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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH/
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT

(MDUFMA)

STAKEHOLDER MEETING

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TR 1

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P R O C E E D I N G S

(9:08 a.m.)

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3 MR. BARNETT: Okay. Welcome to
4 this third annual public meeting on the
5 Medical Device User Fee and Modernization
6 Act, which everybody knows as MDUFMA. I'm
7 Mark Barnett, Assistant Director for
8 Education and communication -- who else is
9 that talking there?

10 MS. KAHAN: I'm sorry. Hold on one
11 second, Mark.

12 MR. BARNETT: So much for the
13 stereo portion of our broadcast. Now we're
14 back to mono. Anyway, as I was saying, I'm
15 Mark Barnett; I'm the Assistant Director for
16 Education and Communication in FDA's Center
17 for Devices and Radiological Health. And I'm
18 going to be your moderator today.

19 A quick piece of housekeeping.
20 When you registered out there today, you
21 should have received a package which contains
22 the meeting agenda and a list of the

1 attendees that are going to be here, a list
2 of the guidances that we've issued under
3 MDUFMA so far, some important web addresses,
4 information on how to get transcripts, and
5 most importantly, information on where to get
6 lunch. And so if you didn't get that
7 package, you can get one during the break.

8 Well, as we all know, MDUFMA
9 authorizes the FDA to collect fees from
10 manufacturers to help offset the cost of
11 reviewing applications for new medical
12 devices. And it also has some important
13 provisions about things like third-party
14 inspections and special requirements for
15 manufacturers who reprocess devices that are
16 labeled for single use.

17 Now, as everybody in this room also
18 knows, MDUFMA is going to expire on
19 October 1, 2007. And so today's meeting is
20 particularly important because it's going to
21 serve as a vehicle for us in the FDA to get
22 your input and recommendations on what any

1 reauthorized MDUFMA legislation ought to look
2 like.

3 Specifically, we want to know what
4 you think has worked well with MDUFMA so far,
5 and whether there are things about MDUFMA
6 that ought to be changed in the future. And
7 so this meeting is basically a listening
8 session for the FDA. There are familiar
9 faces out here, so I know that many of you
10 know that this is not the first MDUFMA
11 listening session that we've had.

12 We've held similar public meetings
13 in 2003 and 2004, and in fact, we based many
14 of the actions that we took in implementing
15 MDUFMA on what you told us during those
16 meetings. So today, we're going to continue
17 that commitment to listen. As before, this
18 meeting is going to be transcribed so that we
19 can review what was said here today, and
20 we'll use what we learned from this session
21 as we prepare for the possibility of new,
22 legislation.

1 Let me say a few words about the
2 format for the meeting. It's going to
3 consist of six separate sessions, each one
4 covering a different aspect of MDUFMA. Now,
5 during the entire day, there's going to be a
6 standing FDA -- actually a sitting -- but
7 we'll call it a standing FDA panel, sitting
8 up here, and I'll introduce them in a few
9 minutes.

10 And then also during each of the
11 six sessions, one or more FDA subject matter
12 experts are going to come up and sit with the
13 other panel and listen to presentations from
14 stakeholders who have registered to speak in
15 advance. Each of these registered speakers
16 are going to have up to 10 minutes for their
17 presentations, and I'll give a little signal
18 when there are two minutes left, and then
19 again at the one minute mark.

20 Now, I might mention, if you are
21 one of those registered speakers, you were
22 told in advance about the 10-minute limit,

1 but if you didn't receive the information,
2 and you know now that your presentation is
3 significantly longer than 10 minutes, this
4 will be a good time to kind of mentally edit
5 it down so that you can fit the time limit.

6 After each one of the speakers,
7 there's going to be a few minutes in which
8 the FDA panelists are going to be able to ask
9 the presenters for clarification or for
10 additional information. We want the FDA
11 folks to understand what you're saying. It's
12 important. And so if they have any questions
13 for you, that's the time they are going to
14 ask you.

15 Now, at the close of each of the
16 six sessions, we're going to open the floor
17 to those people who may have registered to
18 speak this morning when they arrived, and
19 after that, we will open the floor to
20 comments from anybody in the audience who
21 wants to speak. But one important ground
22 rule about speaking from the audience, and

1 that is that the comments ought to address
2 only the subject matter of the panel that we
3 just had.

4 In other words, we just had a panel
5 on the third-party inspection program, your
6 questions or comments ought to address that
7 topic and not something else. We've also set
8 a time limit for the comments from the floor
9 so we can stay on time and allow everybody to
10 speak. So on the comments from the floor
11 we're going to go no more than five minutes.
12 And again, I'll give a reminder when there is
13 one minute left and then call a halt when
14 it's over.

15 Okay, so much for introduction. At
16 this point, we do have some words of welcome
17 from Dr. Dan Schultz, who is Director of the
18 Center for Devices and Radiological Health,
19 who could not be with us today, but he is on
20 video; right? And we're going to show the
21 video now. Is that how it works? Okay.

22 Dr. Dan.

1 MS. RICE: I need to get in here.

2 MR. BARNETT: You got to get in
3 here? Okay.

4 MS. RICE: And I need the laptop.

5 MR. SCHULTZ: Good morning. My
6 name is Dan Schultz, director for the Center
7 for Devices and Radiological Health. I want
8 to take this opportunity to thank all of you
9 for coming to the annual MDUFMA stakeholders
10 meeting, and to assure you that while I can't
11 be with you in person, I am certainly with
12 you in spirit and committed to the mission
13 that you are embarked on.

14 Our mission, getting safe and
15 effective devices to market in a timely
16 fashion, is certainly essential to the
17 purpose of this meeting. Over the last year,
18 we've hired a number of highly qualified
19 engineering, medical, and statistical staff
20 to enhance the expertise of the Center in
21 evaluating new devices.

22 We've also been able to increase

1 professional development as well as
2 increasing the use of outside experts to
3 assist in our mission. We held a record
4 number, more than 500 pre-meetings with
5 industry, which as you know, is a vital part
6 of getting good submissions and an efficient
7 review process.

8 We've performed very well against
9 MDUFMA goals, both 510(k) and PMA in the
10 areas of cycle goals and decision goals.
11 We've also worked hard on the other
12 commitments in the Secretary's goal letter,
13 such as developing GMP and BIMO inspectional
14 timeframes, issuing many device-specific and
15 special control guidance documents and
16 updating our IT infrastructure, especially in
17 those areas designed to increase the
18 efficiency of the review process.

19 During the last year, we've also
20 started to work on developing a more focused
21 and proactive post-market program that will
22 enhance the pre-market review process and

1 improve the efficiency of that process by
2 allowing our staff to consider and use
3 information when evaluating device
4 modifications and new devices.

5 This will also allow us to move
6 more quickly to identify post-market issues,
7 to act on those issues and resolve them, and
8 quickly notify the health care and patient
9 communities to improve the safety and
10 effective use of those products.

11 We recognize that MDUFMA user fee
12 revenue is tagged to improvement of the
13 pre-market review program. But we need to
14 make sure that we don't lose sight of the
15 importance of the post-market program to
16 fulfill our mandate to ensure the safety and
17 effectiveness of medical devices throughout
18 the product life cycle, and to maintain the
19 confidence of the U.S. public in the products
20 that we regulate.

21 Information we learn from
22 post-market on how a device works in the real

1 world, when and how it may fail, is critical
2 to our pre-market review process. We've also
3 been focusing on several important critical
4 path initiatives, including development of
5 simulation-based engineering and medical
6 imaging technology that will help in the
7 assessment of new stent designs; developing
8 clinically relevant animal models to improve
9 the prediction of device toxicity on injured
10 tissue in critically ill patients; working
11 with our trade associations and academic
12 communities in the development of new
13 statistical models for predicting the
14 effectiveness of cardiac stents; and to be
15 able to measure and improve long-term safety
16 of these devices.

17 I want to stress the importance of
18 your participation at this critical point in
19 the MDUFMA process. Next spring, we'll be
20 starting re-negotiation for MDUFMA 2. We
21 need to hear from all of our stakeholders.
22 Unlike previous years where FDA provided

1 updates on our implementation progress, this
2 year is dedicated as a listening session for
3 the Agency.

4 As Mark mentioned, there will be
5 several main topics for which we would like
6 your feedback. This is your opportunity to
7 tell us what you liked and what you didn't
8 like about MDUFMA. We need you to be as
9 specific as possible with your
10 recommendations for MDUFMA 2.

11 Together, we have the opportunity
12 to use the knowledge and experience of the
13 last three years to make a good program even
14 better. I have no doubt that with all of our
15 resolve and commitment, we will accomplish
16 that goal.

17 Thanks very much, and have a great
18 meeting.

19 MR. BARNETT: Okay, thank you, Dan.
20 Our next speaker is live.

21 (Laughter)

22 MR. GOODMAN: I think.

1 MR. BARNETT: We think he is. Dr.
2 Jesse Goodman, who is Director of FDA Center
3 for Biologics Evaluation and Research.
4 Jesse.

5 MR. GOODMAN: Sure. Good morning
6 everybody. We really do appreciate your
7 presence here, and I'm really just going to
8 briefly echo, I think, Dan's comments. You
9 know, I think it's remarkable, the progress
10 we've made in the last couple of years. I
11 think I speak for both the centers, but I
12 have the most knowledge specifically about
13 ours.

14 And I think it's also particularly
15 remarkable that MDUFMA has enabled us to do
16 that in a time when resources have otherwise
17 been quiet constrained for the agency. From
18 my point of view, first of all, I want to
19 thank the people who have worked with us on
20 that. And that includes the industry
21 associations and specific companies who I
22 think have been very helpful in identifying

1 issues where we can work together better, and
2 have also been responsive when we've raised
3 our issues. So I thank you for that, and we
4 sure look forward to that continuing.

5 The other comment I was going to
6 make is that I think some of the improvements
7 in the performance measures, review time and
8 number of cycles, are terrific, and they help
9 achieve the goal that Dan mentioned, which is
10 getting safe, effective products to benefit
11 people more quickly, and I think that has
12 really happened.

13 But I think something that is a
14 little harder to measure has also happened,
15 which is quality and consistency have been
16 maintained, and in many cases improved. So I
17 think those are very important, we're very
18 proud of it and the MDUFMA resources have
19 been really critical.

20 The other thing we've done, and
21 this has been cultural within the FDA, but I
22 think the resources have also helped with

1 this, is we've been able to turn our
2 attention to our internal processes and our
3 collaborations. And I think CDRH and CBER
4 are working together very well in a
5 bidirectional way, and we're relevant, we're
6 getting, I think, high quality guidances out
7 that are meaningful across the industry. So
8 I think those things are good too.

9 Dan mentioned the post-market, we
10 too are more and more trying to integrate
11 that with the pre-market process in the
12 approval, and again, we do look forward to
13 discussing that as part of continuing MDUFMA.
14 And finally, I would like to say, in our
15 area, the tremendous promise of devices, I
16 mean, everybody -- it is very graphic when
17 you have a new defibrillator or a prosthetic
18 device, et cetera, et cetera.

19 But we have many devices that are
20 absolutely essential for the well-being of
21 the American people and for dealing with some
22 of our public health threats. You know,

1 whether it's new infectious agents that
2 threaten the blood supply, BSE, or
3 confronting issues like mass vaccination, and
4 the promise of devices for meeting those
5 needs.

6 Another area that is relevant to
7 the critical path that Dan mentioned is in
8 combination products and tissue-engineered
9 products, and I think that's a perfect
10 paradigm where we and CDRH are working
11 together to make things easier for innovation
12 and bring future products to people. So you
13 know, we just do look forward to your input,
14 and I think even more than that, to
15 continuing to work together.

16 I think it's a very productive
17 interaction between FDA and the industry. I
18 think consumers benefit and are another
19 important group to provide input, and we just
20 thank you all, the industry and consumers,
21 for your support and trust in this.

22 Thank you.

1 MR. BARNETT: Thank you, Jesse.
2 Let me now introduce the permanent panel
3 that's going to be up there all day, and as I
4 introduce them, I'll ask them to raise their
5 hand, because people in the back can't see
6 their name cards.

7 Linda Kahan is Deputy Director of
8 the Center for Devices and Radiological
9 Health. Joanne Less is Associate Director in
10 that Center for Clinical Research and
11 Government Affairs. Diane Maloney is
12 Associate Director for Policy in the Center
13 for Biologics Evaluation and Research, and
14 Bob Yetter is Associate Director for Review
15 Management in the Center for Biologics
16 Evaluation and Research.

17 And I'll ask Linda to just say a
18 few words of introduction if you would.

19 MS. KAHAN: Thank you. Can you
20 hear me? First of all, let me tell you that
21 Dan has been to Taiwan, and he actually cut
22 his trip short. He may be able to make a

1 guest appearance today later in the meeting.
2 He was getting back last night. And he
3 really did want to be here, and he may still
4 be able to do that.

5 I wanted to also echo what Dan and
6 Jesse have said, and thank you for coming to
7 the meeting today. As Dan suggested, this is
8 a little bit different than the meetings
9 we've done in the past. But I don't want
10 anyone to think for a minute that we are not
11 willing and able to provide information. And
12 one of the reasons that you've gotten the
13 handouts that you have is that we have put
14 all the information that we've been
15 constantly making available on our websites.

16 And most of you are veterans of
17 using that tool, but in case you haven't had
18 an opportunity to do that, please make sure
19 that you do take advantage of all the
20 information that's out there, including the
21 guidances that have been put out as part of
22 the implementation of MDUFMA, and the reports

1 that are available right through the website.

2 I wanted to also echo something
3 that Dr. Goodman said about what it means to
4 get resources in this fiscal environment. I
5 think that all of us are painfully aware of
6 the natural disasters and the international
7 unrest that have plagued the world and our
8 country over the last years. And it is
9 really a very bleak situation for most of the
10 government in terms of fiscal funding and
11 resources.

12 And as you know, before MDUFMA, the
13 medical device program was one of those
14 programs that was continually losing
15 resources. Even when we had supposedly
16 steady funding, we were in fact losing
17 resources because of inflation. So the fact
18 that we are now visible, and that we're one
19 of the programs that gets funded and gets
20 thought about when limited resources are
21 being distributed really is a tribute to the
22 work that our stakeholders have done to make

1 this possible.

2 And we're very appreciative of that
3 and we hope that that's going to continue,
4 because it's made a huge difference in the
5 way we can work, and in our ability to work
6 with the industry to get safe and effective
7 products to market quickly.

8 I wanted to just also point out
9 that this is just the beginning of the
10 process. We are very anxious to hear from
11 people today about what's happened over the
12 last couple of years that they think has
13 worked well, and as Dan said, things that
14 need to be done differently and better in the
15 next iteration of MDUFMA.

16 We here at the FDA kind of have a
17 two-pronged job over the next two years. One
18 is to continue to work on the commitments for
19 the goals and the other things that we have
20 promised to do through the Secretary's letter
21 until '07; and at the same time, we need to
22 gear up for what we can plan to do hopefully

1 when MDUFMA is reauthorized in '07.

2 So we're kind of working on both of
3 those tracks. And the purpose of this
4 meeting is to really get input from you about
5 how to work that second piece of it based on
6 the three years of experience that we've had.
7 I also want to remind people in case you
8 didn't realize that there will be another
9 public meeting in the fall, at which we will
10 be able to talk about these things again, and
11 have another year of experience to put under
12 our belts.

13 And I also wanted to let people
14 know that under the statute, once we work
15 with our stakeholders to actually come to
16 some tentative agreement about what ought to
17 be in the next version of MDUFMA, that will
18 be made publicly available through a Federal
19 Register notice, and people will have chance
20 to comment on that.

21 And as Jesse pointed out, the
22 importance of having consumers and

1 practitioners and health care professionals
2 give us some input is a big help to industry
3 and to the FDA, because everybody is
4 interested in that same goal, which is to get
5 good products out there as quickly as
6 possible. So with that, Mark --

7 MR. BARNETT: Okay. Thank you,
8 Linda. I think we're ready now for
9 Session 1, which is on the "User Fee
10 Structure," and I'm going to ask Martha
11 Louvier to come up and sit with us. She is
12 from the Office of Management in FDA.

13 She is taking the place of Frank
14 Claunts, who was going to be here but could
15 not make it.

16 MS. LOUVIER: Good morning.

17 MR. BARNETT: Now that she is
18 seated, we have the full panel. Let me call
19 in our first speaker, who is Mark Leahey, of
20 the Medical Device Manufacturers Association.

21 MR. LEAHEY: Thank you, Mark.
22 First, I want to begin by thanking

1 Dr. Schultz, Dr. Goodman, the staff at CDRH
2 and CBER, and Cindy Harris for putting this
3 meeting together. I think it is a great
4 opportunity for all of the stakeholders to
5 get together and talk about what is working
6 and what improvements need to be made.

7 And I'm pleased, this is my third
8 year at the meeting, and I'll have to say
9 that I think some of the issues that we had
10 address in the past have been remedied as
11 part of the MDUFMA trigger fix in August. So
12 hopefully it will be an opportunity again to
13 identify those things that need some tweaking
14 and improving the future. But I think three
15 years into the program, we are in a better
16 shape than when we started, and I think
17 that's a tribute to everybody in this room.

18 So again, by way of background, let
19 me just start off by saying that I'm the
20 Executive Director with the Medical Device
21 Manufacturers Association. We're a trade
22 association based in Washington, representing

1 hundreds of medical technology companies,
2 many of which are small- to medium-sized
3 companies, and I think that's indicative of
4 the industry itself.

5 Prior to the trigger fix in August,
6 the user fee system was volatile and
7 unpredictable for the industry. I think this
8 is evident by the fee increases that we
9 saw -- just in the first two years of the
10 program, we saw fee increases jump between 55
11 and 60 percent for both 510(k)s and for PMAs.

12 You'll see here, the PMA fee, which
13 started off at \$154,000, jumped to \$239,000
14 and change in just two years, and the 510(k)
15 fee jumped from \$2187 to more than \$3500 in
16 just two years. And this is something that I
17 think the entire industry voiced concerned
18 about, these types of dramatic fee increases
19 that I think, to everyone's credit, there was
20 a recognition that these fees were not
21 sustainable.

22 Another issue that I think we had

1 prior to MDUFSA is the fact that the
2 structure allowed FDA to collect more per
3 submission if they saw a decline in
4 fee-generating submissions. Certainly, we
5 understand the need for FDA to have a stable
6 source of revenue, but the industry also
7 needs that stability.

8 And the structure prior to the
9 trigger fix did not provide that. And again,
10 these increases were unsustainable for
11 99 percent of the industry. And if we want
12 to continue to develop innovative, safe, and
13 effective products for America's patients,
14 it's vital that the entire industry has the
15 ability to innovate.

16 Another note: Prior to MDUFSA, and
17 hopefully we'll see a reverse here, there was
18 a dramatic drop in the number of
19 fee-generating submissions after the user fee
20 was created. So hopefully -- there could be
21 many reasons for that, but I think the
22 numbers indicate that there was a dramatic

1 drop, and hopefully that the lower fees or
2 the stabilized fees will provide an
3 opportunity for those submissions to
4 increase.

5 So where are we now after MDUFSA?
6 Fees are much more predictable for the
7 industry. And I think this is the biggest
8 success under the program moving forward,
9 that for the first time, the elements -- the
10 compensating and work load adjustments
11 that -- a large portion due to the dramatic
12 fee increases we saw in the first couple of
13 years -- are no longer in place.

14 The fee increases are capped at
15 8-1/2 percent annually. I think that the,
16 industry was hoping for something along the
17 lines of inflation, but recognizing that we
18 still wanted to provide FDA resources to fund
19 them without needing dramatic cuts, it was
20 settled on an 8-1/2 percent annual increase,
21 which I think in the long term, it's still,
22 I'll have to see if that's the acceptable

1 rate of increase, because that may be
2 difficult to sustain long-term, but we can
3 take a look at that.

4 I'm also very pleased that it
5 eliminated the workload and compensating
6 adjustments as I just spoke of, and this is
7 something I'm sure many of you will be happy
8 to hear. During the first MDUFMA
9 stakeholders meeting, I talked ad nauseum
10 about the need to eliminate these. During
11 the second, I did as well.

12 Now I can congratulate everyone
13 here for making those decisions. I think it
14 was something that was shared by many. And
15 we're just pleased that we now have, again, I
16 think, the right equation for developing the
17 fees moving forward.

18 And the final important point that
19 was made as part of our provision, as part of
20 MDUFSA, is the fact that it provided greater
21 fee relief for companies under \$100 million
22 in annual revenues. You know, this is

1 something prior to the development of MDUFMA,
2 back in 2002, MDMA was trying to push for a
3 number higher than \$30 million. We were
4 unsuccessful, but we're pleased that now we
5 have this \$100 million threshold.

6 We know for certain that there are
7 companies out there in that \$30- to
8 \$100 million range that were withholding
9 regional PMA submissions, PMA supplements,
10 because it wasn't in their regulatory budget
11 to file, and now they're moving forward. So
12 I think to FDA's credit, the revisions that
13 were made under MDUFMA hopefully give them
14 the resources they need to move forward, but
15 also allows the industry to move forward and
16 innovate. And I think that's the ultimate
17 goal of this program.

18 So user fees, what's ahead? I
19 think we need to evaluate the value of user
20 fees. Now what do I mean by that? Well, I
21 think two things are important to this
22 component, the first being what the actual

1 fee amount is. And that's something that we
2 need to address. The other is something I'll
3 address on a later panel, which is, what does
4 that fee provide in return as it relates to
5 ensuring the patients have safe and effective
6 products more quickly? And that relates to
7 performance goals.

8 So I don't think in trying to
9 determine what a reasonable fee is, I don't
10 think you can just look at a dollar amount,
11 alone in and of itself. You have to look at
12 the dollar amount in conjunction with the
13 performance that's being achieved. Again,
14 this goes along with fees being reasonable
15 and rational, look at fees and performance
16 together.

17 We also need to ensure that fees do
18 not increase at unsustainable rates. I think
19 that again, we took a huge step in the right
20 direction in dealing with eliminating the
21 workload and compensating adjustors and
22 having that 8-1/2 percent cap in place. And

1 I think the industry will get together and
2 determine what is a sustainable fee increase
3 moving forward.

4 There also needs to be an
5 understanding that the fees are meant to be
6 additive to appropriations and not
7 substituted. And this is something that I
8 think shouldn't be looked over. Again, when
9 everyone got around the table and the
10 industry agreed to pay I think almost close
11 to -- generate almost close to \$80 million in
12 the first three years of the user fee
13 program -- this was meant to be additive to
14 hire new employees to help enhance the
15 process. But unfortunately, we saw the
16 congressional appropriations that were
17 promised under MDUFMA and committed to under
18 MDUFMA were not delivered in the first couple
19 of years of the program.

20 And I think there is a concern that
21 a lot of the user fee dollars again that were
22 meant to be additive were actually used to

1 supplement the congressional appropriations.
2 And again moving forward, we really need to
3 make sure, and I know a lot of this falls
4 outside the ability of FDA to guarantee that
5 the monies are there, but do what we can to
6 ensure that the user fees aren't just used to
7 plug in a drop in congressional
8 appropriations.

9 I think the final thing we need to
10 do is determine FDA's actual resource needs
11 related to the pre-market review program.
12 And again, to FDA's credit, they worked with
13 Dr. Geiger to try to get at some of this
14 information, and Dr. Geiger recently put out
15 his report. I think there is some good
16 information to be gathered there, but I think
17 there are some shortfalls related to really
18 flushing out what the resource needs are on
19 the PMA side, between PMA -- original PMAs,
20 PMA's supplements.

21 But again to FDA's credit, I think,
22 that they have put some internal data

1 collection mechanisms in place that will
2 hopefully provide better data to be collected
3 on, again, what the resources are for
4 original PMA, what they are for the 188
5 supplements, and hopefully now that they are
6 in that process of gathering that
7 information, we will really get a better
8 understanding of what the resource needs are.
9 And then once we can determine that, I think
10 it has to be understood that the user fees
11 are not meant to cover that entire cost of
12 that, that the user fees again should be
13 supplemented with the Congressional
14 appropriations and should play a part in
15 assisting FDA but not the overwhelming
16 majority.

17 MR. BARNETT: Two more minutes.

18 MR. LEAHEY: Well, here we are.

19 User fee, what's ahead? Looking forward,
20 we're looking forward we're looking forward
21 to working with FDA, the folks within the
22 other industries and the Hill to ensure that

1 patients have timely access to safe and
2 effective medical technologies, and that
3 smaller companies continue to have the
4 ability to innovate. And I think again, the
5 stakeholder meeting today is certainly a sign
6 that there is an element of a partnership
7 involved here that Dr. Schultz spoke of last
8 year.

9 I think we look forward to working
10 with everybody. Again, MDMA is committed to
11 making this program work, so long as we can
12 ensure that smaller companies aren't harmed
13 and that patients ultimately are the winners
14 with safe and effective medical products and
15 they get access to that in a timely fashion.
16 So with that, I will conclude, thanks.

17 MR. BARNETT: Thank you, Mark. And
18 let me ask the panel, before you step away.
19 Is there anyone that needs clarification on
20 that or has any questions for Mark? If not,
21 thanks very much, and let me ask our next
22 speaker to come up, Janet Trunzo of AdvaMed.

1 MS. TRUNZO: Good morning, my name
2 is Janet Trunzo. I'm the executive vice
3 president for technology and regulatory
4 affairs at AdvaMed, the Advanced Medical
5 Technology Association. We represent over
6 90 percent of the medical devices sold in the
7 U.S., and we're the world's largest medical
8 device trade association.

9 First of all, AdvaMed would also
10 like to thank FDA for providing stakeholders
11 the opportunity to comment on the various
12 aspects of MDUFMA. AdvaMed also would like
13 to recognize Dr. Schultz and Dr. Goodman and
14 all of the CBER and CDRH staff for all the
15 hard work and effort they have made in
16 implementing the provisions of MDUFMA.

17 My comments today are going to be
18 limited to two areas: The elements of a
19 reasonable user fee program; and also, I'm
20 going to make a few comments about FDA's cost
21 analysis study. First, I would like to talk
22 about the elements, make a few statements

1 about the fundamental elements of a user fee
2 program.

3 First and foremost, medical device
4 user fees are additive to the FDA's device
5 budget, and never are or have been intended
6 to supplant FDA's base device budget. In
7 fact, Section 101 of MDUFMA states the
8 following: "Congress finds that the public
9 health will be served by making additional
10 funds available for the purpose of augmenting
11 the resources of FDA."

12 In fact, under MDUFMA, the
13 additional resources provided were a
14 combination of industry user fees and
15 congressional appropriations. The user fee
16 program in fact was designed intentionally,
17 such that the industry contribution was
18 intended to not exceed 15 percent of FDA's
19 entire device base budget. And indeed this
20 is the case and remains so.

21 So what does the medical device
22 industry expect from user fees? Well, it's

1 quite simple. We expect reasonable fees. We
2 expect that the fees will not increase
3 drastically from one year to the next. We
4 also expect adequate appropriations from
5 Congress. Last, but definitely not least, we
6 expect improved performance for the industry
7 contributions. Representatives from AdvaMed
8 member companies will be commenting later on
9 performance during the later panels.

10 Turning now to FDA's cost analysis
11 study: In September of this year, FDA issued
12 its cost analysis study on determining the
13 unit cost for the process of medical device
14 review. And I don't know if any of you got a
15 chance to look at it. It's quite a lengthy
16 report.

17 But after reviewing the report, and
18 also after hearing some presentations from
19 Dr. Geiger, who is the author of the report,
20 I would like to offer the following comments:
21 First, there are some limitations in the
22 data, and those limitations were noted

1 actually by the author himself. Data in this
2 report reflect the '03 and '04 activity.

3 And although FDA recently trained
4 its staff on making improvements to the time
5 reporting system, data collected in '03 and
6 '04 were not precisely collected, such that
7 the time spent on original PMAs and the
8 various types of PMA supplements were clearly
9 delineated.

10 Second comment: In reviewing the
11 calculations for determining the unit costs,
12 it appears that FDA used information from the
13 FY '03 and FY '04 financial reports that it
14 makes to Congress under the requirements of
15 MDUFMA. And it shows -- if you look at those
16 reports themselves, those financial reports,
17 it talks about the budget and how much of the
18 FDA budget was used for device review
19 activities.

20 So that information from that
21 report is combined with the cost analysis
22 study. Please note also that device review

1 activities encompass a lot of activities.
2 They are not just the time that the FDA
3 reviewers spend on the actual review of the
4 application; they also include the support
5 activities, center-wide expenses, including
6 rent utilities, field investigations, and
7 general agency and administrative costs.

8 In the cost analysis report, FDA
9 allocated both indirect and direct costs to
10 the various types of applications, and then
11 divided the number of applications completed
12 during the time reported in the report,
13 that's '03 and '04, and came up with the unit
14 cost. When using the data from this report
15 in the future, we must bear in mind that the
16 reported unit cost represents a fully loaded
17 cost, and in their totality represent a
18 significant portion of the FDA's total base
19 budget for devices.

20 I also would remind the agency as
21 it contemplates using this information in the
22 future, and drawing upon what I said earlier

1 in this presentation, that the device user
2 fees are intended to augment the FDA's device
3 base budget.

4 In closing, we very much look
5 forward to working with FDA for the
6 re-authorization of MDUFMA.

7 We look forward to designing a
8 device user fee program that incorporates all
9 the basic elements of a workable user fee
10 program that I noted earlier, and at the same
11 time, provides FDA with the additional
12 resources it needs so that patients have
13 timely access to safe and effective medical
14 technology. Thank you.

15 MR. BARNETT: Thank you, Janet.
16 Let me turn to the panel now and ask if any
17 one has any questions of Janet.

18 MS. KAHAN: I wanted to ask, is
19 there another presentation for this panel?
20 I'm going to wait; can we ask questions at
21 the end, if we have some?

22 MR. BARNETT: Okay. All right

1 Janet, stay tuned then. And our next speaker
2 is Bob Britain, of the National Electrical
3 Manufacturers Association, or NEMA.

4 MR. BRITAIN: NEMA, we represent
5 manufacturers of medical imaging equipment
6 and radiation therapy equipment. So we have
7 a very special part of the medical device
8 manufacturing community. And again, I echo
9 the thanks of Mark and Janet, the panel, FDA,
10 putting this all together. I wanted to
11 specially thank Ms. Less for moving this
12 program into November, out of December.
13 Remember, I have never been able to get to
14 this because of the RSNA in Chicago. Thank
15 you.

16 Something else special about this
17 industry: We've worked very hard with FDA
18 when we were first negotiating MDUFMA to have
19 an exemption from user fees for manufacturers
20 that use third parties for 510(k)s. So many
21 of our manufacturers actually use third
22 parties and do not pay the user fee.

1 So the other thing special about
2 this part of the industry is that we're
3 mainly 510(k); very few products go to market
4 in medical imaging through the PMA process.
5 So we have not been, so to speak, hit as hard
6 as many of the other medical device
7 manufacturers that put their products through
8 the PMA process.

9 So therefore, I essentially support
10 everything that Mark and Janet have said.

11 The increases in 510(k)s have been
12 substantial, if you look at the percentage
13 increase, but if you look at the total, going
14 from 2000-something to 3000-something hasn't
15 been too hard on the industry.

16 I support the predictability.
17 Things -- increases have to be predictable.
18 You know, industry works from budgets, too.
19 And we can't be taken by surprise. We do not
20 support trying to backfill on shortfalls from
21 the year ahead to the previous year. And I
22 think that's not supportable, it's not right.

1 You've got to do the best job you
2 can in predicting the number of PMAs and
3 510(k)s coming in. You are going to hit the
4 mark sometimes and you are not going to hit
5 the mark at other times. But when you're not
6 hitting the mark, it usually means that you
7 don't have the numbers coming in, you don't
8 have the numbers of supplements and PMAs and
9 510(k)s that are coming in -- so you're doing
10 less. You're not expending the resources
11 that you thought you might have to spend.
12 Gee, forgot to put my -- all that is to say
13 that in the last three years, the 20 to 30
14 percent increases have been quite excessive.

15 We are thankful that AdvaMed and
16 MDMA were able to negotiate a cap, which was
17 8.5 percent last year, and we support that.
18 Long-term, however, I'm not sure that is the
19 right number. 8.5 percent a year seems like
20 a lot to me going forward. So we need to
21 establish some reasonable formulas going
22 ahead.

1 The other thing I'd like to say is
2 that throughout this day, from the three
3 trade associations, you're probably going to
4 hear a lot of concerns, issues, but probably
5 not going to hear a lot of solutions. We're
6 going to be working this spring, we're going
7 to be sitting down with FDA, trying to work
8 out solutions to MDUFMA 2 in 2007.

9 So I think we have to be careful
10 what we can say today in how to fix things.
11 So what you're going to hear today is
12 concerns more than solutions. Thank you.

13 MR. BARNETT: Bob, thank you.
14 Again, let me ask the panelists if they have
15 any questions. Linda, you had a question
16 that you wanted to ask. Do you want to do it
17 now?

18 MS. KAHAN: Let me start. One
19 question that I had, and I guess maybe Mark
20 could be the best person to try to answer
21 this, but I think that one of the things that
22 we've struggled with and that we'd sort of

1 like some ideas about -- and I realize that
2 you're not offering solutions, but what are
3 the tools that we, meaning all the
4 stakeholders: Industry, consumers, Congress,
5 FDA, can use to figure out when a fee
6 situation creates a disincentive for small
7 businesses, for industry?

8 I think one of the concerns that
9 you have put on the table, as has AdvaMed,
10 NEMA, and everybody else, is that we want to
11 make sure that nothing in this program
12 undermines innovation or limits the ability
13 of small companies to get on the market. I
14 guess I was wondering if you have any ideas
15 about how we get to that.

16 MR. LEAHEY: The first answer is to
17 ensure that the fees are reasonable, and I --

18 MS. KAHAN: Well, that's my
19 question. My question is how do we --

20 MR. LEAHEY: I think probably the
21 fee increases that we saw the first two years
22 were unreasonable, and that's one of the

1 reasons why we saw a dramatic drop in the
2 number of submissions. So I think that
3 there's some evidence that the current system
4 was not working as intended, that it was
5 having a stifling effect on innovation.

6 I think the other issue may, you
7 know -- oftentimes, you hear, well, these
8 folks are in business, and it's the cost of
9 doing business. I think the response that
10 many of them feel is, again, if the
11 government would like to regulate an
12 industry, it certainly has that right to do
13 so. But the government needs to fund those
14 regulations. And this was never something
15 that was initially a burden for these
16 companies for the decades and decades of
17 innovation, and this is something relatively
18 new on the horizon.

19 And one of the things that the
20 industry was told -- I guess this was part of
21 the pitch from folks -- was that this is a
22 sound business decision. This will result in

1 faster reviews, enhanced performances et
2 cetera. And quite frankly to date, that
3 hasn't played out. That I think the jury's
4 still out as to whether or not user fees are
5 a sound business investment, and I think
6 that's what we really need to do and look at
7 over at the course of the next two years to
8 determine -- these folks are innovators, and
9 they do run businesses.

10 And again, it goes back to one of
11 my slides, I think, about last year, the
12 benefit of the bargain. We need to look at
13 what are we getting for the user fees. And
14 so I think it's hard to determine -- to say X
15 number of dollars is unreasonable. I think
16 it's very easy to say that X number of
17 dollars with no enhanced performance is
18 problematic, because there, the company would
19 not would view it as, again it is diverting
20 resources from the R&D and other areas.

21 MS. KAHAN: Thanks.

22 MR. BARNETT: Anyone else on the

1 panel want to question? Anyone in the
2 audience want to respond to what they just
3 heard?

4 MR. LASERSON: I have something.

5 MR. BARNETT: Come on up to the
6 mic. Please identify yourself, first.

7 MR. LASERSON: I am Jack Lasersohn
8 from the National Venture Capital
9 Association. I want to strongly support what
10 Mark just said. The question of
11 reasonableness for these fees cannot be
12 looked at in the abstract. Our company spent
13 millions of dollars a month in the start-up
14 phases to get products through the FDA.

15 So even fees of \$100,000 or
16 \$200,000 or \$300,000 for a key PMA in the
17 context of that is not problematic. What's
18 problematic is not having performance results
19 that justify the payment of the fees. So I
20 think that is the balance at least the
21 venture funded medical industry would really
22 like to strike: Rather than a particular

1 concern on the absolute level or the absolute
2 level of increases, we would be happy to pay
3 for increases if they are commensurate with
4 performance increases.

5 MR. BARNETT: Thank you. Is there
6 any one else in the audience who wants to
7 respond to anything they've heard. Mark?

8 MR. LEAHEY: Again while the
9 venture community is very important, I think
10 we need to also be careful that there are a
11 lot of companies out there without venture
12 funding. So to increase the fees across the
13 board without that sensitivity is something
14 that we need to look at the entire landscape
15 of the space. And recognizing again, when we
16 move forward here, it's important to look at
17 all elements of the fees, the performance,
18 and look at all the different folks who are
19 participating, small venture backed, large
20 medical technology companies and those
21 companies that aren't venture backed.

22 MR. BARNETT: Thank you. Before we

1 close out this panel, anyone else?

2 Bob Britain, step up.

3 MR. BRITAIN: This has nothing to
4 do with what's been said, but I think it
5 should be said. And that is this -- the user
6 fee process, whether it's here in the United
7 States or in Japan or China or Canada, is a
8 cost-shifting process. Somebody's got to pay
9 for it; somebody pays for the user fees. The
10 cost of medical devices increases because of
11 them.

12 Medicare pays for your user fees;
13 the whole health system is paying for the
14 user fees. I didn't want to leave here
15 without saying this because the whole world
16 is looking at you and saying, "user fees are
17 okay," and the whole medical device industry
18 is faced with a worldwide user fee system
19 which is dearly going to cost patients,
20 Medicare systems, third-party payers, a lot
21 of money. So just keep this in mind when you
22 want to consider your increases year after

1 year.

2 MR. BARNETT: Thank you, Bob.

3 Janet Trunzo --

4 MS. TRUNZO: AdvaMed represents
5 small, medium, large manufacturers, and I
6 just would like to reiterate a point that I
7 made in my presentation, that companies --
8 and it kind of builds on what the
9 representative from the National Venture
10 Capital Association said, is that paying a
11 user fee, there is an expectation that if a
12 company pays a user fee, that there will be
13 improved performance.

14 And that philosophy and that
15 expectation is an expectation not only of
16 small companies, medium sized companies and
17 large companies, all companies expect some
18 return in the performance and predictability
19 in the performance as a result of a user fee.
20 Thank you.

21 MR. BARNETT: Thank you, Janet.

22 Anyone else before we call it a close for

1 this panel? Then I'll say going, going, gone
2 for this particular panel. I guess we've all
3 talked ourselves out here, right?

4 Then it's time for a break, 15
5 minutes. It's now 10:00, so why don't we be
6 back here, at 10:15.

7 Thank you.

8 (Recess)

9 MR. BARNETT: We're ready to start,
10 so please have a seat. Thank you.

11 We're ready to begin now with our
12 session 2, which is on premarket review
13 performance goals, and up with us to join the
14 permanent panel are two FDA subject matter
15 experts, Donna-Bea Tillman, who is Director
16 of the Office of Device Evaluation in CDRH,
17 and Don St. Pierre, who is with the Office of
18 In Vitro Diagnostic Device Evaluation and
19 Safety with CDRH.

20 And our first presenter is Mark
21 Leahey, again, with the Medical Device
22 Manufacturers Association. Mark?

1 MR. LEAHEY: Thank you, Mark. And
2 unlike years past when I had the pleasure of
3 speaking five times during one of these
4 meetings, I'm pleased to note that I'm only
5 speaking three times, and we're halfway home
6 after this, or more than that.

7 Again, we spoke a little bit about
8 performance in the first panel. Again, the
9 importance of not looking at fees isolated,
10 but looking at fees in relationship to
11 performance. And I think that this is
12 something, probably one of the more critical
13 elements of MDUFMA 2 if we're to get there
14 that needs to be addressed, because again, it
15 goes to the heart of the value of the user
16 fee.

17 So performance issues. The goal of
18 MDUFMA was to ensure patients' timely access
19 to safe and effective medical technologies.
20 Now, back in 2001, there were a lot of
21 attempts to try to enhance FDA through
22 various reforms short of a user fee, but then

1 ultimately the user fee component entered the
2 equation. And one of the things that we
3 heard consistently from FDA and from others
4 was that if you a pay user fee, it will
5 enhance review times by approximately
6 25 percent. And again, I think when you talk
7 to a lot of CEOs, if they're told that things
8 will improve by 25 percent, then a reasonable
9 fee is something that they consider to pay.

10 The problem was that the goals were
11 developed with limited data, and this is no
12 fault of anybody's other than just time. You
13 know, when you're trying to get a sense as to
14 where FDA -- what their performance criteria
15 were, what the data was, back in 2001, when
16 there weren't necessarily the proper ways to
17 collect that data, I think it caused a
18 problem, and people just put their best guess
19 out there as far as what they thought would
20 represent 25 percent enhanced performance.

21 However, three years into the
22 process, we certainly have more data that is

1 available. And I think it's evident when you
2 look at the data that the goals
3 themselves -- and this is not -- again, I
4 want to clear that I make the distinction
5 between FDA's actual performance and the
6 goals -- because to FDA's credit, they've
7 exceeded the goals in many many cases, and
8 exceeded them substantially in some cases.

9 But when we're talking about the
10 MDUFMA goals in comparison to the actual
11 performance from FDA in the years leading up
12 to MDUFMA, it's not clear that they represent
13 enhanced performance.

14 And I think when you look on a
15 percentage basis of the total number of
16 submissions, 510(k)s represent about
17 90 percent, and PMA supplements represent
18 about 8 or 9 percent, and PMAs represent
19 about 1 percent. It's clear that in most
20 cases, those FDA/MDUFMA decision goals didn't
21 necessarily reflect enhanced performance.
22 But as I said again, they're exceeding these

1 performance goals. So there is some good
2 news here.

3 But I think as we move forward to
4 MDUFMA 2 and re-evaluate the goals, I think
5 they should be that; goals; something that
6 you strive for, not something that you're
7 already achieving. And remembering that the
8 ultimate goal is an efficient and effective
9 review.

10 We need to keep the focus on the
11 final review times. The cycle goals are
12 certainly important, but something that I
13 know we've spoken to -- the entire industry I
14 think has shared some concern about the
15 efforts to maintain or meet -- cycle goals
16 may have a -- may have an adverse impact on
17 meeting the decision goals. And I think we
18 need to find a balance that still ensures
19 that we are monitoring FDA's early
20 performance in the review process as far as
21 meeting certain time goals of getting
22 requests for additional information and

1 certain letters out. But we can't lose sight
2 of the ultimate end goal here of performance
3 in ensuring that a patient has access to that
4 technology.

5 Here are just a couple of slides
6 that I put together to illustrate. Again,
7 this is not looking at FDA'S actual
8 performance, this is solely looking
9 at -- it's looking at FDA's actual
10 performance prior to MDUFMA, and then
11 comparing that to what the MDUFMA goals lay
12 out. And here, you're dealing with the
13 percentage of 510(k) decisions, FDA decisions
14 within 90 days. And again, looking at the
15 numbers here, in 2000, 2001, 2002, FDA was
16 reviewing between 77 and 80 percent of their
17 510(k)s within 90 FDA days. The goals laid
18 down in MDUFMA allow FDA to review, I think,
19 75 percent in '05, 75 percent of the
20 submissions in '06 in 90 days, and then it
21 goes up to 80 in '07.

22 And again, to their credit, I think

1 86 percent or so was the number for '03-'04.
2 So they are exceeding these goals, but as we
3 look forward to MDUFMA 2, I think we need to
4 ensure that the goals highlighted in
5 the -- there's a second goals letter in
6 MDUFMA 2, an actual enhanced performance.
7 And I think 25 percent, you know, that was
8 the number that was thrown out in MDUFMA 1.
9 That's a good place to start.

10 And then, you know, whether it's
11 90 -- I don't know what the actual goals
12 themselves need to be, but it's something we
13 need to look at. Again, looking at 180-day
14 PMA supplements which represent I think
15 another decent segment of the submissions
16 that FDA reviews, prior to MDUFMA between
17 2000 and 2002, there were anywhere between
18 90-94 percent of 180-day supplements -- were
19 receiving an FDA decision within 180 days.

20 However, the goals under MDUFMA
21 allowed that number to drop to 80 percent in
22 '05, 85 percent in '06, and 90 percent in

1 '07.

2 And again, I think FDA is meeting
3 and exceeding the goals in many cases, but I
4 think there's an inherent problem when the
5 goal that was established under MDUFMA that
6 was talked about at 25 percent enhanced
7 performance in many cases actually
8 represented a decline in performance with the
9 status quo. And I think this is something we
10 need to address moving forward; are these
11 realistic but also aggressive performance
12 goals, in conjunction with a reasonable fee.
13 And that's going to be the way I think this
14 program succeeds moving forward.

15 Original PMAs. Again, prior to
16 MDUFMA, looking at the baseline between
17 2000-2002, 86 percent of the submissions had
18 an FDA's decision within 320 days, and
19 90 percent had an FDA decision in 347 days.
20 So that's kind of the baseline in which we
21 were operating prior MDUFMA. And I think
22 it's important to note that over the course

1 of first three years of this program, the
2 industry has contributed close to \$80 million
3 in user fees. Congress has appropriated
4 approximately \$30 million, with hopefully
5 more to come.

6 So it's not an insignificant amount
7 of resources that are being invested into the
8 FDA here. And then when you look at that
9 investment coupled with the goals that are
10 laid down in MDUFMA in FY '06, the goals
11 state that 80 percent of the decisions need
12 to have an FDA decision in 320 days. Again,
13 this allows for a drop from 86 percent. And
14 then in '07, 90 percent need to have an FDA
15 decision in 320 days, representing
16 approximately a 4 percent improvement.

17 So these are things that we need to
18 take a look at, and certainly, again, we
19 appreciate FDA's efforts to exceed the goals.

20 By no means do I think that they
21 are only trying to work to achieve the goals
22 and move on. I think the evidence indicates

1 otherwise, that they have taken steps to
2 improve that. But again, I think even the
3 steps to improve probably don't come anywhere
4 close to the 25 percent enhanced performance
5 that the industry was I guess promised or
6 committed prior to MDUFMA. That's something
7 we need to work on moving forward.

8 MR. BARNETT: Two minutes, Mark.

9 MR. LEAHEY: Perfect. I think we
10 need to re-evaluate both the cycle and the
11 review goals. Again, as I said earlier, we
12 do not want the cycle goals to impede the
13 process. I think they are important to
14 measure kind of the process, and ensuring
15 that there is communications early on in the
16 process. But we don't want the fixation on
17 the cycle goals to detrimentally impact the
18 overall review process.

19 And I think the goals should
20 reflect more than the status quo. So that
21 would I think clearly indicate that the
22 current goals need to be enhanced. And we

1 need to work with FDA, Congress and the
2 stakeholders to determine real and reasonable
3 goals. And this is something I look forward
4 to over the course of the discussions this
5 springtime. I think we all have to remain
6 focused that the ultimate goal here is to
7 enhance patient care. And I think if we keep
8 that as a primary focus, hopefully everything
9 else will fall into place. So thank you.

10 MR. BARNETT: Thank you, Mark.

11 Anyone on the panel wants to ask Mark a
12 question? Okay. If that's the case, let's
13 go on to our next speaker, Marlene Valenti,
14 with AdvaMed.

15 MS. VALENTI: Good morning. I'm
16 Marlene Valenti, and I'm the vice president
17 of Regulatory Affairs for Cordis Corporation.
18 And as Mark indicated, I'm also an AdvaMed
19 representative. I actually am the
20 chairperson for that PMA task force. And as
21 I told some of you during the break, I'm also,
22 a very happy hurricane survivor from Wilma.

1 As we all know, MDUFMA mandated
2 user fees, and we've heard over and over this
3 morning in regards to one of the key
4 objectives, and that was to reduce cycle
5 times from the time of submission to getting
6 that product onto the market. And that it
7 obviously includes both cycle goals as well
8 as performance goals, decision goals.

9 And we would like to commend FDA in
10 regards to the fact that have met most of
11 their 2005 performance goals, and based on
12 the numbers, actually most of the 2006 goals
13 also.

14 With that, and as Mark indicated
15 before, we are very happy that those goals
16 were met, but we have to go back to looking
17 at the key objective in regards to this
18 provision. And several FDA officials have
19 recently publicly stated in regards to
20 whether or not it really has met that
21 ultimate intent of that regulation, they've
22 indicated that in some cases, yes, and in

1 some cases with unintended consequences. And
2 I think when they speak to that point, what
3 they're talking about is that in some cases,
4 FDA is managing by the cycle times and the
5 decision times rather than pulling back and
6 looking at the big picture in terms of the
7 overall time from submission to market
8 release of that product.

9 If you talk to industry, I think
10 they would definitely agree with that
11 position. And in fact, I think industry
12 would say that the objective is very
13 infrequently met. In terms of industry,
14 here's some perspective in regards to first,
15 the PMA supplement non-approvable letters.
16 And if you look at the numbers that came out
17 in fiscal year 2003, it was about a
18 15 percent where we were receiving
19 non-approvable letters; that went up to over
20 40 percent in 2004. And that is very
21 significant in the aspect of obviously
22 getting the product to the market as quickly

1 as possible, and also allowing us to have
2 predictable review times.

3 We don't have the numbers for 2005
4 yet. I know AdvaMed has asked for those
5 numbers, but in terms of looking at the
6 preliminary numbers that were published, and
7 also just conversations with our members, we
8 do suspect that it's not any better, and it
9 may actually be higher than the 2004 number.

10 In addition, we've had some
11 conversation with the 510(k) working group
12 that was just headed up by Catherine Beath.
13 And they are indicating that they're seeing
14 an increase in NSC letters that are not
15 substantially equivalent.

16 So again, it seems from our
17 perspective that the FDA is managing to the
18 cycle and the decision goals rather than
19 pulling back and looking at the overall time
20 from submission to market. Now, in regards
21 to the path forward, I'd love to stand here
22 and say that we have all the answers and be

1 able to provide those to you today. We can't
2 do that, but what we can say is that in
3 discussion with our members, we strongly feel
4 that more guidance documents are needed, and
5 that that will facilitate the review cycle,
6 and that these guidance documents need to be
7 kept up-to-date and really reflect the
8 current thinking of FDA, so that when a
9 manufacturer goes through that guidance
10 documents, uses that for an application, that
11 they are putting in that application what FDA
12 is looking for and therefore not receiving a
13 non-approvable letter.

14 And one of the key ones that I know
15 we have been working with FDA for many years
16 on is the PMA change guidance document. And
17 I'm very happy to hear that FDA is treating
18 that as a priority to get that out. But we
19 really feel that is an important document for
20 us, because it really will provide
21 transparency on what type of submission is
22 required. In addition, AdvaMed is extremely

1 willing to work in a collaborative manner to
2 help develop innovate ways to improve the
3 process, and also in regards to the guidance
4 documents. We would love to be working with
5 FDA upfront.

6 I think one case that we can point
7 to in terms of what did work was working with
8 Dr. Gross' group, with OSB, in regards to the
9 conditions of approval. And we met with him
10 several times before he actually published
11 the guidance document. And I think having
12 that opportunity to provide to him what
13 worked and what didn't work allowed him to
14 put out a guidance document in a very, very
15 quick manner in terms of getting it out
16 there.

17 And it's something that pretty much
18 reflects most of the opinions that we had put
19 forward in terms of the key elements with the
20 conditions of approval. So if we were to
21 cite an example in terms of what would work,
22 I would encourage you to look at that

1 process. Thank you.

2 MR. BARNETT: Thank you, Marlene.
3 Again, anyone in the panel who want to ask a
4 question or some clarification? If that's
5 the case, let's go to our next speaker,
6 Marlene Keeling, who's with the Chemically
7 Associated Neurological Disorders.

8 MS. KEELING: Good morning. I'm
9 Marlene Keeling. I am president and a
10 founding director of Chemically Associated
11 Neurological Disorders, or CANDO. I want to
12 thank the FDA for the opportunity to speak
13 before this stakeholder meeting.

14 I'm here representing consumers of
15 medical devices. In particular, I will
16 address the approvable letter with conditions
17 recently sent by the FDA to the manufacturers
18 of breast implants. My concern is not with
19 the time it took the FDA to respond to the
20 manufacturer's PMA application, but the
21 science behind the decision to approve this
22 Class III device. My concern is with the

1 proprietary or secret conditions as set forth
2 by the FDA for ultimate approval.

3 The Washington Post quotes a cover
4 letter recently sent by Mentor to plastic
5 surgeons stating: "In anticipation of a final
6 gel breast approval, the FDA is requiring
7 that study doctors send a letter to their
8 study patients to remind them of the
9 importance of their commitment to continue
10 their one-, three-, and five-year follow-up
11 visits."

12 Does this mean that the FDA is only
13 going to require the manufacturers to follow
14 the breast-implanted patients for five years?
15 In networking with thousands of
16 breast-implanted patients, we know that often
17 it takes seven years or more after
18 implantation for symptoms of systemic disease
19 to appear.

20 The most common local complication
21 of implants is encapsulation. It is
22 well-recognized that this is an inflammatory

1 response in the body's attempt to wall off
2 this foreign material. Recently, there has
3 been much written about inflammation and its
4 role in systemic disease. Common sense tells
5 me that after a number of years, and when
6 these implants start to degrade, it
7 overwhelms the immune system and
8 detoxification ability of the human body. I
9 would like to briefly review the record of
10 the FDA and breast implant manufacturers.

11 Seventeen years ago, the FDA
12 classified all breast implants into the
13 Class III category because of reports of
14 adverse events in the medical literature.
15 Fourteen years ago, PMA submitted by the
16 manufacturers did not contain sufficient data
17 to warrant a review by the FDA.

18 Thirteen years ago, FDA decided to
19 allow silicone gel-filled implants on the
20 market only under controlled clinical
21 studies. Nine years ago, FDA sent a letter
22 to manufacturers detailing information needed

1 for core studies. This year, FDA sent
2 manufacturers an approvable letter with
3 conditions after reviewing only one, two and
4 three years of data.

5 My understanding is that the
6 current third generation implants being
7 considered for approval had been manufactured
8 since 1988. The question then becomes why
9 did the manufacturers not have 13 years of
10 data, or even 9 years of data? I believe I
11 know why, after networking with thousands of
12 breast-implanted patients.

13 The incidence of complications
14 becomes too high of this non-life-saving
15 device, and the women are not being followed
16 in many cases as required by the FDA,
17 especially after they develop local
18 complications or systemic disease.

19 In 1997, when I filed my first
20 Citizen's Petition regarding breast implants,
21 the manufacturers were being allowed to quote
22 a 1 percent rupture or failure rate, and many

1 women were being told that their implants
2 would last a lifetime. This was the
3 information that women were using to make a
4 decision as to how much risk they were
5 willing to take. After independent MRI
6 research by the FDA, it was determined that
7 the rupture rate was 77 percent, with
8 silicone seen outside of the scar capsule
9 21 percent of the time.

10 Manufacturers then changed the
11 wording in the product insert to simply say,
12 "Implants may not last a lifetime." As
13 stated by the Washington Post: "Some of the
14 major reservations voiced by the FDA
15 scientists and 2005 advisory panel experts
16 involve the relatively limited amount of
17 long-term information about the implant's
18 effect on women's bodies."

19 Paul Wooley, director of research
20 for orthopedic surgery at Wayne State
21 University, recently stated: "It's been
22 suspected for at least a decade that heavy

1 metals used in manufacturing of implants
2 might cause problems for women who receive
3 these implants." Independent research by the
4 FDA published after the IOM review in 1999
5 found an increased incidence of fibromyalgia
6 in breast-implanted women. Independent
7 research by the NIH, also published after the
8 IOM review, found an increased incidence of
9 some cancers in breast-implanted women,
10 including brain and lung cancers as well as
11 others.

12 I find it curious that when the
13 manufacturers pay for studies, they do not
14 find an increased incidence of systemic
15 disease for the most part. Former Mentor
16 employees reported to the New York Times that
17 data was falsified regarding breast implants.
18 One employee, who was a former product
19 evaluation manager from '96 to '98, said
20 Mentor never met basic quality standards for
21 implant manufacturing while he was there.

22 One employee who supervised

1 Mentor's complaint department said she
2 received about 6000 complaints of ruptured
3 implants in each of her three years at the
4 company.

5 However, in a recent filing with
6 the FDA, Mentor stated that it received a
7 total of 8060 rupture complaints from 1985 to
8 2003, or approximately 400 a year. How can
9 the FDA rely on any data submitted by Mentor
10 under these circumstances? Inamed stated at
11 the 2005 FDA advisory panel hearings that
12 their gel implants did not leak platinum.
13 Mentor stated that their implants did leak
14 platinum, but that it was in a zero valence.
15 CANDO submitted data to the FDA after that
16 advisory meeting on a woman with 1997 Mentor
17 third generation gel implants, and her
18 4-year-old son born after implantation.

19 Both were found to have significant
20 amounts of ionized platinum in their urine,
21 with a valence up to +4. Ionized platinum is
22 on the suspected list as being a

1 neurotoxicant, immunotoxicant, respiratory
2 toxicant and a sense organ toxicant. Dow
3 notified the EPA in 1996 of substantial risk
4 to their platinum catalyst used in the
5 manufacturing of breast implants.

6 Any detectable level of ionized
7 platinum is a health hazard. The more, the
8 worse it is. Several families with children
9 born after implantation testified at and sent
10 documentation to the FDA of significant
11 platinum urine levels up to 382 parts per
12 billion per liter of urine.

13 In an ongoing research project,
14 CANDO has now tested the urine of 20 children
15 born to breast-implanted mothers. Why is
16 this research being ignored by the FDA?
17 History will reflect that it was under your
18 administration that these devices that
19 rupture at an alarming rate and spill
20 chemicals and heavy metals into a woman's
21 body, were approved.

22 MR. BARNETT: Two minutes, please.

1 MS. KEELING: Sure. Due to the
2 combined lobby effort of the chemical
3 companies, the manufacturers and the plastic
4 surgeons -- these are the beneficiaries who
5 have the money to do clinical trials -- it
6 would be negligent should the FDA allow these
7 manufacturers to follow these women for only
8 five years. It would be negligent for the
9 FDA not to require the manufacturers to
10 follow-up on any children born to
11 breast-implanted women enrolled in a clinical
12 study, or not to require platinum urine
13 testing.

14 Because the chemicals and heavy
15 metals used in the manufacturing of medical
16 devices are considered proprietary
17 information or secret, consumers must rely on
18 the FDA to protect them and advise them of
19 potential risk. If approval is given, will
20 consumers be advised that their implants may
21 leak heavy metals, and these heavy metals, if
22 ionized, may cross the placental barrier and

1 brain barrier?

2 I would consider it grossly
3 negligent of the FDA not to require the
4 manufacturers to inform consumers of this
5 important information when making an informed
6 decision on how much risk they are willing to
7 take when implanted with these devices for
8 many years and during their childbearing
9 years.

10 Thank you.

11 MR. BARNETT: Thank you,
12 Ms. Keeling. Does anyone on the panel need
13 clarification or question? If that's the
14 case, we go to our last speaker, Bob Britain
15 of NEMA.

16 MR. BRITAIN: I'd like to welcome
17 Dan Schultz to the meeting. You made it from
18 Taiwan? You want to say, "What's in a
19 number?" Thirty years ago, the Medical
20 Device amendments came out, and there was
21 established 90 days and 180 days -- does
22 anyone in the room know how those figures

1 were established? Anyone? Other than a
2 political decision?

3 How many resources and hours we
4 have spent trying to defend those numbers is
5 amazing. I think 90 days is pretty good for
6 510(k)s; I think 180 days is probably short
7 for PMAs. It's hard to get a PMA through the
8 process with advisory committee meetings and
9 scheduling and that. But I want to leave you
10 with a good note, at least from the medical
11 imaging industry, since we're mainly
12 510(k)-oriented.

13 The 510(k) process is working very
14 well for us. Most of our 510(k)s are getting
15 through in 90 days. Also, the third-party
16 review process is taking under a total of 90
17 days, so we're feeling pretty good about
18 this. We probably had some ups and downs
19 trying to get digital mammography devices
20 through the PMA process, but that was a very
21 high profile -- at times very touchy issue,
22 and we had to be very careful about the data

1 and how it was derived. And FDA needed to
2 take some time to make those critical
3 decisions for those PMAs.

4 So on the whole, basically, it's
5 fun to be the last person on the panel,
6 because I can say that we certainly agree
7 with everything the first two speakers said.
8 And I'll leave it at that.

9 MR. BARNETT: Okay, thank you, Bob.
10 Anyone want a clarification on that? If
11 that's the case, is there anyone here who
12 would like to come up to the mic say a few
13 words? Sure, come on. Please identify
14 yourself.

15 MR. LASERSOHN: Jack Lasersohn from
16 the National Venture Capital Association. I
17 would like to endorse in part, and disagree
18 to some extent, with the first two industry
19 representatives. On the one hand, while we
20 absolutely believe it is appropriate to focus
21 on quantitative goals; for example, cycle
22 times and review times, it is very important

1 to remember, too, that you should not merely
2 focus on goals simply because they are
3 measurable. And I think one of the issues
4 that we have a real concern about is the
5 exclusive focus on quantitative goals simply
6 because they are measurable.

7 The biggest concern for the
8 venture-backed medical industry, that segment
9 of the industry, is really not how fast a
10 review is completed at the end of a cycle,
11 but rather how long the entire approval cycle
12 takes. And by that I mean not merely the FDA
13 review at the end, but the entire PMA
14 process.

15 Shaving 10 or 20 days off of the
16 end of a five-year PMA process that has cost
17 on average \$40 million or \$50 million is a
18 commendable goal. It's certainly not
19 something I would object to, but I have to
20 say that in the context of the companies that
21 we represent who are really almost always
22 looking to produce very innovative, unusual,

1 almost revolutionary devices, that goal
2 really only affects perhaps 1 or 2 percent of
3 the total cycle time, which can typically be
4 in a PMA, which is unfortunately what most of
5 our companies end up doing are very fat
6 510(k)s, it can be four to five years. So I
7 think that we are going to be asking in this
8 MDUFMA 2 review to begin to try to focus on
9 qualitative goals of improvement that can
10 improve the entire cycle.

11 The other thing that I would say,
12 and in this regard I strongly endorse the
13 views of AdvaMed -- the data that was put up.
14 It is very important to be careful to not
15 have a result that produces wrong decisions
16 more quickly. And that to a great extent is
17 what we hear from the representatives of our
18 industry. That is, we can get decisions on
19 PMAs and in various cycles at 90 days or at
20 75 days, but they are the wrong decisions,
21 and we then have to go back and spend endless
22 cycles trying to fix these decisions.

1 So making bad decisions or punting
2 that as asking for more information, more
3 quickly does not -- while it does technically
4 reach the goals of the cycle times -- has not
5 improved the overall cycle of getting these
6 devices to the market more quickly.

7 Thank you.

8 MR. BARNETT: Thank you.

9 MS. KAHAN: Can I ask a clarifying
10 question? Can you describe what you're
11 talking about in terms of these qualitative
12 goals? Are they things that you think FDA
13 needs to be doing, the industry --

14 MR. LASERSOHN: Well, it's always
15 both, right; it's always collaborative. For
16 example, we find really when we look at where
17 the biggest delays and the biggest problems
18 are in the entire approval cycle, we find
19 it's very often at the front-end of the
20 cycle, not at the back-end of the cycle; for
21 example, in an endless negotiation over
22 endpoints in clinical trials and clinical

1 trial design. Now, we do recognize that that
2 is because we are almost always showing up at
3 the FDA with something that they have never
4 seen before. That's the nature of the
5 venture capital industry, to be revolutionary
6 rather than evolutionary. But there has to
7 be a better way to manage this other than a
8 one- or two-year education process.

9 We recognize the need for an
10 education process, defining the goals of an
11 acute AMI trial, for example -- for an
12 interventional device for acute AMI if the
13 FDA has never seen it before and the
14 physician community doesn't really understand
15 it yet, can clearly take time.

16 On the other hand, it shouldn't
17 take one or two years. We need to figure out
18 a faster way to accelerate the collaboration.
19 And that's what we are going to be -- as one
20 example -- and that's one of the things we
21 will be focusing on.

22 MS. KAHAN: Thank you.

1 MR. BARNETT: Thank you. Anyone
2 else in the panel? Anyone else in the
3 audience want to come up and say a few words?
4 Yes, please.

5 MR. McKEEN: My name is Mac McKeen.
6 I'm with St. Jude Medical. And I'd like to
7 echo and reiterate Ms. Valenti's call for the
8 release of the PMA change guidance document.
9 Such a guidance is key for manufacturers to
10 consider when both sustaining the performance
11 of currently marketed devices as well as
12 iterating and developing new versions of
13 these marketed devices.

14 I say that in a real context in
15 that there was a draft guidance out there
16 that AdvaMed had actually worked with FDA in
17 developing, and it served as a very good
18 guide. Granted it was draft and not
19 official. I think it was pretty widespread
20 throughout the industry -- providing a
21 framework of what were the boundaries, when
22 to submit, when to do an annual report, and

1 how to document such product iterations.

2 In addition, such a guidance would
3 also serve FDA's post-market program by
4 helping to clarify annual reporting criteria.
5 It's not one of life's big mysteries, but
6 making that more transparent and clear as to
7 what goes in an annual report versus document
8 file, or a supplement for a PMA product I
9 think will be helpful for both parties and
10 clearly to the product lifecycle for FDA.

11 So I'd mention that the original
12 version was essentially complete, at least in
13 my use and practice of that device -- clearly
14 now, over time, it may have evolved, and it
15 can have some new items included. But
16 clearly, the 510(k) product has had a
17 guidance in place for years and it's been a
18 very effective tool, so I think we need to
19 build on that.

20 MR. BARNETT: Thank you. Anyone
21 else? All right. If that's the case, let's
22 go on -- yes?

1 MR. ST. PIERRE: Since we're ahead
2 of time -- I'm just going to ask one
3 question. The earlier presentations, the two
4 presentations from Mark and Marlene, talked
5 about the fact that FDA is meeting the
6 performance goals, but maybe the performance
7 goals aren't enough. And managing the
8 premarket program or the programs within a
9 center require managing and lot of different
10 principles. So if you're looking just at the
11 goals of review times, that's not nearly the
12 entire picture.

13 So can you put a weight on how
14 important some of the other aspects are, so
15 if you look at like guidance document
16 develop -- like in our office, we
17 probably -- from the last two years to the
18 previous two years, we've tripled the
19 guidance document output.

20 How much weight should that take
21 from the cycle goals or the decision goals?
22 We've given, as Dan mentioned in his opening

1 remarks, you know, 500 meetings. So we've
2 increased the number of meetings, and I
3 realize they're getting harder to schedule,
4 but they've actually gone up. So that's an
5 important aspect of the program that factors
6 in, too.

7 And I know the Agency's been giving
8 lots of presentations, more educational
9 presentations and things of that nature. And
10 at least in the IVD industry, I'm sure that
11 the rest of the medical device industry isn't
12 any different. There's a lot more innovation
13 that seems to be going on, and it's moving
14 very quickly.

15 And a lot of those newer
16 technologies seem to be going out quicker.
17 We're doing lots more de novo applications
18 and getting newer technologies out what I
19 think are pretty quickly. So how much can we
20 wait all those different things to see, am I
21 managing correctly, to just to give -- you
22 know, to split the resources all that way,

1 because I could take them all off the other
2 things and just put them on just reviewing
3 the submissions that come in, so that's a
4 short-term gain, but probably a long-term
5 loss. So can you help the Agency try to
6 wait --

7 MR. LEAHY: I don't know if I can
8 put specific percentages or weights
9 associated with each of those different
10 initiatives. I think they certainly are all
11 important, and I think the next panel is
12 actually qualitative performance. I mean,
13 this one was focused on the premarket
14 performance goals.

15 I think certainly, the meetings
16 before submission takes place are important.
17 To get it right, the guidance documents are
18 very, very helpful. And I think those are
19 things that'll be brought up in the next
20 session as far as qualitative issues.

21 One of the things I will say is, I
22 don't think it has to be an either/or

1 approach. I think when you have an
2 \$80 million infusion from the industry, when
3 you have Congressional appropriations,
4 maintaining the status quo or simply
5 enhancing it a little bit is something that
6 should be achieved and is being achieved, but
7 I don't think those other things have to be
8 taken off the table.

9 So I don't view it as an either/or
10 approach. I think you're moving in the right
11 direction on all fronts, and I would hate to
12 have it be viewed as an either/or. I think
13 they are complementary, and I think that's
14 indicative of the way you structured this
15 program, where in this session it's the
16 premarket performance goals, the next
17 session, it's a qualitative goal.

18 So I think you're moving in the
19 right direction. I think we just need to
20 enhance all areas moving forward, because
21 again, this is a substantial investment on
22 behalf of the industry. And for that

1 investment, we really need to see returns.

2 You know, we are seeing returns, but we need
3 that to continue to improve.

4 MR. BARNETT: Anyone else want to
5 respond to Don's question? Yes.

6 MS. VALENTI: I would echo a lot of
7 what Mark said in regards to the fact that
8 you really can't say it's an either/or, it's
9 a combination. And like the gentleman said
10 in terms of the whole cycle, we do need to
11 look at the whole cycle in making sure that
12 we're managing appropriately in regards to
13 that.

14 And we don't want to just look at
15 the end. You know, we want to look at the
16 entire cycle, and I know we have some
17 comments in regards to the qualitative goals
18 that were set also. But I think in terms of
19 when we do talk about the review times, it's
20 important to look at how it's being managed
21 in terms of the cycle times versus the
22 decision times or the overall time.

1 And I think we've had numerous
2 conversations, not only myself, but others,
3 in terms of with branch chiefs, and they've
4 indicated that even if they're not sure
5 whether or not they can make a decision
6 within 180 days, they issue a non-approvable
7 letter because they're managing to that cycle
8 time. So even if they're on the fence or not
9 even the -- they're pretty sure you can do
10 it, but they're not 100 percent sure, they're
11 indicating that they're issuing
12 non-approvable letters.

13 So I think there is a lot of
14 flexibility even with what we have today in
15 the funds that you have today, to be managing
16 it a little bit differently, to be able to
17 manage the entire life cycle.

18 MR. BARNETT: Thank you. Anyone
19 else? We have two here. Bob.

20 MR. BRITAIN: Well, I hope this
21 will be helpful. I think that a guideline is
22 a heck of an investment. It's worth doing,

1 and it's worth doing well. At what cost, I
2 don't know, but if you don't have an
3 established guideline, the reviewers are
4 going to have their own. They're going to
5 have the things that they tick off. So
6 invest your resources in 510(k) guidance and
7 PMA guidance, and how you deal with that in
8 pitting that against the actual reviews, I'm
9 not sure, but guidance is a worthwhile
10 investment.

11 MR. BARNETT: Thank you. Go ahead.

12 (Phone Interruption)

13 MR. LASERSOHN: Sorry.

14 (Laughter)

15 MR. LASERSOHN: That's inevitable.

16 Two points: I absolutely agree that the
17 quantitative goals are very important. On
18 the other hand, I would point out again,
19 citing AdvaMed's presentation, that it is
20 possible to meet quantitative goals very
21 often by changing the rules or by asking
22 questions along the way. So for example, if

1 in fact a non-approvable letter rate goes up
2 while the cycle time goes down, that is not a
3 good outcome. So I would suggest, for
4 example, that if in fact we are going to have
5 quantitative goals, that situations like that
6 have to be considered, and one obvious
7 solution is that the cycle time goals will be
8 penalized to the extent that there are
9 increases in non-approvable letters.

10 So I would say that's point number
11 one. With respect to guidance documents and
12 other things, I do have a different position
13 than the rest of the industry, because again,
14 we are representing the segment of the
15 industry that is almost always doing
16 something new, by definition. And the
17 guidance documents almost never help us, they
18 almost always hurt us, because there's an
19 attempt to squeeze a particular completely
20 novel technology that nobody has ever seen
21 before into an existing guidance document.

22 And what we find is the first two

1 meetings that we have with the FDA over a
2 period of three or four months is
3 demonstrating that in fact this doesn't fit
4 into a particular guidance; you cannot apply
5 a particular guidance because it's completely
6 different.

7 So I think guidance can be very
8 helpful for those things for which it is
9 appropriate, you know, the 14th drug-eluting
10 stent -- it's a pathway that's
11 well-understood. There should clearly be a
12 guidance on how to get a drug-eluting stent
13 approved. But the first drug-eluting stent
14 is much more problematic.

15 MR. BARNETT: Thank you. Anyone
16 else? Yes, two more.

17 MR. McKEEN: Mac McKeen again, with
18 St. Jude. I just would like to recommend
19 that FDA work within an existing guidance. I
20 mean, there's been call for new guidance this
21 year in terms of the review process, and this
22 FDA clock. In fact, that's one of the

1 guidances, is how we calculate the FDA clock;
2 the stops and starts. And I think in the
3 end, that's what could put pressure or roll
4 up into that metric of when this thing gets
5 approved.

6 What I would suggest is that the
7 Agency give reviewers of PMA and PMA
8 supplements more discretion, and perhaps even
9 incentive, to engage in interactive reviews
10 rather than deficiency letters, because
11 deficiency letters stop the clock, and then,
12 tagger it, and then the industry has to get
13 back to restart the clock.

14 And certainly there is occasion
15 where that's necessary if there's a gap or a
16 hole in the content of the submission. But
17 in many cases -- or in some cases, I should
18 say -- pretty straightforward questions may
19 be contained elsewhere in the submissions or
20 easily answered through an interactive e-mail
21 or a phone conversation.

22 In business, that's how we get

1 things done. We don't stop the car and get
2 out to fix it. We keep having meetings and
3 working together collaboratively to keep this
4 whole process moving forward. So again, not
5 new or novel by any means, but I think it's a
6 part of the FDA review process that can be
7 easily expanded within the current guidance.

8 MR. BARNETT: Thank you. There was
9 another one there. Yes, please.

10 MR. ST. PIERRE: Well, I hope
11 that's actually happening now. And actually,
12 I agree with those other speakers, too,
13 decision goals are much important than cycle
14 goals. So let's focus on that.

15 MR. BARNETT: Since you haven't
16 spoken before, identify yourself.

17 MR. HAHN: Dennis Hahn, Ethicon
18 Endo Surgery. I'd love to give you a number
19 in terms of the number of guidance documents,
20 but again, it's a qualitative goal; it's
21 difficult to give. The concern that I have
22 is that all of our MDUFMA goals are based on

1 the back-end of the process. User fees are
2 based on -- once all of the data has been
3 collected, it's based on the review cycle,
4 and all the performance goals are based upon
5 that.

6 One of the things that we're
7 missing, and Linda, to your point earlier, as
8 we look forward to MDUFMA 2, we really need
9 to focus both quantitative and qualitative
10 goals on the front end of the process, and
11 that is things like the IDE review process,
12 and even more importantly -- and I have only
13 an NF 2, but really pre-IDE meetings, both
14 the quality and the ability to schedule.

15 What I have been seeing in my NF 2
16 is that pre-IDE meetings are being pushed to
17 the very limit because of the focus on cycle
18 time in terms of PMA review and so trying to
19 schedule a pre-IDE meeting is very difficult,
20 it takes the full 60 days at best, to try to
21 get all of the players together; both from
22 the Agency and from industry.

1 So my focus for at least MDUFMA 2
2 is to look at some of the leading indicators,
3 which is really the early phase in the IDE
4 phase.

5 MR. BARNETT: Thank you. Anyone
6 else. Well, Don, you started a good
7 conversation there. Thank you.

8 MR. ST. PIERRE: I'm not on the
9 next panel.

10 (Laughter)

11 MR. BARNETT: Well, several people
12 have talked about qualitative performance
13 goals, and now we've got a session on that,
14 so thank you, guys.

15 And let me call up the next two FDA
16 subject matter experts, both from the Office
17 of Compliance, Tim Ulatowski and Mike
18 Marcarelli.

19 Our first speaker is Pat Shrader,
20 with AdvaMed.

21 MS. SHRADER: Good morning. My
22 name is Pat Shrader. I'm vice president of

1 corporate regulatory for Becton Dickenson,
2 and I am speaking today on behalf of AdvaMed.
3 My topic is qualitative goals, and I
4 certainly appreciate the nice lead-in from
5 both Don St. Pierre and other members of the
6 audience who have already spoken about this,
7 and have emphasized the importance of some of
8 these qualitative goals in making sure that
9 the intent of MDUFMA is really met.

10 First, I would like to add my
11 compliments to the compliments of some of the
12 earlier speakers to FDA for being able to
13 meet many of the explicit performance goals
14 for MDUFMA. I think FDA has made a lot of
15 progress in this area. It's been a lot of
16 hard work on both sides, but it's been some
17 very important work.

18 We talked last year about
19 qualitative goals, and particularly
20 scheduling of meetings, modular PMA reviews,
21 bundling and pre-approval GMP audits, and,
22 we've seen improvements in some areas, and in