a  
16 good player. If there's a big problem, then  
17 you wouldn't be able to use the program. And  
18 that's the way the program is designed right  
19 now. And, of course, the agency would  
20 still retain the ability to do for-cause  
21 inspections.

22           And then lastly, something a

1 little bit new. This isn't exactly through  
2 accredited persons, but this is now to say,  
3 you know what, a lot of these companies,  
4 where they market in the U.S. and they market  
5 in another country, well, when they market  
6 to the other country, they have to follow  
7 the laws of those countries. And their  
8 requirements for manufacturing may be a  
9 little bit different than ours. However, the  
10 information gathered can be incredibly useful  
11 to the agency. So what we would allow now is  
12 that if you had one of those inspections and  
13 it was to a standard that the agency found  
14 acceptable, not equivalent, but one where  
15 the information may be useful, we would  
16 accept those reports, and we would use it in  
17 prioritizing which firms we would inspect.  
18 So it doesn't mean that you're completely out  
19 of getting an inspection, but by having more  
20 information, the agency may decide that you  
21 can move lower on the priority list.

22 Now let me just turn to funding and

1 fee structure. Remember I mentioned before  
2 the agency needs adequate resources and  
3 stable resources. So funding is about  
4 adequacy, and the fee structure is how we  
5 instill stability. Let me just walk you  
6 through that. The challenge the agency has  
7 faced is that over the last five years the  
8 costs for an FTE, to actually have a person  
9 on board, has gone up 5.8 percent a year.  
10 And in fact the cost for device review  
11 programs, you take the people, you take the  
12 costs for infrastructure, you add it all  
13 together and that's been going up at a rate  
14 of 6.4 percent a year. A lot of that has to  
15 do with our costs of coming right here, to  
16 White Oak.

17           And the big drivers are really  
18 outside of the agency's control. They're  
19 first off statutorily mandated payroll and  
20 benefits, they're the rent we pay here at  
21 White Oak, and they're the contracts we have  
22 for security. Security costs have gone up in

1 the post-9/11 era. So we don't have a lot of  
2 control on those increased costs, but we have  
3 to deal with it. And if those costs aren't  
4 met, then effectively we wind up downsizing  
5 the program. And what we have found is that  
6 our funding needs so far haven't really kept  
7 pace with our costs. So we're hoping to  
8 address that in MDUFMA II.

9           What we did in figuring out what we  
10 needed is we said, all right, what's the cost  
11 of the program we have, and if the costs are  
12 going up at 6.4 percent, what would they be  
13 over the five years of MDUFMA II. And that  
14 number is about \$1.25 billion. And that's  
15 the five years of MDUFMA added together. And  
16 that would allow us to maintain the current  
17 program. So when we figured out how to  
18 apportion it, we said, all right, we know  
19 that historical average for appropriations,  
20 which was 3-1/2 percent, so if that continued  
21 the same, then from user fees we'd be  
22 expecting \$287 million over the five years

1 of MDUFMA II, so that's the total amount.

2           And what that would change is  
3 that -- remember I mentioned right now MDUFMA  
4 I appropriations make up 83 percent of our  
5 funding? Well now we'll just go to 77  
6 percent, and user fees, instead of accounting  
7 for 17 percent of our costs, would now cover  
8 23 percent of our costs on average.

9           So that's the funding amount.

10 That's how much we need. How do we ensure  
11 stability? Well, one of the problems we've  
12 found is user fees right now are only tied to  
13 applications, and the number of applications  
14 can fluctuate from any given year, and  
15 therefore we're never sure how much fundings,  
16 how much revenues and user fees we would  
17 collect from one year to the next. Also, the  
18 applications that have user fees -- not all  
19 the applications have user fees. So we do  
20 work, but we don't necessarily have a fee  
21 tied to it. And we have found that the few  
22 revenues have been chronically short of our

1 expectations. This is not a fault of anyone;  
2 it's just the nature of how we developed  
3 MDUFMA I.

4           So what we're recommending in  
5 MDUFMA II is to create some new fees.  
6 They'll go for applications that currently  
7 don't have fees, but the big change is this  
8 establishment registration fee. It's for  
9 each of those establishments that actually  
10 makes a device, would pay a fairly nominal  
11 fee. Starting in fiscal year 2008, we're  
12 proposing that fee would be \$1,706. But  
13 because there are so many facilities we would  
14 expect that would pay that fee, roughly  
15 around 13,000, that can provide a lot of  
16 revenue, but also a lot of stability. And as  
17 a result, all the fees that currently apply  
18 to applications in MDUFMA I would go down  
19 in MDUFMA II. In fact, most of them would  
20 stay below the 2007 levels all the way  
21 through 2012.

22           We would also put in here

1 predictability for industry. Just like the  
2 agency needs predictability as to the funding  
3 we receive, there's value to industry to have  
4 predictability on the fees that they pay so  
5 that they can manage their businesses more  
6 effectively.

7 I mentioned before, MDUFMA I has  
8 some breaks for small businesses. We're  
9 going to add to those. Right now, you can  
10 get a waiver if you're a small business  
11 defined as having \$30 million or less in  
12 annual sales or receipts. Your very first  
13 PMA, that pre-market approval application, is  
14 waived, and we would continue that. But for  
15 small businesses as defined by \$100 million  
16 in annual sales and receipts, you currently  
17 are eligible for a fee discount, and we're  
18 going to increase those in MDUFMA II. So, if  
19 you submit a PMA or related supplement, you  
20 used to pay 38 percent of the fee, it would  
21 now be 25 percent. And for 510(k)s, it used  
22 to be 80 percent of the total fee, now it's

1 50 percent. So you combine that with the  
2 lower fees, it's a fairly substantial break.

3 We will also make it easier for  
4 foreign businesses to qualify as small  
5 businesses. One of the problems is that if  
6 you're a small business, the way you qualify  
7 is you submit a federal tax return, and you  
8 pay federal taxes. But if you're a business  
9 in another country, you don't normally submit  
10 a tax return to the U.S. You'd wind up  
11 paying U.S. taxes, and you may not be doing  
12 business here. So what we are going to do to  
13 redress this is that we would allow the small  
14 business to get certified by their national  
15 taxing authority, and their chief financial  
16 officer would certify that all the affiliates  
17 had been certified by the national taxing  
18 authority, and send that information to the  
19 agency. We will provide more details on  
20 what, in fact, folks should do through a  
21 Federal Register notice, should this proposal  
22 be enacted into law.

1           I mentioned there are some  
2 triggers. There's an appropriation trigger  
3 and there's two spending triggers. We think  
4 that the success of MDUFMA II does depend on  
5 providing increased funding for the agency  
6 from appropriations and user fees, and the  
7 MDUFMA I trigger for appropriations can be  
8 helpful here for trying to ensure the agency  
9 gets adequate appropriated dollars. So we  
10 are proposing to extend the current triggers  
11 in MDUFMA I through the life of MDUFMA II.

12           So that's the package. Where do  
13 we go from here? Well, we've got the public  
14 meeting today. There's an opportunity  
15 to hear from you all about those  
16 recommendations. The public docket is open  
17 until May 18th, and we will review all the  
18 comments that are submitted, and then based  
19 on those comments, we may make some changes  
20 to those recommendations, and ultimately  
21 put out a final set of recommendations to  
22 Congress thereafter.

1           And as you know, there's already a  
2 bill on the Senate side that's going through  
3 and will actually hit the Senate floor very,  
4 very soon for consideration this week. But  
5 the House still has the opportunity to act,  
6 and if there are any differences, those will  
7 be addressed in conference. So for those  
8 who may wonder does it really matter if I  
9 provide input into these recommendations?  
10 Absolutely, because we're just in the  
11 beginning stages for the legislative  
12 process, so your comments really can make a  
13 difference. And I encourage you, if you do  
14 have an opinion, to please share it with  
15 the agency.

16           With that, let me stop, and we'll  
17 turn to our registered speakers. Let me  
18 first ask Andrew Whitman. All set?

19           MR. WHITMAN: Good afternoon. I'm  
20 Andrew Whitman, vice president of the Medical  
21 Imaging and Technology Alliance, a division  
22 of NEMA. Thank you for providing me the

1 opportunity to address reauthorization of  
2 MDUFMA or MDUFMA II. MITA is the collective  
3 voice of medical imaging equipment  
4 manufacturers, innovators, product  
5 developers, representing 90 percent of the  
6 global market for X-ray imaging, computed  
7 tomography, radiation therapy, magnetic  
8 resonance, diagnostic ultrasound, nuclear  
9 imaging, and medical imaging informatics  
10 equipment.

11 Medical imaging modalities have  
12 played a critical role in advancing the  
13 quality of care for patients by speeding time  
14 to diagnosis and offering better treatment  
15 options with faster recovery.

16 Imaging has become a standard of  
17 modern care for virtually all major medical  
18 conditions and diseases, including cancer,  
19 stroke, heart disease, trauma, and abdominal  
20 and neurological conditions. For this  
21 reason, MITA believes that it is necessary  
22 to have a strong well-funded FDA with

1 the necessary resources to approve these  
2 life-saving technologies in a timely manner.

3 The first thing I will discuss  
4 is the user fees. MDUFMA reauthorization  
5 achieves many goals that both the FDA and  
6 industry are seeking. The concept behind the  
7 device user fee program is to provide the  
8 agency with resources that enhance the  
9 device review program. MDUFMA II provides  
10 predictable funding for the FDA to maintain  
11 a stable device review program while at  
12 the same time providing reasonable and  
13 predictable user fees for the industry.

14 As was mentioned, under MDUFMA I  
15 and MDUFSA, there was uncertainty on part  
16 of the industry and the agency regarding  
17 the amount of user fees and whether there  
18 would be compensating adjusters, whether  
19 appropriation and user fees would cover the  
20 necessary costs of the device review program.  
21 Both parties sought predictability in user  
22 fees. Consequently, the agency and the

1 industry recommended to Congress to extend  
2 the current trigger for appropriations and  
3 maintain the spending triggers for the review  
4 process. In addition, MDUFMA II provides  
5 a modest device establishment registration  
6 fee, as already was discussed, with reduced  
7 application fees, which the industry  
8 supports.

9 In terms of performance goals, the  
10 FDA has committed to ambitious performance  
11 goals under MDUFMA II. The industry has  
12 sought to simplify the performance goals  
13 while ensuring timely reviews. At the same  
14 time, one of the key new features of MDUFMA  
15 II is the institution of interactive review  
16 process as a qualitative goal, which was  
17 already discussed. As was discussed, this  
18 provides for informal communications between  
19 the reviewer and the applicant, which will  
20 avoid unnecessary delays in the review  
21 process. It will also lead to reduction in  
22 the number of review cycles. We are pleased

1 with both the qualitative goals that the FDA  
2 has committed to as well as the quantitative  
3 goals. Other qualitative goals include  
4 quarterly performance reports and reviewer  
5 training, which the industry wholeheartedly  
6 supports.

7 In terms of third-party  
8 inspections, the Third-Party Inspection  
9 program was established in MDUFMA I to allow  
10 an agency with limited resources to utilize  
11 outside, accredited inspectors to conduct  
12 inspections and provide reports to the FDA.  
13 Under this program, a company can choose to  
14 have an inspection done by a third-party  
15 organization that is accredited by the FDA  
16 and reports from the inspection are submitted  
17 to the FDA.

18 Unfortunately, according to the  
19 January 2007 GAO report -- and that was  
20 discussed earlier -- Status of FDA's Program  
21 for Inspections by Accredited Organizations,  
22 manufacturers have been reluctant to

1 participate in the program because of the  
2 number of statutory obstacles to  
3 participation. That's why the MDUFMA  
4 reauthorization proposal would make modest  
5 changes to the program to address the  
6 barriers to participation and will encourage  
7 greater industry participation in the  
8 program.

9           It is important to note that the  
10 statutory revisions to the third-party  
11 inspection program under MDUFMA II are  
12 intended to increase participation in  
13 the program while maintaining all of the  
14 stringent conflict of interest requirements  
15 and eligibility requirements for accredited  
16 persons that are in current law under MDUFMA  
17 I. Also, the Secretary's authority to  
18 inspect a facility at any time remains under  
19 MDUFMA II.

20           Some of the things that were just  
21 also discussed were the removal of use on  
22 third-party inspections. As was discussed,

1 currently a company is limited on the number  
2 of times it may use a third-party inspector  
3 to two times. After two third-party  
4 inspections, the FDA must conduct an  
5 inspection, and this was an obstacle for  
6 manufacturers. MDUFMA II eliminates this  
7 limitation and allows a company to continue  
8 to use third-party inspectors as long as the  
9 company maintains a good inspectional record.

10 Also, as we discussed, acceptance  
11 of ISO certifications. In addition, while an  
12 official authority to conduct inspections and  
13 classify inspection results will remain with  
14 the Secretary, MDUFMA II now will allow  
15 the Secretary to expressly take into  
16 consideration the goals of international  
17 harmonization in quality systems standards.  
18 Specifically, it would allow the FDA to  
19 accept ISO reports of certifications, thus  
20 providing the agency with the opportunity  
21 to receive information on a facility for  
22 the purpose of setting its risk-based

1       inspectional priorities. This is an  
2       extremely good benefit for the manufacturers.

3               Also it would streamline the  
4       notification and approval process for  
5       assignment of third-party inspections.  
6       MDUFMA II would streamline the approval  
7       process and allow companies to use a  
8       simplified application which notifies the  
9       FDA that it will use an inspector on the  
10      FDA's approved list, state the date of last  
11      inspection and its classification, and state  
12      the intent of the owner or operator to  
13      participate in the program and to certify  
14      that it markets at least one of the devices  
15      manufactured at the facility in a foreign  
16      country. The applicant will be deemed  
17      approved for participation in the program  
18      if the Secretary does not respond to the  
19      establishment within 30 days.

20              Also, there will be an elimination  
21      of duplicative data submission requirements.  
22      MDUFMA II eliminates the redundant reporting

1 of compliance data by the establishment. The  
2 FDA keeps records on the past inspections and  
3 can review the establishment's compliance  
4 record without repetitive submissions. The  
5 statute still provides that the Secretary has  
6 the authority to request this data if the  
7 Secretary deems it necessary.

8 In terms of combination products,  
9 as also mentioned, diagnostic imaging is  
10 sometimes used concurrently with diagnostic  
11 drug and biological products, such as  
12 contrast agents or radiopharmaceuticals,  
13 in a way that does not meet the regulatory  
14 definition of a combination product.  
15 Nonetheless, such "concomitant use products"  
16 present important questions of efficient  
17 regulation and consultation between Centers  
18 that are similar to those raised by  
19 combination products. In particular, the  
20 industry wanted a clear guidance on the  
21 processes and procedures for approval or  
22 clearance of these devices, including the

1 coordination of reviews by one or more Center  
2 on the data that should be submitted to  
3 support marketing the applications and  
4 labeling for new uses of imaging devices with  
5 contrast agents and/or radiopharmaceuticals  
6 approved for the same or different  
7 indications. To address these questions,  
8 the FDA will, after consultation with the  
9 affected parties, issue a guidance.

10 I want to thank you for your time  
11 today, and I commend the FDA for all the work  
12 that went into an agreement that benefits  
13 both the agency and the medical device  
14 industry.

15 DR. SHUREN: Thank you. Let me ask  
16 Sibylle Zitko to come forward.

17 MS. ZITKO: Thank you very much.  
18 Thank you. I would just like to make a very  
19 short statement on behalf of the European  
20 Commission. We had expressed some concern  
21 about the fact that small and medium-sized  
22 enterprise based in Europe so far have not

1     been eligible to apply for fee discounts for  
2     pre-market approval filing, as the current  
3     law requires that only U.S. federal income  
4     tax returns may be used to show eligibility.

5             From the recent recommendations, as  
6     was just explained in the introduction, we  
7     understand that FDA is proposing that small  
8     business provisions be expanded to allow a  
9     way for small firms that do not file tax  
10    returns with the U.S. Internal Revenue  
11    Service to also qualify for small business  
12    rates.

13            Qualifications should be based  
14    on certifications from the national taxing  
15    authorities where the firm and each of its  
16    affiliates file their taxes and signed  
17    affidavits from the head of the firm or its  
18    chief financial officer and from each of its  
19    affiliates.

20            And so I just want to say we're  
21    very pleased with this proposal and would  
22    very much like to thank the FDA for taking

1 our concerns into account, and we'd also like  
2 to thank the Commerce Department, which I  
3 understand has also supported the proposal,  
4 and we are, of course, looking forward to  
5 working with the FDA to make the proposals  
6 operational when the time comes to discuss  
7 it. So of course we want to make sure that  
8 the European national taxing authorities will  
9 in fact provide the appropriate certification  
10 forms which would satisfy the FDA  
11 requirements, and we will -- we're welcome to  
12 find out more about which information will be  
13 required and which forms will be necessary.  
14 Thank you very much.

15 DR. SHUREN: Thank you. Let me  
16 next ask Fred Freedman to come forward.

17 MR. FREEDMAN: Good afternoon. I'm  
18 Fred Freedman, representing the Dental Trade  
19 Alliance, the DTA. The Dental Trade Alliance  
20 is a trade association representing more than  
21 200 manufacturers and distributors in the  
22 U.S. DTA is concerned about the new possible

1 regulations and fees for the Medical Device  
2 and User Fee Modernization Act, MDUFMA II,  
3 that are now being considered by FDA.

4 Please be advised more than 80  
5 percent of medical device manufacturers are  
6 small to medium in size, while more than 90  
7 percent of the medical devices are classified  
8 as low- to medium-risk. Of 280 dental  
9 products classified by the FDA, our member  
10 devices fit precisely within the general  
11 medical device category. Furthermore, DTA  
12 surveys indicate DTA members comprise 43  
13 percent of companies with fewer than 50  
14 employees, and another 45 percent of the DTA  
15 members comprise businesses with between 50  
16 and 300 employees.

17 MDUFMA II will redistribute the  
18 fees pertaining to revenue, benefiting more  
19 of the medical device industry with larger  
20 firms that make higher risk devices and have  
21 more 510(k) submissions. Smaller companies  
22 that typically build products around a single

1 510(k) will shoulder a greater burden. DTA  
2 asks FDA to reconsider its position.

3           With regard to third-party  
4 inspection elements of MDUFMA, the general  
5 medical device industry welcomes the use  
6 of the ISO 13485:2003 standard becoming a  
7 recognized standard on the FDA, which could  
8 accept results. This makes sense since  
9 FDA's Quality System Regulation Part 820 was  
10 originally written to be harmonized with  
11 ISO 13485:1996. Since FDA has participated  
12 in writing the newer, more robust ISO  
13 13485:2003, it makes sense to acknowledge  
14 this work by making this the recognized  
15 standard.

16           For concerns about the confidence  
17 of audits performed to the standard in  
18 foreign countries, FDA should consider  
19 participation in co-developing an  
20 accreditation program for ISO 13485:2003 for  
21 which the International Accreditation Forum  
22 has now begun work. Accreditation bodies

1 from Japan, Canada, the U.S., Singapore, the  
2 European Union, and China are all working  
3 through the International Accreditation Forum  
4 to create a certificate for ISO 13485:2003 to  
5 be accepted everywhere under an accreditation  
6 system that includes establishing  
7 independence and transparency to the audit.

8 MDUFMA II should focus on  
9 recognizing ISO 13485:2003 as part of the use  
10 of the third-party inspection system. The  
11 FDA should also consider participation with  
12 the IAF Working Group to co-create the Global  
13 Medical Device Conformity Assessment System  
14 -- that's a mouthful -- known as GeMDCAS,  
15 to have more access to the competency and  
16 independence of audits performed under the  
17 ISO 13485:2003 standard that FDA helped  
18 write. DTA believes this is not an  
19 harmonization issue. It is a recognition  
20 issue. That is why MDUFMA II should be  
21 considered the instrument for recognizing  
22 the standard. The DTA is available for more

1 detailed discussions, since the Association  
2 is actively involved in this issue on many  
3 fronts.

4           Finally, DTA wishes to state  
5 for the record the following important  
6 statistics, which we believe merit  
7 consideration for developing new legislation.  
8 Quoting from a gathered government source:  
9 80 percent of medical device manufacturers  
10 are considered small. More than 90 percent  
11 of medical devices are low to medium risk.  
12 We call this the 80 90 rule. Please keep  
13 this in mind as you move forward.

14           The Dental Trade Alliance is able  
15 to gauge and report on the impact of new  
16 regulations on the general medical device  
17 industry as a whole. This is especially  
18 true for low to medium medical devices. As  
19 we move forward, please involve DTA in the  
20 development of new regulations affecting the  
21 general medical device industry. And I want  
22 to thank you today for this opportunity, and

1 we salute FDA for working so hard to simplify  
2 the medical device and user fee program.

3 Thank you.

4 DR. SHUREN: Thank you. Since  
5 we're ahead of schedule, my suggestion is  
6 just we continue to move on with the next  
7 registered speaker. Is Kelly Slone here?  
8 Why don't we go to Mark Leahey?

9 MR. LEAHEY: Thank you, Jeff. On  
10 behalf of the Medical Device Manufacturers  
11 Association, I too want to thank FDA for all  
12 their efforts in both putting this proposal  
13 together and also conducting this important  
14 public stakeholder meeting.

15 My name is Mark Leahey. I'm the  
16 Executive Director of the Medical Device  
17 Manufacturers Association. We represent  
18 smaller entrepreneurial innovative companies  
19 in the medical technology industry, and I  
20 appreciate -- I think this is the fourth time  
21 that I've spoken at a MDUFMA stakeholder  
22 meeting, and just really wanted to take a few

1 minutes to talk briefly about the MDUFMA II  
2 proposal.

3           As Jeff said at the beginning,  
4 MDUFMA I provided the initial foundation and  
5 framework to achieve I think the primary  
6 objective, which is to ensure that patients  
7 have timely access to safe and effective  
8 products. As we talked with FDA and other  
9 stakeholders and our membership on the MDUFMA  
10 II construction, we thought it was important  
11 to build on this program and make necessary  
12 improvements, again to ensure ultimately the  
13 patient is the primary focus, and at the end  
14 of the day they have access to these safe and  
15 effective products in a timely manner.

16           The first item I'd like to discuss  
17 as part of the MDUFMA II proposal is the  
18 issue of greater fee predictability. Those  
19 of you in the room representing medical  
20 technology companies understand that under  
21 MDUFMA I, there were significant fluctuations  
22 in the fees that companies paid. I think we

1 saw a significant ramp up of about 60 percent  
2 for some fees. And as Jeff said, that was  
3 tied primarily to the fact that these fees  
4 were only associated for application fees.

5 In trying to represent the  
6 industry and determine a way to get greater  
7 predictability, the idea of having an  
8 establishment fee was something that was  
9 attractive to our membership. Doing so would  
10 provide again a greater source of revenues  
11 from FDA, a more predictable, stable source  
12 of revenues, and more importantly would  
13 provide greater fee relief for all those  
14 submitting applications in the future. So  
15 we certainly support that modification.

16 A second important modification  
17 under the proposal is for adding greater fee  
18 relief for smaller companies. MDMA strongly  
19 supported the two-tier structure that was  
20 implemented in MDUFMA I, and also supported  
21 the increased threshold under MDUFSA in 2005.  
22 And under the proposal MDUFMA II, the 510(k)

1 fee for smaller companies, those under a \$100  
2 million in revenues, would be reduced from 80  
3 percent of the full fee to 50 percent of the  
4 full fee, which we think is very important.  
5 And for the PMA and PMA supplements, those  
6 fees would be reduced. Instead of paying 38  
7 percent of the full fee, they'd be paying 25  
8 percent.

9           So again, when you look practically  
10 speaking at these small innovative companies  
11 -- and I would agree with the gentleman  
12 before that, you know, the majority of  
13 the industry are these small innovative  
14 companies -- they're going to see their fees,  
15 those in the PMA space drop close to \$70,000,  
16 I'd say, and basically see their 510(k) fees  
17 cut in half.

18           So again we appreciate the efforts  
19 to provide greater fee stability for smaller  
20 companies. I think it is an important  
21 public policy goal, because unlike the  
22 pharmaceutical industry, where it's the large

1 guys, again the engine of innovation here is  
2 the entrepreneurial sector.

3 I also want to talk briefly about  
4 the simplification of goals under the MDUFMA  
5 II proposal. I think it was discussed  
6 earlier there were dozens of goals, both  
7 cycle and decision under MDUFMA I, and I  
8 think that created some issues as it results  
9 to achieving the objective of, again, timely  
10 review of safe and effective products. And  
11 we too support the simplification of these  
12 goals. We think doing so will provide FDA  
13 with the tools to better manage their process  
14 internally, which I think is something that  
15 we all support, and along those lines, we  
16 also support the interactive review component  
17 that Jeff talked about.

18 I think again this is really an  
19 opportunity here for the industry and FDA to  
20 address issues as they arise in a real-time  
21 manner so that there's not this delay on the  
22 89th day or later in the process, because

1 again those delays often are detrimental to  
2 patient care. So to the extent that this  
3 program and this proposal can address those  
4 on the front end, patients will certainly  
5 benefit from those types of changes.

6 In addition to some of the fee  
7 structures that we've talked about -- and  
8 again, the guidance document that will come  
9 out obviously will be important -- other  
10 improvements that I want to express support  
11 on behalf of MDMA are the modifications  
12 through the third-party inspection program.  
13 As Andy spoke to earlier, obviously this is  
14 an important program I think for the industry  
15 and also quite frankly for FDA and the  
16 patients to ensure that -- I think this is a  
17 program, as Jeff said, that FDA has already  
18 invested millions in, and, if executed  
19 properly and structured properly, I think  
20 it really provides an opportunity to give  
21 greater assurance that companies are  
22 manufacturing consistent with the FDA

1 framework, and we certainly believe that  
2 the modifications being proposed will provide  
3 a greater assurance that FDA's initial  
4 investment will be realized under MDUFMA II.

5 I also want to express our support  
6 for the modifications to the review of  
7 IBD products that exist in the MDUFMA II  
8 proposal. That's a growing industry,  
9 obviously, very important, and MDMA supports  
10 those proposals as well.

11 And then finally, I want to close  
12 by -- really I guess it's a call to all the  
13 stakeholders in the room, whether they be  
14 patient groups, consumer groups, industry  
15 folks. Jeff talked briefly about the  
16 budgetary issues facing FDA. And I think  
17 it's critically important that everybody come  
18 together and do what we can to ensure that as  
19 large a portion as possible from FDA's budget  
20 comes from the appropriations process. I  
21 know that there are coalitions out there  
22 actively pursuing that. They're bringing all

1 stakeholders together, and, again, I think  
2 looking forward into MDUFMA III and IV,  
3 should that time arise, it's going to be  
4 important that everyone come together and  
5 ensure that FDA has the necessary resources  
6 from congressional appropriations so that  
7 we can continue to flourish as an industry,  
8 provide products that improve the quality of  
9 care for patients around this country and  
10 around the world, and also make sure that FDA  
11 has the necessary resources to conduct the  
12 critical role that they play in society and  
13 within our industry.

14           And so, again, I want to thank FDA  
15 for their tireless efforts over the last  
16 year and a half or so and I appreciate the  
17 opportunity to provide the remarks on behalf  
18 of MDMA. Thank you.

19           DR. SHUREN: Thank you. Let me ask  
20 Janet Trunzo to come forward.

21           MS. TRUNZO: Thanks. Thanks, Jeff.  
22 On behalf of AdvaMed, I am very pleased to

1 be here today to make a statement at the  
2 FDA's public meeting on the reauthorization  
3 of MDUFMA.

4           Just a quick note about AdvaMed.  
5 We represent over 800 innovators in the  
6 industry. Over 70 percent of our members are  
7 small companies, and we represent 90 percent  
8 of the \$68 billion of health care technology  
9 products consumed annually in the U.S. and 50  
10 percent of that consumed worldwide.

11           We also believe that the user fee  
12 program that was enacted in 2002 has been  
13 successful in bringing important technologies  
14 to patients sooner, and that is the bottom  
15 line for what we're dealing with here today.  
16 The medical device industry is on the cutting  
17 edge of new technology development. We  
18 recognize the important statutory role that  
19 FDA plays in reviewing the scientific basis  
20 for new products prior to marketing. We  
21 believe in a strong FDA, and we also believe  
22 that FDA at the same time needs to have the

1 necessary resources to fulfill that statutory  
2 function in a sound and effective way. And  
3 we are pleased that MDUFMA I was able to  
4 accomplish that.

5 Over the past five years, FDA has  
6 received significant increase in funding for  
7 the device review program, including  
8 necessary funds for CDRH, for CBER, and for  
9 ORA. This funding came from a combination  
10 of user fees and increased appropriations.  
11 With these added funds, the FDA has been  
12 able to hire and train additional staff, add  
13 scientific experts to the CDRH fellowship  
14 program, and to enhance the IT, the  
15 information technology systems that were  
16 discussed earlier.

17 The result is that today FDA has  
18 met the quantitative performance goals  
19 outlined in the goals letter under MDUFMA I,  
20 and that is good news because it means that  
21 patients are getting access rapidly to the  
22 newest, most proven technologies.

1                   So to build on that successful  
2 start that we had in MDUFMA I, over the past  
3 year, together with my colleagues from MDMA  
4 and MITA, formerly NEMA, we have been working  
5 with FDA to develop a new reauthorization  
6 package that will strengthen the program even  
7 further. We believe we've accomplished that,  
8 and we are fully supportive of the entire  
9 package that FDA has presented earlier today.

10                   I'm not going to go over the  
11 details of the package. Jeff did a nice job  
12 doing that already. But I would like to  
13 highlight some of the features of the program  
14 that I think are important. When Jeff  
15 reviewed the performance goals, he talked  
16 about the quantitative goals and then he  
17 talked about the qualitative goals, and then  
18 he talked about some of the enhancements in  
19 money.

20                   I just want to make a few comments  
21 about the goals, because the quantitative  
22 goals and the qualitative goals work

1 together, and we believe that when you put  
2 these two goal packages together, you come  
3 up with a process that's much more efficient,  
4 and it maintains the high quality associated  
5 with the review of medical device  
6 submissions.

7           So most important in these  
8 qualitative goals is FDA's commitment to  
9 an interactive review process. This is  
10 designed to build more interaction between  
11 FDA reviewers and the sponsors. FDA  
12 reviewers will have a mechanism to obtain  
13 clarifications or request additional  
14 information that's readily available while  
15 continuing the review process. This is  
16 designed to increase the efficiency of  
17 the review process, and, at the same time,  
18 increase the level of understanding between  
19 the applicants and the reviewers so that both  
20 parties understand FDA's expectations and it  
21 minimizes surprises at the end.

22           So we have the interactive review

1 process. Coupled with that, we have FDA's  
2 commitment to meet on a timely basis,  
3 pre-submission, we have the increased  
4 commitment to add more guidance documents to  
5 FDA's repertoire of guidances, and we have  
6 the commitment to enhance the scientific  
7 expertise of the reviewers. So you take all  
8 of these together -- interactive review, more  
9 guidance documents, timely scheduling of  
10 pre-submission meetings, and well-trained  
11 reviewers with the appropriate scientific  
12 expertise, what you get at the end is a  
13 quality submission and a streamlined review.  
14 And I think that is an important bottom line  
15 here, because that means that these products  
16 will get to patients in a timely way.

17 So I'm not going to talk about  
18 fees. We've said a lot of things about the  
19 stable and predictable fee structure that's  
20 been created, which is very good, and I'm  
21 not going to go into details about the other  
22 elements of the goals. But I just want to

1 make a closing statement that all of these  
2 things together we believe, AdvaMed strongly  
3 believes, that this program will enable FDA  
4 to further improve its performance, both  
5 qualitative and quantitative ways, which I  
6 said before work together, and at the same  
7 we've got this stable and predictable fee  
8 structure, and the benefits are both for  
9 FDA and for the device industry. But more  
10 importantly, at the end of the day, American  
11 patients will be the true beneficiaries of  
12 this program, because the patients will have  
13 timely access to this technology.

14           So I want to thank my industry  
15 colleagues. I want to thank the FDA staff  
16 who we've all worked with -- worked many,  
17 many meetings over a course of many months.  
18 Some of the meetings were difficult; some  
19 were not. But at the end of the day, we  
20 worked well together to come up with a  
21 package that we believe is going to improve  
22 the program for the next five years, and we

1 look forward to continuing to work with the  
2 FDA in the future. Thank you.

3 DR. SHUREN: Thank you. I didn't  
4 see the door open, but I'll check again. Is  
5 Kelly Slone here?

6 It is now just about 1:15. Why  
7 don't we go ahead and just take a 15-minute  
8 break? We'll start up again. I'll ask all  
9 the registered speakers to certainly please  
10 stay. We will then open up -- if Kelly is  
11 here, we'll have Ms. Slone present. If not,  
12 we'll move straight into the open public  
13 session.

14 (Recess)

15 DR. SHUREN: I'll ask everyone to  
16 take their seats. We'll go ahead and get  
17 started. Let me ask if Ms. Slone is here?  
18 Kelly Slone?

19 All right. Well, then, we'll move  
20 to our open public session, and let me ask if  
21 there any members of the public who wish to  
22 make a statement or have any questions for

1 the panel? Go ahead. And I ask when you  
2 come up to please introduce yourself and to  
3 give your affiliation.

4 MR. LANPHEAR: Good afternoon. My  
5 name is Norman Lanphear. I am the manager  
6 for public health and manpower for the  
7 American Academy of Ophthalmology.

8 The American Academy of  
9 Ophthalmology is the world's largest  
10 association of eye physicians and surgeons  
11 -- eye MD's -- with more than 27,000 members  
12 worldwide. More than 93 percent of the  
13 over 17,000 practicing eye MD's in the  
14 United States are members of our Academy.

15 U.S. Food and Drug Administration  
16 approved ophthalmic devices such as  
17 intraocular and contact lenses have  
18 contributed significantly to our members'  
19 ability to help their patients, therefore,  
20 in the rapidly growing device industry, it  
21 is important to ophthalmology that the FDA  
22 continue to have a well-resourced ophthalmic

1 device program. The user fee program is one  
2 way of providing additional and necessary  
3 resources to improve timely device review  
4 and ensure that safe and effective products  
5 get to market as quickly as possible. The  
6 Academy commends the FDA for fostering a  
7 process that encourages interaction between  
8 the Agency and medical device manufacturers  
9 on device product reviews.

10 The American Academy of  
11 Ophthalmology supports the U.S. Food and Drug  
12 Administration's proposed recommendations to  
13 Congress, which represent a compromise that  
14 involved key stakeholders for reauthorizing  
15 the Medical Device User Fee and Modernization  
16 Act, MDUFMA II. Thank you very much.

17 DR. SHUREN: Thank you. Are there  
18 other members of the public who wish to  
19 make a statement or have questions? Hi,  
20 you wouldn't happen to be Kelly Slone?

21 (Laughter)

22 MS. SLONE: Yes. You're running

1 early here.

2 DR. SHUREN: We're very efficient.

3 This is new and improved MDUFMA II, FDA.

4 MS. SLONE: Are you ready for me?

5 DR. SHUREN: Oh, we're ready for  
6 you. Come on up.

7 MS. SLONE: Good afternoon,  
8 everybody. This is really impressive that  
9 FDA we're ahead of schedule here. That's  
10 really wonderful. My name is Kelly Slone,  
11 and I'm the director of the Medical Industry  
12 Group for the National Venture Capital  
13 Association, and, although we weren't part of  
14 the negotiations as a stakeholder from that  
15 perspective, the venture capital industry  
16 feels like we're a very huge stakeholder in  
17 medical innovation and feel that this work is  
18 really important and that's why we're here.

19 Venture capital plays a very  
20 important role in medical innovation. In the  
21 life science sector itself, which includes  
22 biotech and medical devices, this sector set

1 pace for investing in 2006 for the venture  
2 capital industry, investing over \$7.2 billion  
3 compared to \$6 billion in 2005. And you can  
4 see the breakout. Biotech has historically  
5 been much larger than medical device at \$4.5  
6 billion. But in the medical technology area  
7 \$2.7 billion were invested in 2006, which is  
8 a significant jump and an area that continues  
9 to grow significantly in venture capital  
10 investing.

11 As you can see, between 1998 and  
12 2006, life sciences were about 17 percent of  
13 investments, and now it's up to 28 percent of  
14 investments. But just in the first quarter  
15 of this year, it's jumped up to 39 percent,  
16 so you can really see the growing trend here  
17 in this sector.

18 The venture capital industry,  
19 again, is really committed to this space.  
20 We're committed to finding the cures to  
21 combat major diseases and advancing medical  
22 innovation. The venture capital industry

1 drives usually typically the next generation  
2 of medical technologies, typically focusing  
3 on real novel/disruptive technologies,  
4 first-ever-seen types of technologies.

5           Venture-backed life sciences  
6 companies produce enormous health gains, cost  
7 savings, and also create jobs. The future of  
8 investment in advancing medical innovation  
9 depends on a balanced, predictable regulatory  
10 environment. Venture-backed life science  
11 investments, again, it's really important  
12 that we have a balanced, predictable  
13 regulatory environment. Some of the key  
14 priorities for NVCA in the life science space  
15 is to really look at where regulatory changes  
16 can take place to help advance medical  
17 innovation, and those three areas are  
18 obviously FDA, a more recent CMS payment, and  
19 patents. But over the last several years,  
20 the main priority has been improving the FDA  
21 review process.

22           And the main reason why is when

1 venture capitalists look at an investment,  
2 and especially now that technologies are  
3 getting more complicated, they really have to  
4 look at, you know, the risk of assessment is  
5 looking at the regulatory environment. They  
6 have to look at the predictability. And if  
7 the regulatory process is unpredictable,  
8 that really weighs in their decision making  
9 to invest in a complicated technology, even  
10 though, from their perspective, it looks  
11 like a promising technology.

12           The market and technology risk  
13 are intrinsically more assessable than  
14 the regulatory risk. Understanding the  
15 regulatory risk early in the process is  
16 critical to health care investors. The  
17 result is that high value technologies  
18 will not receive investment, because of  
19 the unpredictability of a product approval  
20 process of a complex technology.

21           The novel technologies of  
22 challenges at the FDA include that most of

1 these technologies that are disruptive and  
2 truly novel are technologies that the FDA has  
3 never seen before. Because they're uniquely  
4 complex, they're much harder to get your arms  
5 around about where should the agency put  
6 it, who should approve it, you know, what  
7 agencies should approve it. And so due  
8 to the novelty, there's a lack of unclear  
9 precedent in all these challenges, and this  
10 often creates a mutual frustration between  
11 the sponsor and the FDA because of this  
12 novelty.

13           So, again, we were not part  
14 of the negotiations, but looking at the  
15 recommendations, one thing that was real  
16 positive for us looking at this, and  
17 something that actually have been working  
18 with the FDA on, is that we're encouraged  
19 that we're seeing a goal structure that is  
20 both qualitative and quantitative. And I  
21 think the main recommendation that we were  
22 most pleased to see is that the willingness

1 to have pre-submission interaction between  
2 the sponsor and the FDA without having the  
3 review clock stopping and starting. We feel  
4 this is very, very important, especially for  
5 novel technologies, given the complexity.  
6 And the most upfront, most predictable  
7 point would really help investors make a  
8 determination as to whether or not to invest  
9 in these types of technologies.

10 And then, as a note, we'd encourage  
11 senior-level staff at CDRH to also be  
12 involved and have oversight over those  
13 pre-meetings, and a dedicated review team  
14 on the onset of that review process to  
15 sort of manage it through we think could  
16 be beneficial for everybody, FDA and the  
17 applicant. And we believe that by doing  
18 this will help assess the risk of investment  
19 for future novel technologies. Thank you.

20 DR. SHUREN: Thank you. Any other  
21 statements or questions from the public?

22 Well, with that again, let me thank

1 all of you for participating in today's  
2 public meeting. Again, the public docket  
3 will be open until May 18th. If you do have  
4 comments, please feel free to submit them to  
5 the docket. We will review everything that  
6 is sent to us. Again, thank you and have a  
7 good day.

8 (Whereupon, at 1:40 p.m., the MEETING  
9 was adjourned.)

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