FDAMA Teleconference and CDRH Stakeholders Meeting

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MINUTES REPORTED BY: Sandra L. Quinn, RPR

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MS. JOSEPH: Before we start, I don't want to go on without extending a number of thank yous. First of all, to Mark Roh, who is a small business representative for the pacific region for the FDA, and he's a new special assistant to the regional director. Mark has been spending lots of time on this. He has tirelessly worked to get this off the ground. And in the process of doing that, mentioned to Cathy Rangus that we needed a facility, and Cathy told me the story, but it seemed like low and behold she came up with this wonderful place which we can get used to real easily. Cathy is with the San Diego regulatory discussion group, and I thank you.

There are some other people who are working as well: Carol Sanchez and Jeffery Sloan from the San Diego office who were at the registration desk. Thank you all very much. And Michael Kruky, who is here with the center, who's been wonderful in accommodating us. To all of you, thank you for making this happen.

This afternoon's program is in three parts. The first part, Dr. Jacobson would like to make some opening remarks. Then we'll have our stakeholders panel of the five individuals who have graciously volunteered to make statements. And the third part will be from the floor, and

that's when we'll get comments from you all, if you have some comments or questions. And I think there's a mic in the back that you can use to address that.

If you have questions that you would like to write down, Ron will collect them, and we will deal with those in the same format, or you can present them yourselves. But we would like to capture them because we see it as part of the process of collecting stakeholder's comments, and we like to put them in the docket.

Dr. Jacobson, where would you like to speak from?

DR. JACOBSON: Good afternoon and welcome back to part 2. I'd like to thank all of you for coming out for today's event. My opening remark has mutated into a somewhat longer talk than I anticipated, so please don't vote with your feet.

Before we get started, I'd also like to thank some other people we have here, some of the regulatory folks that have come out for today's session. In addition to the panel and the people that Lee introduced, we have a number of FDA investigators. I was wondering if you guys would stand up. Thank you for coming. And I also wanted to say thanks to Aussie Schmidt, who is here from the State of California. Aussie is the supervisor of the California device program, and he's here today as well.

For today, I want to cover a number of topics that are listed on this slide. We had our first stakeholder meeting in Washington D.C. In August, last August, and I wanted to share some of the concerns we heard then and what we've been doing to address them. I'll talk about some of the challenges we're facing, our current resource picture, and several initiatives that we've undertaken to reengineer our programs and to implement FDAMA.

Finally, we're going to be soliciting, obviously the major portion of this, is to solicit your questions, advice, et cetera on how we can best meet the regulatory requirements that we have while insuring product safety and effectiveness.

We heard at the last stakeholder meeting that we needed better and more communication between stakeholders and the center for devices and radiological health. We think we're doing a fair job here. We're doing, at least from our perspective, a lot. We are implementing the FDAMA requirements that call for earlier and more frequent meetings with sponsors in the premarket review process.

We've had meetings with experts from all sectors such as the one we're holding this week on hospital beds. And we're also having one next week on reuse of single-use devices, so sort of specialty meetings that we reach out to people and try to bring experts in.

We've done video teleconferences like the one we did today. We also do them on specialized topics. We had one this winter on latexology which is sort of a mega affair involving us and about seven other federal agencies that were involved in putting that on. We've also been doing grass roots meetings. The field has had some very successful grass roots meetings with industry. But I think communication is one thing that you never get to say, "Okay. We do that really well." I think you have to keep plugging away and trying to do more and more and being open and receptive to what people say that they need to hear.

We also heard at the last meeting that you wanted more use of third parties. To be honest, we put an awful lot of effort into third-party program for pre-market review. We now have 13 accredited third parties and 157 different types of devices that can be sent to those third parties for review. And I've got to say that so far, we've seen very little use of that program by industry, and we'd sort of be interested in feedback on that too. Why not? We recognized 300 standards. It's actually more than 400 consensus standards that can be used by manufacturers and declarations of conformity maybe to skinny down some of the applications that we get to review.

We're continuing to strengthen the science-base through staff college and through a lot of interactions

we've had with outside groups in academia and government and industry to help us in our regulatory issues.

We're also trying hard to involve more consumers in our decision making. I think I mentioned this morning changing the advisory panel structure, or rather process, to allow more consumer comments. We also are having consumer forums. I think the pacific region is putting on a series of consumer forums in a couple weeks in three different cities. So we are working hard to try to get more consumer input.

What the law says we're supposed to be doing is a lot of things. This summarizes our major responsibilities, and the law does establish a bunch of performance objectives that we have to meet. I think we're doing better in terms of meeting our statutory performance objectives. We've improved our premarket review times in every category, and we're continuing to maintain a zero backlog at the end of the year, but we were a long way from meeting our statutory goals. In the enforcement area, as well, we are not able to meet our statutory requirement for biannual inspections. I'll talk about that a little later on a later slide.

Another of our responsibilities is to insure that radiation emitting electronic products are safe and to set performance standards for them. We're really not going

to talk much about that. That seems to be very deivice-oriented. But that's the "Rad Health" part of our name, and it includes the responsibility we have for insuring radiation safety not only of medical products but also of consumer products.

We also conduct science-based reviews of new technologies. We inspect mammography facilities, conduct inspections of device manufactures, and review adverse event reports to identify safety problems. I'm going to be talking a little bit more about adverse event reports in a later slide.

I think all of this is being done against a backdrop of a very dynamic and innovative device industry. The medical device industry is growing. There are about 10,000 or so manufacturing establishments here and abroad. Most firms are relatively small. I think the numbers vary a bit, but it's something like 68 percent of our device manufacturers have fewer than 50 employees, so that's a very small number of people to try to meet a lot of regulatory requirements.

The value of shipments by the industry this year is estimated at about $72.5 billion compared to $65 billion in '97, so it's a very productive group. And the industry is also characterized by an increasing diversity and complexity of products. Much of it brought about by

computerization, by miniaturization, and by a variety of new emerging technologies.

The only purpose of this slide really is to try to illustrate the complexity of the device world. I'm not going to go into each of these device types. But it is to try to underscore the contribution that device innovations have made to patient care.

If you think of how patient care has changed over the last 10 or 15 years in the hospital setting, for example, just compare what a gall bladder patient had to go through ten years ago with a week-long stay in the hospital and six weeks or so recuperation. And now we do Band-Aid miniaturized-type surgeries where the patient is -- maybe it's an overnight procedure, and they're back to work in a few days. That kind of change in patient care really has been driven by the device industry and by the innovations in medical devices.

I want to take just a couple minutes to talk about the center's workload and the resources we have to manage it. Last year we received just under 18,000 different types of submissions related to our pre-market review activity. We also got lots of adverse event reports, medical device reports, about 70,000 to 80,000 of those last year. We have about 10,000 or so establishments that are subject to GMP inspections, and we're also working with the

American College of Radiology to inspect about mammography facilities every year.

We are continuing to implement FDAMA and to develop mutual and recognition agreements with our foreign colleagues. And we also are dealing with really fun items like the Y2K millennium bug, which has really absorbed a tremendous amount of energy and effort to try to get the word out to make sure that everybody is thinking about incorporating Y2K thinking into their manufacture. And as I said, we've been trying to build our science base both internally through continuing education and through partnering with external organizations.

This display really shows our PMA and humanitarian device workload. We just wanted to put this up there to give you some idea of how the number of PMA's that we get fluctuates a bit. You can see the blue lines at the bottom are the actual original submissions every year. And then the green lines are the supplements that we get.

We see clusters from time to time. The numbers bounce around a bit. There is sort of an upward trend here. During fiscal year '98, we approved 46 original PMA's. Some of those represented significant medical device breakthroughs. We just listed them on the side.

And we're also looking at the way we process PMA's. We've come up with an alternative that we call

"modular PMA's." This involves receiving submissions in parts. As each part is done, we're open to getting it and to reviewing it right there so that when the final piece comes in, we have that piece to review and we're done. We do track those separately, and they don't appear on the chart. They appear in the year that they are complete. FY98 we got about 20 modular PMA's started for review. So that's -- we're very enthusiastic about that. It looks like that is going to work.

What you don't see on this chart is that we cleared about 4,600 510(k)s at the same time we were doing these PMA approvals. And hundreds of those were really very complicated. Just because it's a 510(k), doesn't mean it's not a very important contribution to medical technology. Many of those required clinical data and team reviews. So, again, another way of underscoring the fact that innovations seem to be continuing at an impressive clip.

I mentioned adverse event reports a minute ago. The message here is that we have been getting a lot of these reports. As I said, some 70,000 to 80,000, and we really wanted to rethink how we're processing them and how we're handling them. It's easy to get overwhelmed by paper and not actually get to the important trends that may be emerging in that data.

We began to allow summary reporting of data,

problems that we know a lot about. If we understand a product, and we understand the kind of adverse events that might be going on with that product, we don't need to hear about them time and time again. So we had agreements reached with 45 different manufacturers who are participating in the summary reporting program. They are providing summary reports on 52 different kinds of products. And, again, that reduces the number of individual reports we get and allows us to focus more on trends. We got about 20,000 reports last year in summary format, so I think that also is going to work.

We're also pilot testing a new Sentinel reporting system. That's what this slide was meant o represent. Rather than getting lots of different reports from different places, Sentinel tries to concentrate on collecting data from selected medical facilities who are not left out there all on their own. We have an intensive training program for the personnel in those facilities. We provide them with electronic report and with electronic ability to do their submissions rather than doing them by paper.

This was expensive. We were only able to do it in a small pilot last year of 24 or 25 hospitals, but we really thought that it showed great promise. We got better reporting, more consistent reporting, more reporting from

the facilities, which have not been very good at reporting otherwise. And if we get the funding that we asked for at FY2000, we're going to expand that pilot to 90 to 100 more hospitals. And eventually, the goal is to have a nationwide system of Sentinel reporting. So we hope that will be successful.

I wanted to talk a little about our routine GMP inspections. This is one of those areas where we are not meeting our statutory requirements, and we're very concerned about it. We have a requirement for inspecting every two years. We're not anywhere close to that. The current average for device GMP inspections right now is about one every seven years. That's an average. So for your Class I, II devices it may be ten years, longer maybe. For the more sophisticated, higher-risk devices we try to get them more often.

This really is not good, and we're concerned that our coverage this year will be even worse than this picture that we're painting here. We're also concerned about the fact that we're very involved in the mutual agreement that was signed between the United States and the European Union. We have an obligation to train the performance assessment bodies, and we're in the process now of being notified by Europe as to which bodies those will be. But, again, that's going to be a relatively

resource-intensive operation.

I wanted to talk about FTE history a little bit. What this history shows you is that we got a major increase in headquarters and in the field in '94 and '95 to help implement the Safe Medical Devices Act, that was the last major act before FDAMA, 1990. That resource has helped us. That's what got us to eliminating the backlog. That's what helped greatly in reducing the review times down to where they are now.

But since we got that last bolus of resources, the resource picture has been steadily eroding. And for the last five years we've been at level funding, which means we have not gotten a cost-of-living increase, if you will. We haven't gotten current expenses. We've just gotten a flat line, which has translated to a real decrease to something like 20 percent over the last five years. We did get about one and a half percent increase, which was sort of after the fact, and it helped, but it didn't get us where we needed to go.

One of the things we've been doing -- one of the reasons we've been so invested in reengineering is because it is very important. We can't do more with less. We have to do things differently with less, and that's why we have such an emphasis on reengineering. I think we see ourselves at a resource cross-roads in '99.

We have a lot of new responsibilities under FDAMA. We have a lot of emerging technologies that we do not want to be a barrier to in terms of getting them to the market. But we are investing something like 90 percent of the resources we get, in CDRH, are spent supporting people in terms of salary dollars. So we have very little program money left over when we get finished paying salaries.

So our staffing numbers are going down, our total payroll possibly going up. Staff numbers going down because we can't afford to replace people. We don't have the money to do it. And our capacity to undertake new initiatives is somewhat strained.

This is an attempt to illustrate the fact that we are not meeting statutory obligations, although, we are coming close in some areas. If you look from the top down, we have premarket approvals. We have first actions within 180 days. We're up at almost 80 percent, so we're doing fairly well there. Final actions for supplements is around 90 percent. We have 510KS first actions within 90 days. We're almost there, but that's first actions. People want final actions within 90 days.

These last two are the inspection pieces and the bi-annual nature of the requirement. That's why it's 50 percent instead of 100 percent, because 100 percent would be once every two years.

I wanted to talk a little bit about reengineering. What are we doing in the face of all this resource constraint business to try to keep the boat afloat? We have been reexamining how we do our work and how to refocus our resources from lower-risk stuff to higher-risk. We've been using a business-style reengineering process that Ms. Burlington pushed very hard in CDRH. We've had a number of changes, and we listed some of them on this slide, not all of them.

We've used a risk-based approach to target resources, and so in the 510(k) program we've exempted most Class I's and some Class II's from 510(k)s, again, based on the risk-analysis that we did. And we've revamped the process to allow speedier handling and some changes to 510(k) devices, and also allowing manufacturers, as FDAMA gave us the authority to allow manufacturers to declare a conformance to standards. All of that is sort of a package that we call the new 510(k) paradigm.

We've reduced the number of rewrites and improved project management for our regulations development. So we've been able to keep up with all the regulations that FDAMA demanded that we write. And we think we do it much faster and better than we we're doing reg writing before.

We've delegated authority for some lower-risk recalls to the district who have had been making

recommendations anyway, and we're very seldom, if ever overruled. It seemed to make tremendous to do that. The field now notifies companies before routine inspections. Something that came out of the grass roots initiative, and it makes, I think, for better, organized, and more efficient inspections. Companies can now make some corrections to deficiencies that are found during the course of the inspection, resulting in faster resolution of problems.

And we also revitalized an authority that we always had since '76, but nobody really felt comfortable using. That was the product development protocol where we actually reach an agreement with the manufacturer as to what type of data is necessary to demonstrate the safety and effectiveness of that product. The company goes out and does its studies to meet that agreement, and as soon as they have satisfactorily completed those, they go to market.

We have a process for accepting PMA's, as I said before as a compilation of modules, so that rather than waiting until the whole PMA is complete, we start reviewing it piece-by-piece before it is totally completed so that we're ready to go when the last piece is ready.

And we also, as I said before, recognized over 400 standards, national and international standards, and we have developed a standards database for use by center staff.

We have some new reengineering efforts that

we're embarking on, three in particular, the postmarket process, registration and listing, and QSIT and HACCP. The postmarket process, to us, refers to everything that happens in the life of the product after it's on the market. We think we need to do a much better job within the center of integrating the postmarket experience that we gain as we see what happens to the product once it goes on the market.

Integrating information with our premarket effort and also feeding it back to both industry, for sure, but also consumers and users of the products. We get a lot of unhappiness from people who submit adverse event reports that, for example, "We send you all of these reports; we never hear anything back." I think that is a very legitimate criticism, and one we have to do something about.

We're also looking to see in the registration and listing area -- we'd like to see how many manufacturers might be able to use the internet to register and list electronically, and we've got a lot of interesting things that we are trying to do there.

QSIT and HACCP, of course we have to have acronyms. QSIT is the Quality System Inspection Technique. HACCP is the Hazard Analysis Critical Control Point. These are processes that we're developing to try to implement a quality-systems approach to inspections to enhance the types of information that we get out of inspections and also

giving manufacturers much more control in a very real sense what we'll be looking at. Because they will be looking at what are the critical control points and the critical processes in their manufacturing processes, and who better to do that.

So the goals are to achieve shorter inspections that focus in on the important problems and also involve more positive interactions between the inspectors and the manufacturers.

This is the science-based side. I'm not going to spend any time on this. I think we heard an awful a lot about this from Henney. I just want to make the point that we are looking very much forward to working with her on this as an initiative. It's crucially important. We've always felt terribly invested in the idea that we need to have people, as she said, "at the top of their game." And it's wonderful to have commissioner support for that, and we're all very enthusiastic about it.

FDAMA, everybody is interested in how we're doing in implementing FDAMA. Linda Suydam this morning ran through a list of all of the accomplishments that the agency had done, and I was really pleased that an awful lot of those were ours. They are just listed here. It involved a tremendous amount of work both on our part and also on the part of a lot manufacturers, consumers, people that

interacted with us to help us get our act together. The other thing that helped was we were ready for FDAMA, because we had already been doing a lot of this stuff in our reengineering process. And as Linda mentioned, a lot of FDAMA codified the directions we were already going in, which made complying with it -- we were sort of not behind the 8-ball. We were right there ready to go.

To proceed down the side a little bit, we have been trying to interact with stakeholders earlier during the application review process for years and years. FDAMA does really codify that, and we now have procedures for agreement meetings and determination meetings. We've made and we continue to expand. We've been trying to make information available through our website.

We have a Y2K page where device manufacturers can supply information on the Y2K status of their products. And actually that's stating it a little too mildly. We've gone out and begged manufacturers to come in and give us information on the Y2K compliance status of their products on our website. Both noncompliant products and now we're also trying to do a compliance product page.

That's not necessarily because we think it is a good idea, but the users, the hospital associations, and other people have come in and said, "We'd like a place to go to where we can get that information." So we're running

that for the government. We are the government's Y2K website for information on Y2K compatibility for equipment. We also have more opportunities for stakeholders to interact with advisory committees, and as I said, we're piloting the Sentinel postmarketing reporting system.

I'd like to finish by asking for your help. We have three areas we'd like your comments in, these are in addition to Jane's five, so there is eight questions that you were given today.

The first question has to do with our reengineering and FDAMA initiatives. Are we making the changes that you support, that you are concerned about, that are getting in the way of your doing business or getting in the way of your consumers getting information from us? Do you see the need for other changes? And if so, what are they that we should be involved in doing?

I'd like to ask from a personal point of view if there are people in here that could address the standards issue. Standards is another area where we recognized over 400 standards. We're waiting for those applications with the declarations of conformance to come pouring in, and guess what? They're not pouring in.

We thought this was going to be great because people would be able to -- they would still be doing the same work they've been doing ordinarily, in terms of

developing the information, making sure they have the data, et cetera in their files, but they don't have to give us any of it. They just have to give us a sheet of paper that says they did it. So it would make our review process much simpler. So to the extent that people feel that they'd like to comment on that we'd, love to hear.

The second question is how do we work together to communicate how ready the industry is for Y2K to the stakeholders out there, to consumers, to hospitals, to purchasing agents, to the people -- it's not just an equipment question. We have put a lot of effort into the equipment issue. Do you have a piece of equipment that has a component in it that may be vulnerable? But it's also a supplies issue.

In the supply area, if people are worried that transportation is going to be disrupted or that there is going to be shortages because people will be over-ordering, things like that, that would be a self-fulfilling prophecy. The question that we're trying to get to here is: What do we do to get the word out that people are or aren't ready to the extent to which the industry is ready to try to calm those fears without having people say, "If they're taking the trouble to tell us there is no problem, then obviously, there must be a problem." It is really difficult, and we appreciate your help in figuring it out.

The last slide is in the area of international harmonization. We'd like to hear from you about the kinds of things that we should do to encourage harmonization in device regulation and how we can work together to address its costs.

We'd also like to invite everyone -- we'd like to invite you or tell you that we're having a global harmonization task force conference in June. It is first-come-first-serve, so I can't say, everybody come, because the room is somewhat limited. But if you want more information, we do have a website address that you can look at to get information about global harmonization. It's www.ghtf.org -- notice it does not say ".gov" it says ".org" we were very proud of being able to get a ".org" website through FDA, because the harmonization task force is more than FDA; it's the world, regulatory agencies of the worlds' medical device industries.

DR. JOSEPH: The next part involves our stakeholders who will be making presentations. You can speak from the mic at the table. You can speak from the podium.

MS. KEELING: As president and co-founder of Chemically Associated Neurological Disorders, a non-profit organization dedicated to raising funds for education and unbiased research on the toxic effects of silicone, silica,

or its components, I applaud FDA commissioner Dr. Jane Henney's use of new communication technology to enhance communication between stakeholders and FDA officials. This is an important first step for identifying problems, getting feedback, and evaluating ongoing modernization efforts.

Current research and diagnosis are contradicting each other. While some research, paid for in part by the manufacturers of medical devices, indicates little or nor correlation between implants and disease, common diagnoses of implant mutations indicates significant correlation.

Research suggests mothers with implants may unknowingly be passing toxic residues to their unborn children through the placental barrier as well as to newborns through breast feeding.

I represent the thousands of women who believe their health has been affected by ruptured, leaking breast implants. We, like the general public today, believed and trusted the FDA was protecting us as consumers. Only after doing extensive research, did we learn that no breast implant has ever been approved by the FDA, because manufacturers have never been able to prove them to be safe or effective as is required by law of a Class III device.

In answer to your question, what actions do you propose the agency take to expand FDA's capability to

incorporate state-of-the-art science into its risk-based decision making? I propose consumers be allowed to submit published research to the FDA and receive timely written answers regarding levels of risk tolerated by the FDA and have those levels of risk be accurately reflected in informed consent forms and product inserts.

For instance, a failure rate of 5 percent was regarded as not a safety standard the FDA can accept, according to former FDA commissioner David Kessler; however a failure -- occurred from 11 research papers of 1,652 implanted prosthesis showed a significant direct correlation of failure rates with implant times and can be used to predict a failure rate of 50 percent at eight years.

Nevertheless, the FDA has allowed the manufacturers to quote a 1 percent rupture rate in their package inserts. This kind of misinformation on the part of manufacturers and under-reporting of complications is serious and cannot be tolerated, along with other protocol violations, which are currently occurring in mentor adjunct study on breast implants.

November of '97 in a meeting with the FDA a Baylor College of Medicine researcher presented data documenting the release of low molecular weight silicones and platinum from intact implants which spread to ten major organs in the body, including the brain in mice.

Baylor's recent research published February '99 documents fatal liver and lung damage in mice. Dr. Luberman states, "Injection of about 4 percent of a teaspoon kills approximately 50 percent of the mice in seven days." This degree of toxicity is about the same as that of carbon tetrachloride and trichloroethylene, two compounds that are widely recognized as model toxins and, in fact, are used by many researchers in their work to understand how toxic chemicals harm the body?

Does the FDA have a safe level of risk associated with the implantation of silicone, silica, or its components, such as platinum, which can leak before it becomes toxic in the human body.

In '97 Dr. Louis Brenton of the MCI and Dr. Lori Brown of the FDA published an article reporting, Silicone gel has been found to migrate into both surrounding and distant tissues as a result of ruptures or bleeds, with reports of evidence of silicone found in the breast, implant capsule, lymph nodes, arms, fingers, groin, blood and liver. Recent evidence has documented that it is immunogenic.

You ask what actions do I propose to facilitate change and integration of scientific information to better enable FDA to meet a public health responsibility?

I propose if the FDA does not have scientific information about the safety or effectiveness of a medical

device, it has an obligation to inform the consumer of this fact to meet its public health responsibilities. I propose that the FDA mandate the use of percentages of risk from reported, published complication rates in manufacturers informed consent forms and product inserts to better enable consumers to determine the rate of risk they are willing to assume. The FDA is currently allowing Magan to state, "Most women who have had breast implants have had satisfactory results, and complications are uncommon."

You ask what actions do you propose for educating the public about the concept of balancing risk against benefits in public health decision making? I propose the FDA issue public health information on a regular basis to television and media contacts to counterbalance the misinformation provided by the public relations firms of the manufacturers and plastic surgeons who regularly tout all of the benefits and none of the risks of breast implants and other cosmetic surgeries in the media.

You ask what actions do you propose to enable the FDA and its product centers to focus resources on areas of greatest risk to the public health? I propose that FDA allocate its resources based on the products with the highest percentage of complaint or serious adverse events. In '92, 30 percent of the total mandatory adverse events reported to the FDA on medical devices was on breast

implants alone. Over a 170,000 adverse events have been reported to the FDA on breast implants.

The Wall Street Journal on June 24, '98, in an article entitled "Med Watch System Comes Under Fire" quotes Brian Strom, chairmen of the University of Pennsylvania's biostatistics department saying, basically, "Nobody is looking for problems. The system has turned into a big waste basket." The process for adverse event injury reporting is the most urgent task facing FDA. He states, "Who at the FDA is looking at long-term consequences of breast implants?"

With the reported latency factors an average five to fifteen years for symptoms to appear, the current med watch system is inadequate. It appears it was designed as an early warning system only, and a problem occurs when the doctor who put the device in is not the doctor who is seen for systemic disease systems. What modernization efforts have been put into place in this area?

Lastly, you ask what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and for evaluation of our modernization efforts? Periodic live satellite teleconferences are a great start at communication processes which include consumer participation. More open communication with feedback, regardless if negative or positive, to problems

identified by consumers is essential. I'm still waiting for feedback on my proposals made at the August 18, '98, compliance public meeting. Thank you.

DR. ALBERT: Thank you very much for your comments. I want to clarify one thing because I think it is important, in that, any health care professional or individual can, in fact, report to med watch on adverse events. It doesn't have to be the implanting surgeon at all. It can be anyone who sees a patient and determines that, in fact, there is an event potentially related in time and raises a concern about a medical product, be that, drug, device or biological. There's no restriction on who can report.

I also wanted to say that I think it's very important for consumer participation. You are absolutely correct. It is in our plan as we move forward on the issues related to breast implants for the companies bringing forward the information that, in fact, those public discussions, as the products move forward, will clearly include consumers both being able to present to the panel as well as being represented at our panel meetings as part of our panels because that is a process that has, in fact, gone into place.

We've had several medical device panel meetings where a consumer was added in addition to -- it's not the normal consumer representative to the panel, but a patient

representative as well. And we intend fully to do that as we move forward on any panel meetings related to breast implants, so we do hear you in that sense.

Your other concerns about what information is being communicated, be that, in labelling or in informed consent, clearly we'll take under advisement, and I also want to say that we have attempted -- and I'd like your feedback on this -- to update the consumer information, that is, put together a booklet that is put together on breast implants, and I wondered if you have any specific comments about how that might be updated, because we hope that that is a place where we do capture the publications and the global issues perhaps more -- globally is the only word I can use -- globally a cross-product.

When we deal in an individual study or an individual consent or labeling, we're dealing more with a specific product. I'd like to hear your comments, if you have any additional comments or things, that you think we can do better in our consumer booklet. I'd really like to hear that as well.

MS. KEELING: Overall, we're very pleased with the booklet. We would like to find ways of getting that in the hands of woman, young woman of childbearing age particularly who are considering this surgery, so we would like to see that as a priority.

One comment I would like to make regarding that is the issue of the polyurethane implants. There's been some research that was published in July of '98 regarding the breakdown of the polyurethane form into TDA is an unreasonable risk to the health of the patient, and I have not seen any patient advisory. That information was not included in the most recent breast implant FDA information booklet.

I have a young woman who just recently reported to me that she has nine-year-old polyurethane implants. They are still in her body, and she's pregnant for the first time. So we desperately need guidance from the FDA on patient advisory and breast feeding issues.

DR. ALBERT: Again, if you have any suggestions on how to make that booklet more available. We've had some conversations with advocates, and we're very concerned about being able to alert people to its existence. It is on the web, but if you don't know about finding it on the web, you can't find it.

MS. KEELING: Unfortunately, there's still a large population, percentage of the population, that doesn't have access to the web, and that is a problem.

DR. JACOBSON: I think early today I gave you the number to our consumer affairs group. I think if you engage in a conversation with them, and I certainly will on my

return, we can be creative in figuring out different ways of getting that information out that won't be limited to the web.

MS. KEELING: I also had a question that didn't get asked to the commissioner that I would like to ask today if I have time.

DR. JOSEPH: Can you hold your question? If we go through the other speakers, we might have time to return to it. Steve, I think you're next.

MR. NORTHRUP: I'm Steve Northrup, Executive Director of the Medical Device Manufacturers Association, Washington D.C. We're a national broad-based trade association representing around 130 manufacturers of therapeutic diagnostic products, and I appreciate the opportunity to come out here today and not only talk to the FDA, but talk to you all, because it's people like you in industry and consumers as well, who are really responsible for spurring much of the reengineering and Food and Drug Administration Act of 1997. It was your concerns that really brought it to the attention of members of congress and to the FDA. And it was the FDA's responsiveness in addition to your concerns that have brought us to where we are today.

There's been a great deal of change throughout the 1990's in the way the FDA does business, and you all continuing to participate in that process is important as we

move into the next decade as well. I also encourage the FDA to have more meetings in garden spots like La Jolla -- anything to get me out of Washington D.C.

I think you all have the questions in front of you. I'll dispense with that slide and move right along. Looking at the two first questions, I decided to combine those two because I think that both can be addressed by some of the points I'm making here.

With regards to strengthening the science base of the agency, we agree 100 percent with what Dr. Henney has said in a variety of forums, including today, about building a strong science base at the agency. And it's important to, number one, insure that CDRH does has a very strong core of professionals of scientific experience. We believe it is also important for the agency, recognizing resource constraints, to collaborate with other governmental agencies and with academia. It's important for the agency to have that strong core, because if you don't have the core in the agency, there's no way the agency can really look to outside parties and then be able to judge the work of outside parties with any sort of critical thinking.

Clearly there is a role that institutions, like this institution we're at here today, can play in the process. One of the great things about medical research in this country is that the federal government several decades

ago decided, rather than nationalizing all of the research that goes on in this country, they made a decision to create a government academic partnership through the National Institutes of Health. We all hear about the NIH, but what you may or may not realize is that most of the research that goes on at NIH was done at institutions like Scripps and UCSD and the academic medical centers and teaching hospitals in this country. So we need to look to those types of institutions as well for some scientific expertise.

Encouraging the use of third-parties, I'll get to in a little bit. Working with industry to identify trends and developments early, I think, is important. I'll give you an example: The FDA did an excellent study back in April of '98 called "Future Trends in Medical Device Technology", and I think Dr. Jacobson referred to some of these trends that the FDA has identified. And we'd like to be able to work with the agency to help the agency identify more of these trends, identify what the agency and industry needs to do in order to cope with these trends and how we can help the agency be ready for what is to come in the future so that they can do their job more efficiently, and these new products can get out on the market safely and effectively in a timely fashion.

The third question on educating the public about balancing risks and benefits. I think one thing we need to

understand is that there's been a change in the way the public decides the questions about drug and devices. The public over the last five years has started taking a much more critical approach toward the suggestions that are given to them by their physicians. And I think the internet is one of those things that patients are using more and more as a tool for making critical decisions about their choices and the choices that the physicians and other health professionals are recommending to them.

Unfortunately, some of what's on the internet isn't necessarily accurate, and it's important for consumers to keep that in mind, that the internet shouldn't be the only source that they use to make these decisions. But we need to encourage the use of the internet for disseminating information about the intended uses and contraindications of devices.

We talked about this with Dr. Albert recently the fact that oftentimes with devices, if the labeling is on the box or in a package insert, once the device is out of the box, the labeling is thrown away. How do we deal with that? Certainly you can't print a 200-word labeling instruction on a catheter.

But if manufacturers can post that information on the internet, I think that is something that the FDA should encourage, and we should encourage. We just need to

be careful about regulating the use of the internet. One of the things that's great about the internet is the fact that it has and spread and grown without much government regulation at all. That has contributed to some negative instances as well, but by and large, that's one of the things that has made the internet great. And I think we should think carefully before we do serious regulation of how the internet is used.

Allocating scare resources and focusing on areas of greatest risk. I look to the agency to focus first on the statutory obligations and encourage them to continue doing that, focusing on device reviews and device inspections. Those are the two main obligations set forth by congress under -- and protecting the public health.

Continuing reengineering efforts. I can't say enough about what the FDA has done over the last few years and the change in the interaction between FDA and industry that we've seen. But we need to work together with the FDA to educate industry on these new pathways to market. And it goes back to a slide that Dr. Jacobson showed us about how this industry is primarily comprised of small businesses. And it's important for us to get the word out to those small businesses.

Most of the companies that we represent and we look out for are the entrepreneurial companies that are new

to this industry, and we need to do everything we can to educate companies on how to use these technologies in a way that's useful for them and doesn't require them flying all over the country, because most of the companies have very small budgets and can't handle that.

Continuing to identify Class I and II devices exempt from premarket review when appropriate and continuing to streamline not just the PMA but the 510(k) processes as well and also promoting standards. I don't want to ignore that. We think that is very important. Something we at MDMA are putting some effort into. We asked Harvey Rudolph from the office Science and Technology to speak to our members on a conference call next month, and if any of you are interested in participating in that, please give me your card, and I'll let you know how you can participate.

Enhancing communication between public and regulated industry. These public meetings are great, and I hope we'll continue to see sessions like this. The new mediums -- things like web casts, videoconferences, teleconferences -- it's very important once again with an industry comprised mainly of small businesses with limited resources to get the information out to the user in the easiest possible way.

The FDA CDRH website is great. If it hasn't won awards, it probably should. There's so much information out

there now that sometimes it's hard to find. I'll give you an example: Device Advice -- how many of you are familiar with Device Advice? Maybe about half. It's a program on the FDA website that takes you through the steps you need to go through when you are considering -- how do I file this submission with the FDA? I think that should be something that's made more prominent on the website. You can find it if you know where it is, but it's knowing where it is that's half the battle.

The dispute resolution process we think is very important. The advisory committee, for instance, is not necessarily the way to resolve scientific disputes, because in many cases, the advisory committees are part of the scientific dispute problem. Expanding early collaboration meetings with the agency, where, again, I think is also important as well.

Turning to specific questions, the completed efforts that we support through FDAMA reengineering -- I didn't list them. Dr. Jacobson already did; that's why I didn't put them on this. Promoting third-party review. I think that third-party review is one way that we can really help the FDA conserve its resources and focus on the devices of highest risk. We as an industry association and the FDA needs work on promoting that as a viable option to manufacturers.

The FDA has done such a good job in reengineering. Unfortunately, the time has come down to the point where for many manufacturers it's not really worth it to go third-party because they may not get the device through fast enough to make a difference in terms of how much they are going to pay the third-party. The median review time for third-parties I believe Dr. Albert said is about 22 days, and for 510(k)s somewhere between 80 and 90 days. So it is something for manufacturers to consider. We just need to promote it.

The user fees issue. I really wish we didn't have to deal with this issue, frankly. I think it's time for the FDA and the Clinton Administration to move on. We as MDMA, the only national broad-based association of device manufacturers, oppose user fees because we don't feel it's an appropriate way to fund the industry. It may work in the pharmaceutical industry where you have a few companies with deep pockets who fund most of the programs. But even there, I've heard Dr. Suydam say the user fee program for drugs, because they have to focus so much on getting resources in there to trigger the user fees, is hurting the drug program in many ways. I could go into user fees a lot more. If you want to find out more on it, you can visit our website at medicaldevices.org.

If I had some time, I'd talk about this export

regulation that came out April 2nd. Anyone that wants to know more about it can talk with me afterwards about it. Very simply, it's just an unnecessary regulation. I will be talking to the FDA about it.

As far as Y2K compliance goes, I think we need to stay the course. The FDA has done a great job of trying to help manufacturers come into compliance with the year 2000, get the information out to the user community. I think we just need to continue down that road.

As far as harmonization goes, the one thing that worries me is that we're focusing too much on the harmonization of the regulatory systems. What we should be focusing on is the essential principles. I don't think we'll ever come to, at least in my lifetime, a situation where there is one worldwide regulatory body, so let's focus on the principles, rather than the specifics of the regulatory schemes. Thank you.

DR. JACOBSON: You mentioned something that is near and dear to my heart which is identifying trends and trying to keep up with an ever-burgeoning technologies. It is something that requires a fair amount of creativity on our part to keep up with.

You suggested we should be working with industry to help identify those trends and work together. Do you have any specific ideas, or as you come up with specific

ideas, can you give them to us? As you said, we had our study that we did in the spring to try to look at what are the trends that are coming up over the next five to ten years. The reason we did that is because we'd like to try to get our resources lined up with those trends. That's always a little risky because obviously you can't predict everything, and there's liable to be some technological advance, some quantum leap, that nobody envisioned right now, but at least it's an attempt to get there. Any suggestions?

MR. NORTHRUP: One of the examples that your staff came up with in this report was device -- products, and there are some companies that are on the cutting edge there. To the extent that the agency and some of those companies can sit down and look at some of the difficulties they faced in getting through the process and see where the FDA -- and work with industry to identify ways to streamline the process.

Obviously, some of these new products raise significant questions of safety and effectiveness, and we have to be careful about how they do that. But I think getting together with some of these companies that are performing the cutting edge, because cutting edge is sort of the point of the vanguard -- just getting together with those companies.

DR. JACOBSON: Like a work shop?

MR. NORTHRUP: Yeah. Those companies who are in the vangaurd can probably contribute a lot to what you're already doing.

DR. ALBERT: Two things: One is -- and it's really not to be answered now -- but you made a provocative statement about further streamlining of the 510(k) process. I think it would be very important for us to hear what kinds of further streamlining you had in mind, and if you can submit those to the docket, that would be great for us and that would make it available for other people to comment on as well.

The second thing was, I just wanted to make sure I understood your issue on the internet. Although we don't have our office of compliance and the folks who deal in the oversight of marketing and promotion from CDRH in the room, I think it's important for us to capture what you are concerned about. I wanted to make sure that it was clear. Obviously, we can't regulate the internet. The internet isn't a medical device. I want to make sure we understand what aspect of our behavior is raising your concern.

MR. NORTHRUP: It's nothing that actually you've done yet. It's more a let's think about as companies start using the internet to disseminate information about their products to the public and to health professionals. I think we need

to be careful before we step in too heavily with a heavy hand. I'm not suggesting that you are or that you even will. It's something to keep in mind.

DR. ALBERT: I guess I put the placemarker that that has to be done within the bounds of understanding that whether you communicate in electrons or written words, that the regulation of that communication is part of our charts. So not just a concern about it, but if you have specific suggestions, I think that would be helpful to get on the docket as well.

MR. NORTHRUP: One of the things that manufacturers may do is put frequently asked questions about technologies on the website. And depending on how you look at some of the answers, I think it's just careful that as manufacturers try to get more information out using the internet, to work with us to help us understand what's appropriate, what's not.

A chat room that's hosted by a manufacturer on their website, are they responsible for everything that goes in there? And if something gets in there that seems to promote the use of their product in a way that is off-labeled or somehow detrimental, what is the responsibility of the manufacturer there? That's something I don't think we have thought through. Those are just a couple of examples of things we need to think about.

MS. MESSA: I would like to encourage everyone as an ORA representative here, I think it is important that the science base, as Dr. Henney mentioned, deal with field investigators and meeting statutory regulations, also a very the important piece of our operation. So I would encourage you to provide suggestions to CDRH to the field staff.

MR. NORTHRUP: We certainly support sections of the FDA budget that requests more money for inspections, and we're all looking forward to the quality assistance inspection technique as a way for you to focus more on a systems-based approach, and hopefully that will enable you to do more inspection in a shorter fashion.

Maybe some of you will shoot me for saying this, but maybe if manufacturers were inspected more frequently, but in shorter and more concise and more focused fashion, they would probably prefer that than the system we've got now. I think that would as a whole be good for the industry because it would weed out a few of the bad apples that are out there.

DR. JOSEPH: Tuesday on the website we published scientific dispute documents. That's up on the web.

MR. NORTHRUP: We'll take a look at it, and if we have any comments, I assume there's an opportunity to comment.

MS. SAIGET: My name is Susan Saiget, and I am an

employee of PharMingen a business unit of Becton Dickinson Biosciences. I have been asked to represent Becton Dickinson Biosciences here today and will be presenting comments prepared by our regulatory affairs department.

We wish to thank the Center for Devices and Radiological Health for providing this opportunity to share our suggestions for FDA's efforts to improve its implementation of the law.

First, how should FDA incorporate state-of-the art science into its risk-based decision making? We wish to address the use of risk-analysis and review of new products. We all acknowledge that the rate of scientific discovery and development is accelerating. Under today's product development system for devices, any truly novel product reaching the U.S. market will be at least one generation or more removed from state-of-the-art. This situation can be beneficial. An extensive program of design and testing is not only a regulatory expectation but has become an industry and a public expectation for any truly novel healthcare product entering our market.

One result of this careful and organized approach to product development and evaluation combined with the almost daily changes in technology and science is that no product will be state-of-the-art when it reaches the

reviewer's hands. If FDA insists on state-of-the-art, companies are continually thrown into a round of revisions for each significant improvement, and products that will have significant benefit to patients and their providers will not reach the market in an appropriate, timely manner.

FDA should not feel that it alone has to provide incentive to manufacturers for continual product improvement. For high-technology industries making regulated products, there's ample incentive to continue state-of-the-art product development. Our competitors provide these incentives. For most of us, the motto is "Improve or die."

Two, in review FDA should principally base its expectation for product performance on what is currently available for use in the U.S. market and not what is being explored at the NIH or other world-class research institutions. Risk-benefit assessments for marketing permits should not be conducted on what could be developed but on what is currently available.

Three, for issues concerning product safety, FDA should base its review on the very latest information, as long as that information is based on labeled claimed products, statistically valid scientifically sound studies, and is not anecdotal information whether obtained from peer review scientific journals or other sources.

Four, on use of state-of-the-art science and the assessments of risk for which FDA deserves commendation is their consideration of new surrogate -- for clinical studies and new invitro analogues for animal studies. These advances in science serve to shorten testing time and allow innovative products to reach the market sooner, thus shortening the product life cycle.

We expect FDA will continue to encourage advances in these areas. By encouraging more scientific ways of establishing product conformance, FDA will also assure that the product reaching the market is as close to state-of-the-art as it reasonably can be.

Educating the public about risk-benefit analysis. Risk-benefit analysis is not well understood by the general public. We see this frequently when the news of a single disaster with a product outweighs the years of positive health effects obtained by the use of the same product. Disasters command attention, statistics do not.

If FDA wishes to provide outreach to the general public about risk-analyisis, we suggest FDA try an approach that capitalizes on the familiar choices people have to make that involve risk benefit. Develop an outreach program that explains in simple terms what people have to consider when evaluating treatment options with their physicians, what they need to ask their doctor, and how risk benefits

provided the information to answer their questions.

Do this for a couple of key diseases with three or four alternate therapies to explain the concept of risk evaluation. Then once the basic idea is established, you could explain how the same techniques are employed by FDA on a more global scale to review recent therapeutic or diagnostic products aimed at the same disease categories.

Educating the exchange of scientific information between government, academia, and industry scientists. We suggest FDA take advantage of the resources it already has and use them differently: Use your advisory committee members to provide training to reviewers; acquire more advisory experts in the physical sciences, such as materials, physics, electronics, and software development, as well as life sciences; provide more science training to your inspectors who must apply your regulations to an increasingly high-tech manufacturing community; have manufacturers provide more information about basic sciences and follow up in the development of the product prior to product review; seek out reviewers who have both scientific expertise and experience in the practical application of medical products; look for opportunities for reviewers to participate in externship programs where they can gain current experience with medical products in the practice of medicine; consider more engineering strength at the higher

levels of CDRH; when there are scientific disagreements, have available mechanisms to take the issue to an outside scientific review short of convening an advisory committee.

Next, improving FDA focus. In FDAMA, FDA has given CDRH the basis for focusing its resources in the area of product review. This is the mandate for the least burdensome approach to product review and approval. At this point the least burdensome concept is open to widely varying interpretation and in order to be effective, should be better to find. Industry has suggested some steps to work toward its definition, and we expect that FDA will respond and move forward with this task.

Additionally, CDRH has employed a risk-based triage approach to product review. Risk-based triage is unevenly applied. We suggest ODE come in and review expectations for Class I devices, with those for Class II and higher in all reviewing divisions, and evaluate whether risk-based triage has actually taken place.

If there are any questions, I would be happy to deliver them to the appropriate personnel within our company.

DR. ALBERT: I do have a question and it would help to get some clarification from the staff. Early on in your talk you talked about a demand or -- what you articulated was that FDA was demanding that things be state-of-the-art.

It was an implication that a product has to be better than something else in the market or newer than something else in the market. I, as the person responsible for the review program, would really like to know where that is happening because it's not in the law. So if, in fact, there are some examples that you have with that, that would be very useful for us.

The second, you talked about publishing a risk-assessment. I think that's an extremely intriguing idea for us, so I want to thank you for that, and one that I know I'll take home to think about. We try to get some things out, but I think the idea of publishing some of that risk-base experience or the approval of some of the products, might be very useful. We'd have to be careful not to be dealing in proprietary information that was not ours to deal with, but I think that's a great idea.

The third thing that would be helpful to get some clarification, you talked about having some other kind of review besides our recognized advisors. We're kind of constrained by the law to use our advisors, but if there was something else that they were intending in terms of bringing more expertise from outside, leveraging in some way, that we haven't thought of, getting some more specifics on that would be real useful to me as well.

MS. SAIGET: If it's acceptable, I would like to take

these questions back, and we can send them to your office.

DR. JACOBSON: You mentioned we need to be -- sort of hitting on the whole topic of scientific training and keeping the staff at the top of their game. Do you see a role -- we've been talking a lot about this, and we've had a lot of outreach activities in the sense of vendor days and things like that where we get a tremendous amount of information from those things. Do you see a role for industry/FDA cooperation in the area of scientific training?

MS. SAIGET: I have to be honest with you. I don't work with the regulatory aspects on a day-to-day basis. We do have other people here that might be able to answer --

MR. ARBITTIER: Yes. The person who wrote that statement is not Susan. I didn't write it either, but I can speak for myself and my company that we'd be happy to work with the FDA.

DR. ALBERT: Repeating the comment for the record, was that the person who wrote the comment is not in the room, but the comment will be taken back, and it will be addressed.

MS. MESSA: I want to add onto that and also thank you for recognizing the field investigators in that comment. As part of the medical device initiative, there is a subgroup working on training for field investigators with industry. We would love to be able to do vendor days, but

obviously they don't work in the field. So whatever suggestion that you might have in terms of discussions, we would very much like to have those.

MS. SAIGET: I know there is a lot of people that would be happy to provide suggestions.

MS. SHEA: Good afternoon. I appreciate this opportunity to address some of the questions posed by FDA regarding the implementation of FDAMA and the spearheading of their reengineering efforts within the agency.

My name is Cheryl Shea. I'm currently RA/QA for a medical device start-up company here in San Diego named CryoGen.

First, I would like to applaud the agency for the overall progress made in the implementation of FDAMA and the spearheading of the reengineering efforts. There appears to be a growing level of scientific and medical expertise in FDA. The division that I'm currently working with the most has brought at least two MD's on board in the last few years. Our company participated in vendor day last November, and it was very encouraging the number of FDA staffers that came down and were very interested in technology. There were about 20 companies exhibiting.

Our efforts of scheduling early collaboration meetings have been very successful overall. In some instances, however, we have discovered that true

collaboration, which is defined by Webster as "to work together to cooperate" has not really existed.

For example, in one case the agency had already made up its mind, regarding an issue that we had gone in to speak to them about, before we walked in the door. And there was no willingness to hear our presentation nor to consider the relevant facts of the case.

I personally see very little progress regarding the least burdensome provision of FDAMA. In fact, at the reviewer level there seems to be a lack of understanding of the concept. I know it's still a growing area. I encourage education at all levels of FDA regarding this provision of FDAMA as well as collaborating with industry. PMA has an ongoing working group addressing this issue. I trust that the agency will openly embrace the comments and suggestions of the working group.

Recent history has shown that joint FDA and industry working groups have been very successful. The efforts in international harmonization continue to be encouraging, though slow. There appears to be a lot of progress in this area, though. With respect to the dispute resolution provision of FDAMA, our company has actually utilized the dispute resolution process through the ombudsmen's office over the last year. And I have to say, we have nothing but positive regard for Amanda Norton and

her staff. They have done a great job. Unfortunately, the process has been very lengthy, time consuming, and bureaucratic. This is certainly an area for ongoing improvement.

One area that is of key concern to our company, and I believe the device industry as a whole, is the general specific use guidance document that was issued by the agency in November 4th, 1998, in response to Section 206 of FDAMA. I believe that this document actually entered into the new paradigm of products approval within FDA which significantly affects all of us, and wasn't necessarily intended by congress the way it was written.

I also believe it was released hastily with little acknowledgment of industry concern in an effort to meet the time frame mandated by congress and FDAMA. This document blatantly overlooks regulatory law. It allows the approach of basing SE and NSE decisions on the important public health impact factor for every 510(k) under review. This is not in line with the Food, Drug, and Cosmetic Act, which it pertains to devices. It overlooks the device classification process.

During the classification process, FDA classified many broad use devices by regulation into Class I or II. During that process, FDA determined that these established devices should not be subject to premarket

approval. FDA and the advisory panels that participate in that classification process were keenly aware that broadly indicated devices were used and would be used in the future for multiple specific medical procedure.

Congress did not direct FDA to protect the public from the medical community's use of established tools in varying new ways, but to protect the public from poorly designed devices and from new devices with unproven technology. With this new paradigm, FDA wants to arbitrarily subject selected specific uses of established devices to premarket approval requirements, even when those uses are included within the existing labeling of the device.

Rather than introducing consistency and offering specific general principles for determining when a specific intended use is not reasonably included within a general use, it allows the agency to be arbitrary, I believe. For example, the document is not entirely accurate in its description of cryosurgical devices used in OBGYN. It states that "a PMA is required for the indication of endometrial aglacion or aglacion," which is aglacion of the lining of the uterus under ultrasound guidance. The document fails to mention that the device is already cleared and labeled for use in enterouterine uses.

The significant distinction between the term

endometrial aglacion, which FDA has chosen to make a PMA required indication, and agalation enterouterine tissue is very difficult for OBGYN physicians to comprehend, particularly considering that both the predicate and the new cryosurgical devices for enterouterine ice balls, which aglate endometrial tissue.

In closing, this guidance, I believe, places a far greater burden on industry by allowing the agency to require PMA's for specific indications for use, which should be covered within broader indications for use. Rather than a PMA, why not a middle ground? Why not a 510(k) submission for clinical data, especially for devices that are historically Class II?

PMA submissions place a heavier burden on us, the manufacturers, and on and the agency. At a time when FDA is attempting to understand and implement least burdensome, as well as expressing concern about the allocation of preciously few resources, it doesn't make sense to impose unnecessary and heavier burdens upon both the agency and the industry.

DR. JACOBSON: You were talking about little progress -- you felt there was not much progress being made in the least burdensome in terms of interactions with staff. I want to make a comment that, not agreeing or disagreeing with that statement, I just want to make a comment on the

difficulty or the challenge that's posed by culture changes that have to be implemented by large organizations.

We have almost a thousand people in the field and another hundred or so that are devoted to device work. One of the ways we've been doing that is through our staff college to get reviewers and other staff people educated, brought up to speed on the changes in FDAMA.

We had hundreds of people involved in our reengineering efforts, so it's quite well understood throughout the center. But obviously not down to every single individual. So educating people to new ways of doing business is always an interesting experience. I'd be curious to know other people's experiences, whether other organizations have tackled that. We've gone out and talked to other organizations and tried to incorporate as many features of successful education programs as we could. We can always learn a lot more, and we'll have a lot more changes to implement over the coming years. So we'd be curious to hear your suggestions.

DR. ALBERT: I'm going to make a couple comments. Least burdensome is an issue that is in an early day of being articulated in ways to have a focus for specific training. We've talked to our staff in multiple trainings to FDAMA early on, recognizing that least burdensome, as Dr. Henney pointed out, is an issue of most appropriate.

But we have been asked by industry, by you, to be more specific and to create guidance. We've had some early discussions.

We have heard from the HIMA group with suggestions on what to incorporate in our first attempt to articulate least burdensome in writing, and we've taken their comments and we will be coming forward with a Level I guidance, which means something that is a document that everybody gets to talk about before anybody gets to use it. That takes really just a global approach at trying to articulate some of the concepts and doesn't try to tie down anything into a box, because we think we have a lot to learn. Nobody has experience with this, not the industry and not us. So we think that's an area that needs a lot of work.

I don't want to speak about any specific device or any specific issue that is being dealt with in the center. I would point out two things: One is that new uses for technologies are in the law and are addressed in the 510(k) in the way in which we deal in 510(k) and the question that is raised about even already marketed products when you look at new claims. So I want to remind everybody that that is there and that is a question that has to be answered device by device.

The other issue you commented on, Cheryl, is

extremely important to clarify and that is that we deal with manufacturers and claims but not uses, not the practice of medicine. And I think there was a point where you talked about us restricting doctors from use. I want to again remind everyone that we don't deal in the practice of medicine and the devices that are available to be used by medical practitioners as they see fit for their patients. We deal with the manufacturer and the claims on the products that go into distribution.

I would ask you, as I asked Steven and Susan as well, for specific comments. The general and specific document was our articulation of what we do. It wasn't directed to industry at all. It was a compilation of what we do. We were asked to say how we got there. If you have some specific suggestions about how industry can get there, we'd be happy to hear them and add to that document. That would be helpful for us.

Ms. ZAGAME: Hi. I'm Susan Zagame. I'm with the Health Industry Manufacturers Association, and we will be submitting four written comments to the docket that will further explain some of the points that I would like to talk about today.

We also would like to thank the agency for holding these meetings and welcome the opportunity for further collaboration.

Just generally, speaking we would like to insure that our basic principles are on the table here. And that is we believe, as others have said today, that FDA should focus on its core statutory obligations, especially in an era of limited resources; that resources should be devoted to high-risk devices and new technology based devices as well.

Continue to reengineer and implement FDAMA. It's an evolutionary process. It's a culture change. This ensuing both with the agency and industry. We all have to come up to speed. We also believe that FDA needs to seek additional resources. We wish their budget had devoted more of their resources to the device review functions, but we have gone on record as supporting a budget increase for FDA.

With regard to the first question, we want to make sure that when FDA considers the answers to this question, that they also keep in mind the regulatory construct of law; that science for science sake is not the purpose of the question. The purpose is to insure that there is adequate science available to answer the questions required by the law.

I was really pleased to hear Dr. Henney say a lot of these things. Obviously, the agency recognizes these are ways to get science into the agency: Company tutorials on things like materials and software, these are great

suggestions; vendor days; cosponsored educational workshops; some workshops that will mutually benefit both the agency and industry.

We also believe that CME requirements for FDA docs are important because some docs are simply not aware of current procedures once they are in the agency environment and something that might be equivalent for scientists that are not doctors.

We think the collaboration meetings are an opportunity to bring together the best scientists on any discreet particular issue. So the right statisticians and the right biochemists and all of the right people should be at these collaboration meetings. There is a need for continuity. Once these discussions are held, that subsequently a year or two down the road on a complicated PMA another scientist or expert comes in and second-guesses the first one. That should not be allowed to happen.

We think that FDA needs to look at the use of outside experts. I know there are some certain constraints to that now and perhaps the concept of interest policy could be revisited in order to determine whether there are situations where you still have a conflict, but with full disclosure, make a determination that it is still appropriate to use a scientific expert.

We talked about the need for funding to hire

competent scientists. There are many on board already. We think that FDA's focus on participating and conscientiously participating in standard setting activities really is an effective surrogate for independent scientific review for all of the data that a company may present. And the focus in that area should be on standards for high-risk and new technology devices.

Change of integration of scientific information. Again, the theme here is that whatever this involves should focus on the principles of risk assessment, in other words, training the reviewers to ask the right questions, the right scientific questions; optimizing the use of staff, which has been mentioned here before; and staff training. Private sector has done trainer-to-trainer programs. Learning should be disseminated to the non-attendees. Diversification of attendance. Not just the senior staff should go to these things but all levels of staff. And industry and other experts should be considered as resources in the staff colleges. That might help as well.

Annual reports are an incredible mechanism for obtaining information about the devices, and with regulatory requirements that manufacturers have inserts new information about the device in those reports, we'd just like the agency to take a look and see how they are being used.

The third question has to do with public

education, risks and benefits balance. This is a difficult question. How does the public assess risk and benefits? There is no magic bullet. A lot of this is consumer-driven, marketplace-driven. FDA does have a great website, and we also believe it might be a forum for putting in some general basis for how FDA does make its decisions and educating consumers about questions that they may be advised to ask. And also we've recommended before that there be links to other sites.

The fourth point has to do with focusing FDA's scarce resources on the greatest risk. Again, it's an overall theme. We think device funding should be at the appropriate level, and FDA should not reallocate that money to other initiatives that might be the favorite flavor of the day.

We also believe that continuing FDAMA implementation and reengineering, such as increasing the number of exceptions, expanding standards, streamlining reclassification, optimizing use of collaboration meetings -- that all of those will actually save resources and allow us to focus resources on the greatest risks.

Industry and agency education -- the more we all know together, the better off we'll be. Redundant function should be eliminated. FDA should not become another NIH or NSF. The primary role of FDA is not to conduct scientific

research. We also believe that the inspection initiatives should be continued. They're giving a full presentation of this at the ORA, so I won't comment too much on this except to say there have been a lot of initiatives in this area. There have been good ones. Time-saving mechanisms are available, but we also believe that FDA ought to consider whether or not biannual inspection requirements are absolutely necessary as part of the law.

On the fifth question, ongoing stakeholder's feedback. I like this format a little better than some of the other ones. It seems -- even though we have to talk fast, it's a good opportunity to chat with folks. I think continuing to have true consultations, and it's not just comments, it is meeting to discuss and brainstorm. There is a feeling that at times we do get the black hole coming at us and comments -- we don't understand why they are not adopted sometimes.

It would be nice to have face-to-face meetings to try to understand FDA's position, just as we like FDA to understand our position. That doesn't mean we have to meet on everything. We agree that everybody's time is at a premium. We have to focus on select issues -- those that are the most difficult, the most complex, or have the most resource savings potential, those that would be the most mutually beneficial for both sides.

I'd like to make an announcement. We have a questionnaire that's out. It's a quick questionnaire, ten questions, sent out to 3,000 people, and we've gotten some feedback already, experiences with FDAMA. And we're going to share that with the agency.

And then finally, we want to congratulate the agency on the level of effort it's put forth. It has been considerable. It hasn't gone unappreciated. We realize that it's been a difficult time. There has been a lot of progress made. There's always room for more. We like the idea of coming to expect these stakeholder meetings, and I guess we'll have more of them in the future. We all agree that the promise of FDAMA must be achieved and is why we fought so hard for. I think patients and industry and the agency are all going to mutually benefit from it.

DR. JACOBSON: I noticed in your slide you talked about wanting expansion of recognition of standards, which I totally support. Do you have ideas or things you could give us or for the record what isn't working for manufacturers on that program? Why isn't there more use of that in the 510(k) program.

MS. ZAGAME: My understanding is that there was a focus group that met between Harvey Rudolph and HIMA, and some of the manufacturers gave back some of the reasons why the abbreviated 510(k) was not being used. It has to do

with -- largely with the fact that you have to certify your inconformance at the time that you submit your 510(k), whereas with the regular 510(k), you can say you will be in conformance when you go to market.

I think that's one of the biggest impediments we need to look into. Apparently, I've heard there is some statutory legal issues involved there. I think the inspection issue was another one where we had heard and understood that as soon as you filed a declaration of conformance, you were going to be the subject of inspection, which was a deterrent.

DR. JACOBSON: Which I hope everyone understands that is not the case.

MS. ZAGAME: My observation too is that it's not clear -- I'm not sure industry fully understands that you don't have to have a standard that applies to 100 percent of your product, that you can determine which standards might, and pick and choose --

DR. JACOBSON: And which aspects.

MS. ZAGAME: -- and put in the information on those parts of the device that are not covered by the standard. I don't think there is a full understanding of that.

MR. NORTHRUP: We participated in that meeting as well. I think there was a general lack of understanding -- when it is appropriate? And what is going to happen when

you do declare conformity to standards? Also the point that Susan raised -- did you have to declare here and now, or is it enough to say we are testing for this standard and are going to meet this standard?

DR. ALBERT: More complete and more information.

DR. JOSEPH: Is it just getting the information out, or do you see it more interactive like a workshop?

MS. ZAGAME: We're going to deal a lot with it at the July workshop that's coming up.

DR. JACOBSON: I had a question. One of your slides you had the primary role of FDA is not to conduct scientific research. If you're talking about NIH-style research, I don't think you'll have any arguments from anybody. Is that code for something else? I wasn't sure why you would go to the trouble of putting that on the slide.

MS. ZAGAME: I think there is an impression among some of the industry that the OST, which was a great resource for assigning reviewers, is not really worth the money now. Maybe that's going a little bit too far because I think there are appropriate roles. But I think FDA always needs to ask itself when it's looking at what the science function is; is it being done to support a statutory obligation?

DR. JACOBSON: My only reaction to that would be that of course it's the office of science of technology that is

coordinating the standards pitch, which is very statutory.

DR. ALBERT: I think I hear that we have not made our science agenda as public as we probably should so that it is understood when we spend money on science, what we spend it on.

You talked about the use of agreement meetings and talked about early interactions. And you also raised a concern about -- I want to make sure that I got it right -- that it was a concern about when a meeting or when an understanding is reached between a review staff or a team and a company that that might change later. Agreement meetings are intended to do that, to bind the agency and the company, not just us, but to bind the agreers to not allow a different scientist who has a different background with a different set of concerns to change the obligation.

We thought that was addressed. The other thing that addresses that is modular review, because modules, once they are reviewed are reviewed to completion, and they are not reopened unless they must be reopened by some information in a later module.

I wondered if there was anything else that you thought or your membership thought would also strengthen that understanding of requirement or of the expectations within specific submissions, because it sounded like you were talking about specific submissions in those comments.

MS. ZAGAME: I'm not sure if this addresses the question. I think that there is a couple of different answers. There's been a preperception that sometimes FDA is not really willing to sit down and have an agreement meeting, because it's somewhat threatening. The perception, whether it's true or not, is that there's a reluctance to do that at times. You're right FDAMA was intended to address that issue. That's in the PMA context. There are 510(k) issues, where there are not such things as agreement meetings for 510(k)s that are equal --

DR. ALBERT: There is pre IDE, so we have the ability to do that in a pre IDE, which is the one that is called the determination meeting. So there is an opportunity.

Two other things: One is a comment; one is a question. The comment on inspections for every time somebody declares conformity with the standard. That would be hard. There's no way we get the inspections we want to get, never mind ones we think might be fun to do. That's why we asked for more resources so that you have more staff to do the inspections.

I think the issue that -- it is true that we had a pilot program where we did inspect a few 510(k)s that came in very early on to build confidence between the industry and the reviewers. We were very open about the fact that we were going to inspect a couple of them. But it was never

stated that this was going to be a program where we were going to inspect everybody's declarations because that is not possible. It's not a risk-based inspection process. We did a couple of times. We were up front about it, saying that early on we might go out a couple of times to see about the data behind the declaration because we have a lot of concern on the part of the staff.

This was a major change for the reviewers to not see the data. When you're used to seeing a set of data and comparing two sets of data in front of you, in terms of making a substantial equivalence decision, and now you have the piece of paper that says, "I did the testing, and it met the standards. Thank you very much. We're done." It was a real concern on the part of staff, which leads me to the last thing.

We did talk about in the abbreviated 510(k) that the declaration replaces data. It doesn't replace design. It doesn't replace a description of the device. In those places where descriptions have been enough, descriptions are still enough. There's no requirement to submit a declaration. There's no requirement to do anything about standards. The idea for the declaration of conformity to standards was in replacement for places where we currently see the data that came out of the testing.

Now, rather than giving the data and all the

test descriptions and so forth to give a declaration of conformity, i think there's been a misunderstanding about a requirement that you declare to every standard, even if it's not something that we require in a 510(k). I think you are absolutely right about issues. If you have any other suggestions about how we might bring education forward, whether it's at the submissions workshop, that would be helpful.

MS. ZAGAME: Maybe we should simulcast it.

OPEN SESSION

DR. JOSEPH: I would like to open it up to whomever would like to go first. Please do so.

MS. KEELING: Keeling, K-e-e-l-i-n-g. First name is Marlene.

My question is: What failure rate of silicone gel filled implants is acceptable to the FDA? Dr. Lori Brown's own published research can be used to predict a 49 percent failure rate at 12 years with extra capsular spread of silicone gel reported in 11 to 23 percent of ruptured implants. The FDA is currently allowing Magah to state in there informed consent to patients, "Implants may not last a lifetime," with no reference to percent of risk.

My second question is: With over 170,000 adverse events on breast implants alone, research documented fatal toxic liver and lung damage in mice to low molecular

latent silicone. What modernization efforts have been put into place to improve med watch reporting to track the long-term consequences of implants?

DR. ALBERT: I'll take the first question, and that is we don't have an answer with a specific rate. Our determinations of what the rate really is and whether that rate is acceptable, balanced with the benefits for the specific populations that are being investigated for breast implants, will lead us to a determination as to what is and whether they have reached a threshold of reasonable balance of benefit and risk, safety and effectiveness. That's a determination we cannot make until the data is in our hands.

We're working very hard with the companies that manufacture these products to be sure that we're seeing the data. These are being done in modular reviews, and we are seeing the preclinical information on those products. We don't have a firm rate for you.

The issue that you raised that in fact rates are variable and knowing what the durability of permanent implants is true for all durable implants. None of them have a permanency. They all have an average expected lifetime, and some fail early, and some last much longer. That's the kind of information that we have been focusing on obtaining about breast implants, whether they are silicone gel filled, saline filled, or with other fillers.

Those are in fact the questions that are of issue for us as well as for those who have already been implanted or those contemplating implants. Since these are not currently improved medical devices, they are an unusual construct between being pre-Amendment III's already in the market and under investigation, if you will.

Simultaneously, those are hard questions to answer. I hear your concerns, and they are shared by us in terms of knowing the accurate rates and making the determination. As one of the people involved in making that determination, those are our questions.

DR. JACOBSON: In terms of your question on med watch reporting, there's not an easy answer to that one either. I think med watch is set up, and we use it as a warning system for adverse events that are happening. One of the things -- I think you were looking at how to track long-term low-level type effects. How do you get information about those? One way we use med watch -- should be using med watch more is to do data minding of the stuff that's already in med watch.

One thing that we do, or we try to work with other groups to do this, is to use the kinds of effects that come up in med watch to guide study questions and things like epidemiologic studies or studies that can take a long-term view and look at these long-term effects. The problem with doing these studies is simply money. They are

very expensive. We're not able to --

DR. JOSEPH: And they take a long time.

DR. JACOBSON: We have been doing everything we can to get the kind of adverse events that are in the med watch system related to breast implants out into the public. They've gone into all of the documents that we've published. We've talked to other funding agencies and people that are funding the agencies to get out questions on the table, to get the questions of the people who reported to med watch on the table in the context of those studies. But it's not a crisp answer, which I think you're after. We don't have an easy 1, 2, 3. It's sort of a lot of different efforts that go on at the same time.

MS. ROSENTHAL: Thank you for this forum. My name is Ilena, I-l-e-n-a; Rosenthal, Rosenthal. I'm the director of the Hematics Foundation for Women Breast Implants Recovery and Discovery. I'd like to second everything, all of the suggestions and opinions that Ms. Keeling made, and also address a corollary concern.

Just this morning members of my support group and myself called a number of plastic surgeons around the country, and in 100 percent of the cases either the staff or the plastic surgeons were telling the woman that "Absolutely FDA implants are approved." What do we do? Who do we report to? How do we get the plastic surgeons up to telling

the truth to the potential implants?

DR. JOSEPH: 100 percent of -- what was your denominator?

MS. ROSENTHAL: We had a group of women and myself call different plastic surgeons, usually the ones who are advertising in the paper, and say, "I'm calling about breast implants. Are they FDA approved?" And in every single case, we were told, "Absolutely. They're FDA approved."

DR. JACOBSON: Far be it for me to speak for the plastic surgeons. What may be operating here is a semantics distinction. To the plastic surgeons there is a legal way for women who need breast implants for reconstruction, for example, to obtain them. In that sense it is FDA approved, not in the sense that we speak of it or that manufacturers might think of it. Words don't carry the same weight when you carry them from one place to another. It may be that's what the plastic surgeons are hearing or thinking when they are using the term "FDA approved." They're not doing anything illegal by using the implants in those particular cases. It's just a guess.

DR. ALBERT: There also are proved studies, and I know that confused a number of people when a study for augmentation is proved, and it's announced that there is an approval for the study. That is a confusing issue. I think your comment relates to something that Ms. Keeling talked

about earlier, that is, how do we make sure that people can get access to the appropriate information?

I think any suggestions you have again about how we can we do more public -- we do speak at the organization for plastic surgeons. We've had someone there each year talking about the regulatory environment and trying to find out what is and what is not available and what the progress is about these issues.

Any specific recommendations for how to get information out of other mechanisms and other multiplier groups, we'd be happy to hear them.

Allow me to say something else, that is, one of the things that I think would make this interaction even more productive, would be for people to be brave enough to bring their specific recommendations as well. If you have a specific recommendation about something that we could do or a place to post information that you think would be useful, a way in which to provide that information in a way that we haven't done, something very specific, that would be helpful. We can then respond to very specific recommendations, something that would be very useful to us. You don't have to do that now; you can do it to the docket or to us at the center.

MS. ROSENTHAL: I understand what you're saying about the semantics and what approval might mean to a doctor

assuring a woman that what he is doing is legal. It's important -- the women who find me are often implanted only a few months, and they are already having symptoms and problems. When I tell them that the FDA has not given their approval, the women are often shocked. I think having this on every consent form that the patients are required to sign would be step one. Maybe even in their advertising, because they do an enormous amount of advertising in their products. Even sometimes I'll see it say, "FDA approved."

MR. STEVENS: My name is Larry Stevens. I work for a company called -- Medical a small interventional cardiology company in the area. I wanted to speak to the issue of the FDA plan for statutory compliance, particularly the issue of applying resources where they can best be utilized in the inspection side.

Speaking as a consumer, which we all are, when I saw the chart on the ability to meet the mandatory inspection of two years and how it has gone to an average of once every seven years, my immediate reaction as a consumer is "Oh, my gosh. What's going on out there?" But as a member of the industry, particularly as the vice-president of regulatory affairs and quality assurance, I have to have a little more confidence from the standpoint of what's going on in the industry. The FDA knows it too.

That is that every U.S. company will enter the

European market before they enter the U.S. market with their products. In order to do that, most companies are required to be inspected by an independent authority to certify them to an intentionally recognized quality standard.

I wanted to know what extent the FDA could utilize those certificates of compliance to exempt the lower risk companies, in other words, count that as the bi-annual inspection and exempt. More importantly, assure the American public that these U.S. companies are not operating out there without some kind of inspectional oversight, which we all pay for incidently from notified bodies from the European Union.

DR. ALBERT: One comment, that is that I think what you're suggesting is essentially a third-party inspection program. There are some pilot things being done about people other than FDA doing those inspections both here and under the MRA. I think you are talking about getting there already as opposed to where we are, which is just building a pilot process to look at third parties doing the FDA inspection, other than what you heard here in California doing some inspectional work. We're on the road, but we're not as far as you would like us to be.

DR. JACOBSON: I think the fact that we're spending time and energy and implementing the MRA, which does have the third-party inspections, and we're getting ready to

train the conformance assessment bodies, really speaks to the fact that we're really not that far apart in thinking that there is a real potential there.

MR. KWAIN: I'm Michael Kwain. I want to comment on the point that was discussed -- as a matter of fact, a suggestion I was going to bring out, but I'm glad somebody did already. We're recognizing third-party registration into a harmonized standard.

The comment I was making is that under the MRA in the third-party review program and also the MRA CAB program, it is true that the FDA is training the CAB for quality inspection, but not the U.S. CAB, and I think I understand probably the political reason, it may be the rationale behind the MRA, that could put the U.S. manufacturer in a disadvantage position. If a company wanted to sell a product in Europe, they can utilize the system, but they can't utilize U.S. CAB for inspections for that matter.

You also raise an interesting question because a lot of the companies are pretty globalized. What prevents a U.S. company to set up a subsidiary in Europe and actually use a European CAB to do some inspections and also third-party reviews? I think that is an interesting inconsistency.

MS. MESSA: What you've just said has been publically

stated by others that the next step down the road, since we are training the CABS, would be that they would be able to do inspections in the U.S. I just don't think at this point the center is ready to go from the resources that are being used for the MRA to start that process. There have been some that have said that's the next logical step.

MR. ARBITTIER: I'm Lane Arbittier. I would like to emphasize the importance of training. Having the FDA training of industry has been a tremendous benefit to the LA district. We've had the pleasure of several representatives from the LA district office hold training sessions with the Orange County regulatory affairs organization and most recently last month with the San Diego Regulatory Affairs Discussion Group.

We had several attend the -- we had 97 people register for that workshop. Unfortunately, only 72 attended but that's the largest turnout we have ever had, and I attribute that directly to having FDA investigators do the presentations. And we surveyed the group and found out that 100 percent of the attendees responding to the survey said that they could use the information they learned in that training session to help their companies comply with FDA regulations in the future.

This in turn gives companies the ability to anticipate what the FDA will expect from them during an

investigation during an inspection and to be in better compliance. It's a good way to prevent problems. We also asked the attendees about an ombudsmen position in the LA district. There was a position for that. Nobody in the audience knew about the position, the person in that position unfortunately.

For those of you who are familiar with that position that, I believe, was intended to act as an assistace to industry and anybody, I guess, to deal with the LA district office of the FDA. When we asked the audience if they would be interested in replacing that position if they, in fact, knew that that position was there, and if there would be somebody there to answer the questions and help them deal with the FDA, about over half of the audience said they would use a person in that position.

Also over half the audience said they have used the Department of Small Manufacturers Assistance in CDRH, so it seems like the group appreciates having that assistance, and we would encourage you to continue that kind of support for industry.

DR. JACOBSON: I really appreciate that comment. There's no substitute for face-to face interactions. There just isn't. And at the same time, we've been madly looking for substitutes, because it's so difficult, given that we're spending over 90 percent of our budget on salaries, to get

the kind of funding that it takes to get people out there. It's wonderful to use the resources in the district because they're here on the spot, and they really have a flavor for the interactions that we don't have in the center.

I guess back in the old days, we used to do a lot of traveling around and do workshops face-to-face. And we have been phasing those out because they're very expensive, and they don't reach many people at a time. And we have been trying to substitute things like video conferences and the web. There are advantages and disadvantages. We'd like to keep talking about how to do training the best. I think what we need is a mix.

Some topics may lend themselves very well to a video conference and other topics may not, so if we can work together to figure out what are the topics and the training and information that needs to get out there? What's the best vehicle for each? We're acutely cost conscious these days in terms of what we can afford to do. We have a lot more tools than we ever had. Back in the old days, we didn't have the web and those other kinds of modalities to help us get together in training sessions.

We really appreciate the feedback, and if you can give us things that you want interaction on and suggest what vehicle might be appropriate, that would help.

MR. ARBITTIER: I passed along a survey, indicating

the topics that San Diego Regulatory Affairs people would like to hear more about. I'd like to emphasize the advantage of having -- first of all, the local ombudsmen or the local DSMA helps us deal with the time difference. We lose three hours in getting a hold of DSMA. Sometimes that can be quite a challenge.

MS. MESSA: We had a person that was part-time in that position as an industry facilitator or liaison. We actually now in Los Angeles have been given authority to hire a small business representative in the Irvine office, a Mark Roh but in Southern California. Having said that, I heard by telephone today that we may be on a hiring freeze, but actually, I'm glad you raised it. That announcement will be on the OMB website. This may be an excellent opportunity to hire a person who has industry experience. So in you know of anybody that likes our salary ranges, it might be a good opportunity. No. Seriously, it may be very well work to our advantage to have someone.

One thing that I would like to add on to what Lane has said, in that, we ORA are trying to work with all the centers in terms of recognition in our work plan for industry outreach, because every time we do an outreach event, we actually are using inspection or laboratory resources that would be doing regulatory work.

So ORA, in general, is working with each of the

centers to try to get recognition of what you said, the impact that it has on training industries, the ability for them to use the information for compliance. And we're trying get the centers to recognize that resource use as part of our reporting requirement that we have.

MR. ARBITTIER: The motto that we used in this last workshop could be applied around the country. I think it would be worthwhile. We had two investigators on overtime. They did their presentation at 5:00; it lasted until 7:00, and we were able to, I think, get some extra communication and training without impinging on any inspection or their day job. So it worked out for the industry representatives who in fact didn't have to take off from work, and we had the advantage of talking with our local representatives who in fact would impact -- who would interpret the regulations for our inspections anyway. We were getting first-hand knowledge of what their interpretations were.

MS. MESSA: I think we need to mention it is a two-way information exchange. The FDA investigators do benefit.

MR. SCHLADOR: My name is Fred Schaldor. I'm with ThermoScan here in San Diego. Just to comment, earlier Susan Zagame and Susan Albert, I think, the two of you were having a discussion about the alternate 510(k) submissions.

I attended the HIMA session last July in

Washington D.C., and I came away with a very distinct impression that if a company used the abbreviated 510(k), there was a high probability of inspection. When I spoke to people at that session and I said, "Did you hear what I heard? What was your interpretation?" I asked three or four people that, and they all came back with, "Let's not use it until FDA is satisfied with it, and once they finish their inspection processes, let's use it. There's no reason to give FDA an invitation to come visit you." That's one persons take away.

DR. ALBERT: We'll fix it this year.

MR. SCHLADOR: In see that in some of the trade journals and comments from FDA saying, "No. That is not the case." But at least the 250 people that were there, probably walked away and told their colleagues, "Don't touch it."

DR. ALBERT: On the plus side, I will say that we had a couple of companies who did get inspected and were very willing to work with us and share the experience of using the abbreviated 510(k) and how it had serviced the products. It's been helpful, and it served the reviewers to say, "Here's what the company had in support of their declaration, and here's how it served the company in being able to be useful." So we got the full message out. But, again, any suggestions about how to make those teaching

examples, experiential examples, a reality more available, would be helpful.

MR. SCHLADOR: I appreciate an event like this. Really the progress that I believe is being made between FDA and industry -- I think that it's becoming less of a child/adult relationship, industry being the child, than it was in the past. That's appreciated.

One specific comment on the review process is industry can deal with predictability even when they don't like what's predictable. One specific thing that I've experienced is that the rules change in the middle of a submission. In other words, there's a previous agreement or previous submissions that have cleared -- you submit a new submission for a similar type product and the reviewer comes back and says, "What we would really like is --" fill in the blank. My suggestion is this: If you're going to make a change, announce it to the stakeholders separate from the submission, and don't use the submission as the lever to make the change.

DR. ALBERT: You're absolutely right, and we've told our staff numerous times that the place to make the change -- if there is a change, if people believe there needs to be a change, that's a guidance document. And I'll tell you what I tell the rest of the industry, and that is if you think somebody's doing that to you and to your

product, then you need to widen that discussion with their managers and with the division management so that you're sure that the question being asked is being asked because of something in your submission related to your product and the question of your product going forward and not because someone thinks that the experience of the division needs to change.

So I really urge you -- it's not a matter of being worried about the review's reaction to that because this is what I tell my staff as well. If they have a problem with the company, I tell them the same thing. If you're dealing with somebody in a company, and they're telling you that they don't have to or they want something that you have a problem with, then you want to ask them to bring a wider group of people from the company to the table to have that same discussion.

It's not an individual-to-individual discussion. It's an organization-to-organization discussion that needs to held with the right people at the table to solve the problem. It should not be between any two people or between a company and any reviewer. These are global issues, and if you think that someone is trying to use a submission in a way that seems to be asking different questions, you need to be sure and the reviewer needs to be sure that the questions are appropriate. It's partly less burdensome. It's also

partly level playing field. And it's good management practice. So you can be assured you've got support all the way up in the office.

MR. MICHAEL: I'm Ken Michael with KRM Associates. I want to applaud you for this meeting and all of the input and also the reception and the responses.

There's one area that you covered in the presentations that I think could be addressed that's with the classification for Class I. Most of the manufacturers, 93 percent, 53 percent, are under 50 or 100 people, but the average entrepreneur does not know what Class I means. What does he need for a Class I?

At one time FDA put out a booklet "Questions you always wanted to ask but never did, a simplified type approach for a CEO's, for venture capitalists. That would help them especially in the Class I device. I wondered if you have anything underway in that area, because there is some confusion among a lot of the companies.

DR. ALBERT: You're suggesting that we need better values for exempt products.

MR. MICHAEL: Yes. They don't need all the data you do in Class II.

MR. SMITH: I have a very brief comment. This morning one of the comments was to get more advanced notice about writing guidelines or input for guidelines. One

suggestion could be that if you are going to have proposed guidelines, that you could publish whatever you are going to consider on the website so that anyone who wanted to put input early on in the development, would be able to give you some input.

The second suggestion I have involves the emerging technology. I know the grass roots here in the Southern California area has been very effective. Elaine Messa has done an excellent job leading that. And one of the areas -- technology could be identified is through the grass roots groups. If they can identify a particular or group of technologies that they could give to the center to explore, that might be helpful.

DR. JACOBSON: With respect to the guidelines, we do have our guidelines on the web. I think what you're saying, though, is in the formative stages, have the early drafts on the web. We've done that with some of them.

MS. SMITH: I wasn't thinking drafts. I was thinking the ones that you are planning to propose so that the organizations that might want to give you some input, would be able to identify what is coming into the pipeline.

DR. JACOBSON: You mean topics?

MS. SMITH: Yes.

DR. JOSEPH: We did that recently on a human factors guideline, saying this is what our thinking is -- it wasn't

a guideline. It was just an outline of what our thinking was. What we are going to do, and we were soliciting comment. It's probably true that we're not very consistent about that. It's a good suggestion.

DR. ALBERT: I would remind people, I think it's important especially in the light of guidances, that we are very receptive to having guidances initiated outside the agency. If there is an area where you think guidance ought to be made available and have some good ideas about what that guidance ought to contain, please feel free to make it a first draft attempt and submit it to us for incorporation or for creation of a guidance, because we are happy to have people take some of the initial work and then suggest that the FDA, put the FDA pieces around it, or open the dialogue around a proposed guidance document.

It came up in the context of the least burdensome at the January 4th meeting. At that meeting a number of representatives of industries suggested to us as a way to least burdensome is have guidance in every device area. Honestly, with a hundred and some-odd on the web already, we don't have time to rewrite all of them. But if people want to take them on and make suggestions about them, we'd be happy to have that. I want partnering on that as well because that's very useful in leveraging your expertise.

Dr. Jacobson: I was thinking we could marry those two thoughts. If we have a list of upcoming topics that would serve as advance notice that we will have preliminary draft documents that they would like us to consider. My only hesitation, the obvious one, is that at some point resource issues kick in. The reason we're not doing guidances on everything simultaneously is very often a resource issue. That would be kind of a nice thing to have those two concepts put together.

MR. FOOTE: My name is Kerry Foote. Just three comments: Our company benefited greatly from the summary of reporting from MDR. I think we could probably go one step further than that in talking with these guys, a lot of things we still report under summary reporting, they aren't interested in receiving that information. To go through and get an exemption costs us thousands of dollars and a couple years to get exemptions on some of our products. I think that FDA -- if they were a little more proactive and identified the kinds of complaints they are receiving -- provide some sort of guidance on that. That would be very helpful. Cut down a lot of our time, a lot of our money, as well as the MDR group.

Another suggestion that we would have is on complicated 510(k)s it would be nice if we could meet with FDA like we do on the pre IDE. It would be nice if I had a

complicated 510(k), if we could meet 30 days or 60 days into their review and sit down with them and present as if I would a panel meeting on PMA's, and this is on 510(k)s -- this is the rationale we used; this is the worst case product; this is why -- I think we find that a lot of questions that we get back from FDA are simple miscommunications.

The third comment that I have is we've been attending the ISO meetings, trying to get international standards set up for our industry. And FDA has not participated on that until last year. That was extremely helpful. You sent two reviewers, and it was very -- many of the international, especially the French and the Germans, have a very strong opinion on what is supposed to happen, and FDA totally disagrees with that. It's helpful to have FDA sit there and say, "We will not accept it if the standard comes out looking like this." That was very helpful. It would be very helpful to ISO meetings so we can have some standards to work with.

DR. JACOBSON: I want to comment -- thank you for the feedback on the standards issue. If you could let me know who the people are, we'll go back and see what the issue is financially speaking. We have real concerns about the fact, as companies do too in terms of supporting all of the international standards, because it's expensive to send

people internationally on the one hand. On the other hand, we have a real commitment to making the standards process work and we have a separate budget for standards travel within the center and have put a prioritization scheme together for all the standards efforts that are ongoing to see which ones we'll be able to fund and sort of prioritize them and have a cut off line.

MR. FOOTE: The feedback was invaluable.

DR. JACOBSON: That's good feedback. We want to support getting people out to the standards committee meetings as much as we can.

DR. ALBERT: The second comment you made about the 510(k) process -- it sounded to me that you were saying you were getting resistance about meeting with the division, not the part during the 510(k) but before in planning. You're saying no, that is not the issue.

MR. FOOTE: The division works real well with us right now.

DR. ALBERT: We have been approached about having more frequent meetings on 510(k)s like we do on PMA's. But I have to tell you that resource really is the issue. We have 4,000 plus 510(k)s a year. And even if you take just the ones that we would consider in the highest complexity category, there are probably a thousand or close to a thousand that are complicated 510(k)s, maybe more than that.

MR. FOOTE: I think you could cut that down. There are a lot of companies that won't take advantage of this.

DR. ALBERT: I have a suggestion. We have a real resource issue in terms of being able to do that, responses out within 90 days and deal with the number of 510(k)s that the program sees.

You mentioned that one of the most problematic areas can be easily resolved by having the 510(k) reviewers understand your rationale. I was going to suggest or ask if you if you think that some discussion between CDRH and the industry about how to present that rationale in the 510(k)s might, in fact, deal with a lot of the problems. There will always be certain 510(k)s where there are problems. I was wondering if there might be a more global approach, again, resource saving for all of us, whether it is time or travel or whatever it is, in terms of clarification.

One of the things I've told my staff is one round of questions is fine. If you're asking a second round of questions on a 510(k), you ought to be on the phone with the company having a meeting because you should have figured that out the first time.

Sometimes you get 510(k)s with questions in them. That's fine. You ask your questions. If the answers aren't coming back that you need, there's something wrong in the communication, and you need to do something more

appropriate to the problem which is a dialogue.

If that's not working or you're not hearing that, contact the divisions when you get a second -- or you think you are getting a second round of questions. But let's see if we can't do something more global because it is really a resource issue. There are many fewer reviewers than there are incoming submissions.

Most cue time is still waiting to be opened. It's the time it takes to get to a submission, not the actual time in the actual review of the submission. That's a real resource problem for us. So any suggestions about how to articulate the rationale, the selection of a predicate, whatever, and if there is some nice straightforward ways that we could do that, that would help.

I think ours are more reviewer specific. They didn't understand why we choose to test against a certain type, a certain angle or whatever. In an attempt to explain that, they still come back with questions. It's easy to resolve over the telephone. If we could resolve the issues up front, we would get that 90 days clearance. We end up having you miss the 90 days, and us missing the financial benefits.

DR. ALBERT: I hear you.

DR. JOSEPH: I think we have time for one more question or comment.

DR. ALBERT: Can I take his first comment then?

The first comment has to do with post market -- signal me yes or no -- I think I heard you say that an easier way of getting an exemption from MDR reporting would be helpful --

MR. FOOTE: Right.

DR. ALBERT: I wanted to make sure I heard that clearly.

DR. JOSEPH: I think we'll wrap this up. I'll start down with Elaine.

MS. MESSA: I want to take an opportunity to thank Susan and Liz and Lee and Ron for selecting San Diego and coming to the west coast for this meeting. We're always encouraging that we come. I also want to thank mark Roh and mike Stokey from our office who were here and some of the investigators for putting in their time and all of the panelists and yourselves for taking time out of your busy schedules to come and let the center listen.

DR. ALBERT: I found this very helpful for me in hearing specific issues focusing down on some of the specifics. I want to thank you for participating and encourage you to continue to send suggestions and recommendations and keep thinking with us on things we might reengineer even, because those kinds of recommendations from you or dealing on the other piece of the regulatory process

is very useful to us. I'd also like to thank everybody for coming. I know a lot of you traveled as far as we traveled.

DR. JACOBSON: I just want to add my thanks to everybody for coming. It seems like coming to the part of the country is sort of like being called to New Castle in terms of communication. From everything I've heard and seen, the west coast crowd seems to really be into good communications and lots of interactions. I think that's great and anything we can do to contribute to it is very helpful.

Elaine Messa is the chair of our device field committee and has shown a lot of leadership and helped out incredibly in terms of being a sort of laboratory for a lot of the changes that we're trying to make together as an agency. It's been an exciting time, and we look forward to a lot more exciting times. Thanks again for coming.

DR. JOSEPH: Elaine, thank you for all the help that you and you your staff have contributed. Mark special thanks to you, lots of hard work. Ron, thank you. And Jeff and Carol as well. And also I've been told by my manager here that I should remind you to turn in your blue evaluation form.

I found this very, very informative. You've given us a lot of great ideas, a lot of things to go back and to see how further creative we can be. I hope that the

time between seeing you again is not as long as this one has been. Thank you very much.

(At 3:56 p.m. the meeting was adjourned.)

STATE OF CALIFORNIA)
:SS
COUNTY OF SAN DIEGO)

I, Sandra L. Quinn, CSR NO. 11714, hereby certify that I reported nonverbatim minutes of the above meeting on Wednesday, April 28, 1999, in the City of La Jolla, County of San Diego, State of California.

DATED: May 5, 1999.

Sandra L. Quinn

Sandra L. Quinn, RPR
CSR. No. 11714