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DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

STAKEHOLDERS MEETING

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P R O C E E D I N G S

MS. SUYDAM: I think we're ready to start. Good morning and welcome. I'm Linda Suydam, and I'm the Associate Commissioner for Strategic Management at the Food and Drug Administration, and it's my pleasure to welcome you here today. My apologies to those FDA people who have been here for the two previous meetings because you're going to hear the same message again.

We are very pleased to begin this phase of FDA's engagement with our stakeholders. This is the third in a series of meetings. The fourth will be tomorrow for veterinary medicine. We are then also having a meeting in California on the 28th for CBER and an agency-wide meeting on September 14th where we will be looking at cross-agency themes. And we are anxious to have input at that meeting as well. Also, if you know people who weren't able to meet this schedule because it's August and most people are on vacation, we'll be happy to have input at our agency-wide September 14th meeting.

The process of this stakeholder input was really generated by the passage of the FDA Modernization Act in November which in Section 406(b) requires us to consult with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer

advocacy groups, and the regulated industry. But this passage really legitimizes a need that FDA has felt to hear from the people who we interact with, to get us to have the kind of input that we need to do our job, and also to get some messages out to people about where FDA is at this particular point in time.

I think it's important that we understand what 406(b) does. 406(b) requires us to have a plan which focuses on six objectives, and these six objectives are: to maximize the availabilty and clarity of information about the process of review; to maximize the availability and clarity of information for consumers and patients about products that we regulate, and I think we want to have input in each of these objectives, if at all possible.

The next two are to implement inspection and postmarket provisions of the act; ensure access to scientific and technical expertise necessary to meet our obligations.

And the final two deal with statutory deadlines and time frames in that they require us to establish a mechanism for meeting the established time periods for review for all applications by July of 1999, and then, finally, by January 1, 2000, to deal with the backlog of applications that we have.

In trying to meet these objectives, we are looking for input on creative solutions to how FDA might be able to meet its mandatory workload given that there is a finite number of resources dedicated to this agency. And in the past few years, the agency has suffered from a number of reductions in our budget.

In addition, in our message to stakeholders, which is on our Web site and is also available from anyone if you need it here at this meeting, we talked about some areas of concern, issues that we think are of highest importance to the agency at this particular point in time. And these are issues that are a combination of those where we have spent some time and focus and energy and resources and those where we have minimized the amount of time and energy we've had to place on these activities. So adverse event and injury reporting is a key focus for us because as an agency we believe it has suffered because we have had to focus on other areas. And so it is presenting new issues for us. The agency receives hundreds of thousands of reports, and we think those are really only the tip of the iceberg. We want to be able to make products safer, but at the same time be able to address the issues related to adverse events.

In addition to that, product safety assurance is an area of concern because as an agency we are not now

meeting our statutory obligations for our inspectional mandates, and this is an area where we have devoted less resources in the past few years.

Product application review, we've made significant progress. A lot of that as an agency has been the result of the Prescription Drug User Fee Act, but the Prescription Drug User Fee Act, while providing us with resources for that particular activity, it also gives us the dilemma of having to maintain the base in that program while our base has clearly been eroding. And so we want to focus on product application review in a way for those areas where we have not had user fees. And so we have to look at that activity in ways that are creative and look at the concept of user fees for other product areas as well.

Finally, we have four areas that are broader in terms of focus: the Food Safety initiative, which is a presidential initiative that affects other agencies as well as the Food and Drug Administration. That includes the Centers for Disease Control and the Department of Agriculture. And the outreach initiatives we think have to be strengthened for this agency, and the stakeholder engagement is just the first part of an additional attempt to talk to people about what the agency is doing and to convey the information that we have about the products we

regulate.

Our scientific infrastructure and research are keystones. They're the building blocks of our program. They have suffered also because of budget restraints, and it is now necessary to build those again. We are a scientific regulatory agency, and I think unless we have appropriate research and the scientific infrastructure, we cannot perform the other functions that we are mandated to do.

Tobacco is on this list because it, too, is a presidential initiative. We do not know at this point in time what the agency's role will be in tobacco in the future.

I want to present a few numbers to you about the FDA budget, and the point I want to make from this slide is that while FDA's budget apparently is growing, from the outside, if you look at it from 1993 to 1999, it appears as if the agency's budget has grown by almost 50 percent. But that number is very misleading in a number of ways. One is because we had new statutory mandates that gave us and dedicated resources to specific activities. And those activities were the Prescription Drug User Fee Act. It was also food safety, mammography quality assurance, and it was also the Food Safety Initiative. And those resources came out of the base, and so as you look at the agency from a

real-dollar number, you will see that the agency's resources have shrunk.

So we have an unfunded workload in the base of the agency that ranges from $300 million to $1 billion worth of activity. And so I think that it's necessary for people to understand that if you are asking us to do more, we have continually done more with less, and we are now looking at creative solutions, looking for creative solutions on how we are going to do our work unless we get additional appropriated resources.

So I'd like to encourage you all to provide us comments to the docket. We'd like you to focus on the six questions that we have in our FR notice and in the message about how we are to meet the requirements of Section 406(b), and you can report three different ways. You can report the normal way, by sending your comments by mail to the Food and Drug Administration, you can report via e-mail, and you can report online on our Web site. So if you would, we would encourage you to send us comments on the FDA activities and on our priorities, and we're looking forward to hearing from you all today.

We've had two very effective meetings so far. We've had some wonderful suggestions about how we can do our work. We've had wonderful suggestions of partnerships with

other parts of the regulated community. And I think we're looking forward to hearing from all of you and the ideas that you might have.

Bruce Burlington, the Director for the Center for Devices, is now going to talk to you about that particular Center, because I think it's important that you look at this agency and present your comments in context of where we are and what we've done, because we've made magnificent strides in the last few years.

Bruce?

DR. BURLINGTON: Thanks very much, Linda, and thank you all for joining us today.

I'm not sure if it was clear to everyone, but Linda has accepted the job, the enviable job of having to develop this plan and get it through the agency, through the Office of Management and Budget, through the Department, and back to Congress, and has joined us as the--

MS. SUYDAM: All before November 21st.

DR. BURLINGTON: All before November 21st, a Herculean job if ever there was one.

I'm joined today by a lot of folks from the Center and other parts of the agency. At the table we have Elaine Messa, who is Chair of our Field Committee and Director of the Los Angeles District; Susan Gardner, Deputy Director of

our Postmarketing Office; and Lillian Gill, Director of the Office of Compliance.

As well, we have Phil Phillips, Harvey Rudolph, and a number of other folks so that we will have an opportunity to clarify, to interact, and I also notice a lot of the folks in the audience are Center for Devices or FDA alumni. So I suspect that it's a pretty knowledgeable group.

On the other hand, there are some of you who are not as familiar with our programs, and I'm going to try and walk quickly through some of what does the picture of the agency or at least the Center look like today. There was a handout in the back that was really an enumeration of the obligations of the Secretary under the act. It listed 53 various specified things that the Secretary is supposed to do on a recurring basis, 21 of which have explicit statutory time frames.

In reviewing it, we realized that there are perhaps a few of them left out. For instance, we inadvertently left out 510(m), the class II petitions, which is yet another one that has a specified time frame for action. It actually is a hammer if the Secretary doesn't act in that time.

The point is there are a lot of things that have

to go into this plan, and that's just our Center. When you look at the other Centers, this number just keeps headed up.

If I may have the next slide?

Okay. In today's presentation, we're going to be talking about--I have to wander. We're going to be talking about growing responsibilities, what our resources look like--that is, what the Center perspective of the overall agency resource picture that Linda shared with you is; what we have done to reengineer, because we're not simply saying let's keep on doing it the same old way and just build a bigger program in order to accommodate more work; and what reengineering does, but what the problems with reengineering are that are emerging; and the need for public advice on meeting the FD&C Act requirements that the statutory directive is we need it and we have to come up with a plan that really makes sense in terms of how we will meet these obligations.

This slide is simply to remind you of the gamut of things that we deal with. There are in vitro diagnostics, a lot of high-tech applications, and who's producing those things. This is information that HIMA shared with us. This is value of product shipped from the United States. It's going up over the last 15 years at a pretty incredible pace. If you added in the radiation health component, that would

be a relatively constant $5 billion on top of this. It has been pretty--that is, the non-medical radiation emitting products.

What are the legislative mandates? And in terms of looking at the legislative mandates, the section of the Food and Drug Modernization Act that Ms. Suydam cited has all the obligations of the Secretary under this act. So it's clearly talking about the entire spectrum of things in the FD&C Act.

You will notice down there at the bottom that MQSA is not incorporated in the FD&C Act, so we're not going to talk about that. That's not covered by this directive. However, everything else we do at the Center is, including the Radiation Control for Health and Safety Act, which has been statutorily incorporated in the Food, Drug, and Cosmetic Act. So we've got to meet those obligations as well.

Next?

What are the themes that we saw coming out of FDAMA? It is clearly for the agency to work more closely with industry, for the agency to be decisive and timely. There is a separate theme of patient access to make sure that while products are in development, patients have an opportunity to get them. It codifies a number of the

changes that we had already been working on in terms of reengineering. And there's a clear strengthening of the sense of agency accountability manifest in this plan and in the periodic reports to follow this plan on how the agency is doing against the plan.

There's a separate theme where Congress, probably in its desire to deregulate somewhat, took a number of mandatory requirements and made them discretionary for the agency, and those include such things as tracking postmarket surveillance orders. And last, but not least, a very strong directive to the agency to work hard on international harmonization.

One of the problems with FDAMA is Congress gave the agency a lot of new direction, a lot of new responsibilities, at a time when there was no appropriation increase to work with.

Next?

I would add on FDAMA so far we have done a remarkably good job in keeping up with all the new requirements, all the new regulations, et cetera, that have been required, and we are implementing it far faster than most pieces of legislation.

All right. This is the Center's perspective on our resources from a manpower point of view. These are

FTEs, people or person years, and we peaked in 1995-96 and have been on a downward trend for a couple of years and a straight-line projection, which is what's going to happen with constant dollar budgeting, which is where we are marked on the Senate bill right now in constant dollar budgeting for 1999. It's just going to head down. And in 1999, we will have the lowest manpower level of any time during the 1990s, and in 2000 it's headed further south.

Now, we took mammography out because, again, mammography is a separate program.

Next?

One of the challenges that we have to deal with, with this declining manpower base, is the increase in complexity of products. I think that what's happened to reading Pap smears is wonderfully illustrative. Many years ago, FDA regulated the microscope, the slide, and the stains. The whole complexity of reading Papanicolaou smears was in the mind of the technologist and the pathologist who read the smear. It was not in the machinery. Today, the Pap smear is prepared automatically by machinery. It is read electronically by mapping functions. It is scored by artificial intelligence built into a computer. Twenty-five percent are never looked at by a human being. So the complexity has moved from the medical practitioner into the

device.

We see this time and time again as we look at miniaturization of devices, as we look at addition of microprocessors, artificial intelligence networks, as we look at remote operation capacity, and as we look at combinations of devices with pharmaceuticals and biological products. What we are dealing with in terms of assuring safety and effectiveness in premarket review is just skyrocketing.

Next?

PMA workload is growing. It's growing in complexity. We're illustrating some of the complex products we've seen. We're looking at the number of products received as well as the number of PMA approvals over the last few years. This year I think we're at 32 so far and three more, which are HDUs, so I think it's 35 altogether right now, and clearly we'll get some more before the end of the year. So this trend is continuing even if we don't quite reach last year's mark in number of PMAs.

Next?

The number of 510(k)s has not gone up as dramatically, mainly because--in fact, it's gone down, and the reason it's gone down are for two reasons: number one, we exempted and subsequently FDAMA exempted an awful lot of

class I products, simply 510(k)s we never spent much time on anyway. So we say, you know, there's diminution of the numbers of 510(k)s but not very much saving of workload. The complex 510(k)s continue to come in and are very demanding, but it's not just in premarket that we're seeing increased expectations of the agency. If you look at the number of adverse event reports--and this is comparing 1991 to 1997--you see the number of folks we have to apply to looking at adverse events and follow-up has gone up modestly. The number of reports has gone up far more dramatically, requiring new strategies to deal with them.

If you look at GMP inspections, you see the disappearing inspector. Back in 1993, we were getting to the class--actually, we were getting to the facilities one in three years. Right now we're getting an average of one in seven for surveillance inspections. In part, that has represented an intentional choice of the agency. We thought it more important to maintain for-cause inspections and to take the cuts in surveillance inspections. But what's happened is the inspector just isn't there very often. A lot of companies are going in and out of business before we come and see them.

Next?

Rad health has taken its share or more than its

share of the reprogramming and decline of truly available resources. If you look at the number of X-ray systems tested per year, excluding MQSA, you can see we've been on a rather dramatic downward trend from, what is that, 1988 up to 1998, and it looks like it's once again headed south. The contracts are actually expiring in the year 2000. We may be down to zero unless we do something fairly dramatic.

Next?

Well, what have we done? We undertook to reprogram, some of which you've already seen, and to reengineer. This illustrates the conceptual basis for reprogramming, refocusing our effort on premarket resources. We said we need to continue to pay attention to clinical investigations. That's where a lot of the decisions that subsequently support applications are made. We need to be involved. If anything, that actually probably should show a slight increase even as we move from 1996 to 1999, even with a slightly smaller staff to do the work.

We should put most of our effort, most of our review effort into working with companies on high- and medium-risk devices, and we should look to alternative mechanisms for the low-risk products. And you'll see later on some of those alternative mechanisms.

In order to accomplish reprogramming in a way that

still met our obligation to the American public for consumer protection to make sure that we were looking at safety and effectiveness, we have chosen to reengineer, and we've done it the same way that American business has done it. We looked at the textbooks on management. We said, What do they teach us about reengineering? They said, Find out the stakeholders, what they need, find out your customers, what they are looking for in terms of outputs, what they view the inputs as, what's of value to them. Figure out what your internal process is. Reduce the number of handouts--handoffs, I'm sorry. Reduce the number of handoffs. Delegate responsibility to the lowest level, and support the decisionmaker with information systems that provide them with enough knowledge to do 80, 90 percent of the work one-stop without having to consult and pass the work around. Model that new process, pilot evaluate it and implement it.

Next?

In our reengineering process, we have gone aggressively through at least half the program. We are piloting or implementing our reengineered processes that we hope will end up saving a lot of time and effort in the long run. It does, however, require industry to work with us because we can't reengineer these alone.

For instance, when we develop a product development protocol process with the expectation it will save time on a class III product, industry has got to come in with the application. They've done that a few times, but we expect to see more of it.

When we put out a remodeled 510(k) process, where it used to be we looked at a complete data set on every 510(k), we said if your product is modified, you have to come in with a new 510(k), that is, a complete application. We said no, that doesn't make sense. There are different strategies we can adopt for different categories. First off, we can use standards and we can use declaration of confirmation of standards to substitute for part of the data. So we don't have to review that. The fact that the company conforms to the standards skinnies down that application.

We can say if it's a modified product, if they already have a 510(k) and they're using design controls to rebuild the new generation of that product, redesign the new generation of that product, then relying in part on those design controls should once again get us an application that's far skinnier, that ultimately we would look at a fair number of applications that consisted of little more than the labeling and declarations of conformance to standards

and design controls.

This is an exciting idea. We have it up and running. But we've got to have industry working with us. Industry has got to submit applications this way. Otherwise, we'll never be able to achieve the potential promised efficiency in the way we manage the program.

There's another element, and that means what used to come to the agency for premarket review, that data still exists but it's now at the factory. It's at the corporate headquarters. When we're looking at it--or when are we looking at it? We're supposed to go look at it during our surveillance inspection. Do you remember what's happening to our surveillance inspection program? The inspector isn't there anymore. So if we're doing that tradeoff, if we're saying that more of this is going to be corporate responsibility, the data's going to be in the company's files, then to meet our public health obligation to the consumer we have to be there and do the inspections. That's one of the issues that we need to have addressed in this discussion.

Next?

Medical device reports. This is an idea we've been working on. It was codified in FDAMA. Congress said develop a sentinel system. It used to be we--the current

system, we get reports from all user facilities, all hospitals, nursing homes, diagnostic centers, et cetera. We've been inundated with paperwork. What we need to do is develop a system where we focus on a sample, where we have reporting that is electronic and online and facilitated, where we get a better understanding of the use spectrum of devices and better numerator data as well as better denominator data. It is one of those things that we've been piloting on a very small scale with some money we've scraped out of our declining resources. However, to do it on the scale to really understand what's happening nationwide would require substantially more resources than we have. Congress didn't ante up the money to do that. They just told us to figure out how to structure a sentinel system. So if you guys have ideas on how to do it, let us know.

Next?

Okay. The law says our job is to do a lot of different things: meet all the statutory performance objectives, make sure that safe and effective new products are to users in a timely fashion through a number of mechanisms, ensure radiation-emitting products and materials are safe, conduct science-based reviews on new emerging technologies, and let me emphasize that point. Ms. Suydam made that point as well, that we are a science-based agency.

We are constantly hearing from industry they want us to have up-to-date scientists come to the table who can talk meaningfully with them about the development of their products; that we need to have an infrastructure so that we not only have knowledgeable people but also we can do independent evaluations of products when they fail and that we can participate meaningfully in standard development programs. After all, as we're moving more and more to a standards-based premarket review, we have to participate in those standards activities. And there's nothing that gets you a seat at the table like the capacity to bring your own data, your own test method. That is what is compelling in standards discussions.

We also have a statutory obligation to measure conformance of radiation-emitting products to the standard--clearly, an activity that needs to take place in laboratory facilities--and we're supposed to conduct biennial inspections of device manufacturers in class II and class III, the surveillance inspections, something we're falling far short of; review adverse event reports to identify safety problems; and the list goes on.

Next?

This slide shows you how we are performing against statutory directives in a limited number of areas. These

are premarket inspections. The black bar shows you the percent of actions in a given category which are taken within the statutory directive. The red bar is the gap against the statutory directive. The inspection programs on the bottom, domestic and foreign, only go to 50 percent because it's a biennial requirement. So we're only supposed to do 50 percent of the smokestacks every year. But there's a lot of red on that slide, and obviously our plan is supposed to figure out how to get it all black.

Next?

This cartoon is supposed to have me say we believe at the agency and I'm sure a lot of our colleagues in industry and in the health professions believe that the public is well served by keeping products flowing through the pipeline efficiently, not letting FDA become a bottleneck. We all remember how horrible it was during the early 1990s when FDA did serve as a bottleneck. Business conditions were uncertain. There was a slowdown in industry. Industry tells me that they began to move overseas. We still haven't seen all the data on that, but there's clearly more companies doing operations in Europe.

In order to keep the industry strong and in order to keep products flowing through for patients, I believe we need an efficient and a strong FDA that can take the full

responsibility, do all these actions that are directed by the Secretary.

Now, with that as introduction, we are going to go into--we are going to hear from a number of you, and we will have some open time for discussion at the end of each panel. We're going to ask FDA staff to be available to clarify issues. We understand there are a lot of different viewpoints in the room. We expect people to have different viewpoints. One of the advantages of meeting with stakeholders is you sort of get it all out on the table.

So we're not going to enter into debates. Our role at FDA, if there are misunderstandings, will be to try and clarify them and hopefully to ask more about your good ideas of how we should develop this plan to meet all these statutory obligations.

Our first panel is Mr. Fitzgerald. Is that right?

MR. FITZGERALD: Yes.

DR. BURLINGTON: Okay. Why don't we do this? Can we ask, do you have slides or are you--

MR. FITZGERALD: I have some overhead projections.

DR. BURLINGTON: All right. Well, then, why don't we ask you to go ahead and present them? We'll ask the other two panel members to join you for their presentations in a minute.

MR. FITZGERALD: Good morning, ladies and gentlemen. My name is Brian Fitzgerald. I'm with Underwriters Laboratories in the North Carolina office. I have a very short presentation.

I want to present our two cents' worth. Please regard this just as suggestions. We would be glad, we would be honored to assist the agency in any way that we possibly can, not only in the CDRH sphere of activity but also in the food safety programs for which we also have other divisions, and possibly even in veterinary. But let me limit my comments this morning to some suggestions, humble suggestions on the way forward.

If anyone in the audience would like a copy of my presentation, please see me at lunchtime before you leave. If you leave me a business card, I'll be glad to send you a copy of these slides.

Next slide, please.

When it comes to device information and the dissemination of that advice, we have found at Underwriters that the single greatest obstacle to the goal of perfect compliance is simply our own inability to communicate our requirements to those that wish to comply. Education, information, dissemination of those two issues, has always been our greatest hurdle. This is particularly true, of

course, in any scientific discipline.

We would suggest that the maximum number of resources that can possibly be spared be moved to this goal. It's the way to achieve the long-term increase and better achieve efficiencies within the organization.

Use the Web site. Everybody's got the Web. The Web is international. The Web will help with the international compliance issues.

Maybe this is off the wall, but accredited formal training programs for those members of the industry who make it a living to go out and teach manufacturers what they need to do. This is something that has not surfaced before, but we've learned in our organization that by holding seminars, which, frankly, we recoup our costs, we've increased the level of compliance of applicants for UL and decreased the time within UL necessary to assure that compliance exists. Education is a key element. Maybe some resources could be spent that way.

Next slide, please.

When it comes to the custody of the laboratory and science base, why not broaden the scientific input base by developing a subcontractor network. I use subcontractors in the sense that these would be people that have honoraria and can provide you with the cutting-edge technology issues.

I would like to see perhaps the movement of some of the expert resources from non-critical inspection duties, and I think my presentation will elaborate on that somewhat, and perhaps increase the diversity in the participation in FDA Advisory Committees--in other words, more committees with more types of representation on it.

Many of these committees you might think of as analogous to the open standards method where industry funds these meetings themselves and perhaps an FDA person could be present in order to take these issues back.

Next slide, please.

When it comes to radiation programs, we know that 1020, 1030, and 1040 sections of the Code of Federal Regulations, many manufacturers that are required to adhere to those regulations already use some of the testing requirements that we have in place to do that. And this is one example, I think, where reliance or at least partnering with third parties could achieve significant benefits, and certainly from the resource standpoint. I don't think anyone, especially the third parties, would like to substitute FDA's role. We would like to perhaps complement it and allow the FDA to concentrate more on its scientific role and much less on its inspectional role.

Next slide, please.

Premarket approvals. Here's another radical one. Why don't we seriously think of a plan to adopt a European model? Now, there will be many people that would say, well, it's an unproven model, and, frankly, there are holes in that model. I know. I participate in the work of two notified bodies on this issue, and I can assure you it's not perfect. But what it does is it turns loose the market forces on this issue while retaining control at a competent authority level. And I know that Mr. Burlington--Dr. Burlington, excuse me, is very well acquainted with the British model in their medical devices agency.

It would be difficult for us to transition very quickly to this model, but I would urge FDA to put in place the means by which a transitional plan could be achieved, maybe over five years, relying more on fewer standards. The rate at which standards are being assimilated and, quote, recognized by the agency is bewildering. There are hundreds and hundreds of standards being recognized. How can it be that FDA has control over whether manufacturers are complying with these? Rely more on fewer standards.

And partnering non-critical conformance roles to third parties through accreditation. I can't see why FDA couldn't accredit third parties for activities for which they are competent. And MDKS(?) provides a method to

accomplish this if FDA should choose not to. I think our preference is that FDA should do it itself.

And adopt the identity of a competent authority. For those of you in the audience, a competent authority is a model set up by the medical devices directive in Europe. It represents an agency nominated by the Ministry of Health to administer the role of third parties--they are known as notified bodies--for the market placement of devices. This incidentally does not cover the market surveillance of devices, which should remain and must remain in the domain of the agency. In fact, a greater role in that is obviously required.

Next slide, please.

Our thought is that this process should work at all costs. The postmarket studies, if the agency can't do this, nobody else can. This cannot be privatized. This is what the public expect the agency to have complete control over.

The analysis and coordination must be considered an absolute core role of FDA. And, if necessary, create a center for that, a whole center. The epidemiological study of failure rates and things, this could be funded separately.

Next slide, please.

Establishment registration. Of course, this must work at all costs, and this is particularly true in a global conformance environment where, with the advent of FDAMA and also the MRA, many more internationalist, transjurisdictional issues will emerge, and FDA needs to have a very strong handle on this issue. And resources must be diverted in order to keep a very, very strong handle on this.

Just as an aside, I've noticed that many countries in Europe, now that they have the medical device directive, have all kinds of people that never hitherto knew that they were medical device manufacturers, suddenly realizing they are. This is an issue of education, an issue of information dissemination, and establishment registration.

Next slide, please.

Well, inspections--we would like to see the ongoing development of the accredited person program, and we would like to see it include ISO 13485. There are two good reasons for this, in our opinion.

Firstly, we need in the third-party domain to be--well, to be partnered by the agency in this taking a partial credit for QSR inspections initially, and a plan in place for it to move to perhaps full credit down the road when a confidence-building period has been achieved.

The second reason is that there are engineering benefits to having a manufacturer who submits his 510(k)s through a third party or his abbreviated 510(k)s through the current new processes, and then the loop is tied back through the quality system assessment process. There are economies to be made there that complement each other. The sum of those two economies is greater than the individual parts.

We'd like to see a two- to five-year plan to move to a full QSR credit for ISO 13485. 13485 is called out in the preamble to 21 CFR 820. It's called out in the Global Harmonization Task Force, Document Study Group 4, and FDA contributed mightily to both those efforts.

We would ask also that the advent of CABs--conformity assessment bodies--under FDAMA and under 21 CFR 26, be substantially rethought, at least on the jurisdictional issues that have unfortunately cropped up. It looks like the current suggestions from the agency allow European-based manufacturers to single-source their conformity assessment, but this is not true for American-based device manufacturers who will not be permitted that luxury.

Perhaps the cure to that would be the incorporation in the accredited person program of 13485.

But at the moment, American manufacturers and the conformity assessment bodies would be disadvantaged by the current model.

And last, but not least, we would ask that you do not promote the HACCP process for device conformance, but keep it within the food service domain where it's an eminently successful idea. The device manufacturers are isocentric, and worldwide they are becoming isocentric.

Next slide, please.

DR. BURLINGTON: Mr. Fitzgerald, that's 10 minutes. Will you be brief?

MR. FITZGERALD: Yes. One more, I believe.

We believe CDRH should become a competent authority, build for the 21st century by harmonizing not only requirements but also processes, realize that FDA is uni-jurisdictional but manufacturers aren't and consumers aren't and CABs aren't. And we think it should rethink its implementation of the MRA. Multiple bilateral trade deals don't make a free market nor do they foster harmonization. Only a multilateral agreement can do that.

Thank you very much.

DR. BURLINGTON: Thank you very much.

Let me ask my fellow panel members if they have questions--or actually, no, I'm sorry. We're supposed to

save questions until we've heard the next two speakers. We'll get back on track here.

Ms. Kono, please. And do you have slides as well?

MS. KONO: I have a few.

DR. BURLINGTON: Okay. Great. Also, if you could restrict yourself to 5 to 10 minutes, please.

MS. KONO: Certainly. My name is Kathleen Kono. I am the Washington representative for ASTM, better known as the--or for the American Society for Testing of Materials, better known as ASTM. I came here today to address one of your questions: What needs to be done to reconcile the Center for Devices and Radiological Health premarket approval activities with statutory directives? Should the agency be making increased investment in developing additional national or international standards? Or are existing standards sufficient?

I cannot answer the question of whether or not there's a need for new standards or if standards are sufficient, but what I can tell you is that the organization that I represent, ASTM, is a marvelous forum for FDA to use in the development of those standards. And FDA has used it wisely and well for at least the last 20 years.

I looked up in the registration to see who all was coming today and to see how many of you were members of ASTM

and only saw just a few. So if you will allow me, I want to give you a little bit of background about our organization.

Next?

ASTM is a 100-year-old standards developer, probably the largest in the United States, if not the world. Today we have 132 different technical committees developing standards on everything from steel and concrete to football helmets, to medical devices. Those 132 committees have jurisdiction for 10,000 full consensus standards, and all of those standards are kept up to date on a regular basis--a very important point.

We have 34,000 members from 100 countries throughout the world participating on these technical committees. ASTM committees are open to anyone anywhere in the world who has an interest in the development of those standards.

We have 1,500 government representatives, many from FDA and other parts of Health and Human Services, many from EPA and all over the Federal Government.

We only have 180 people on staff outside of Philadelphia. We do not standards development on staff. All we focus on is providing the forum to enable those standards to be developed, and all we do every day that we've done for 100 years is facilitate the development of

standards.

Often, when new standards are being developed or when new standards are being talked about, you just don't jump into the development of those standards, but there's a need to talk about the need for the standards or to present research. ASTM is also a marvelous forum to bring together device manufacturers, surgeons, regulators, to talk about the need for a particular standards arena. Every year ASTM sponsors at least 40 symposia on the state of the art of a particular industry. Committee F4 on medical and surgical materials and devices has sponsored 18 of those symposia to talk about various research aspects dealing with standards on medical devices.

Next?

In the medical arena, we have these activities: a committee on medical and surgical materials and devices, one on anesthetic and respiratory equipment, emergency medical services, search and rescue, consumer rubber products, health care informatics. And FDA is currently participating on all of these committees and a few others as well.

Next?

I'd like to focus on just one for a minute, and that is our Committee F4 on medical and surgical materials

and devices. It was organized in 1962. It has 575 members from 13 countries. They have developed 164 standards, and we have broad and great representation from FDA, 32 members. The committee's success over the years has been due in large part to the active and enthusiastic participation of the surgical device manufacturers, working alongside surgeons and regulators. In open and often heated debate, difficulties have been worked out in a democratic manner, resulting in a body of standards that have changed the face of fracture and implant surgery. It would be difficult to overestimate the benefits patients around the world have gained from this cooperative effort of medicine, science, industry, and government. And I congratulate FDA on being a real part of ASTM in this activity and hope that it would continue and grow in the future.

Next?

This committee has a number of new activities that are just currently beginning, all as a--and FDA was a real push to get these activities started. We have a new division on tissue engineered medical products, new task group on interventional cardiology, and another new task group on magnetic resonance imaging compatibility testing. All that needs to be done to organize a new activity in ASTM is to bring the request to our headquarters, and we will

determine whether or not there are enough key stakeholders to organize a new activity.

Finally, one last point that has been my pet peeve for a few years, and that is that many government agencies participate in the voluntary consensus standards process. And once they have adopted a standard, they incorporate it by reference in the Code of Federal Regulations. But once it's incorporated in there, nothing ever happens to it, and it may be there for 15 or 20 years and never be brought up to date.

We did a little study, and we found 900 references to ASTM standards in the CFR. Of those 900, 90 percent were out of date by an average of more than 10 years, some by 15, some by 20. So my job is to go out and tell all of you guys that we're doing all this work to keep these standards up to date; you ought to make it a practice to look at them and keep them up to date as well.

I'm happy to say that we've let FDA know that there are 58 standards that you currently reference that only four are current. The rest are out of date, but you are reviewing them. And I have been told that in a few months, hopefully, there will be a notice in the Federal Register that you will bring them up to date. What I would hope is that you would also implement a policy to keep them

up to date or review them once every one or two years and bring them up to date.

That's my little spiel from ASTM. We thank you, and I'll sit down.

DR. BURLINGTON: Thanks very much.

Our third member of this panel--okay, you can get your overheads, and then have a seat--is Ms. Susan Zagame from HIMA. We've asked her to speak at a little more length as representing the largest trade association. I understand you're going to be about 20 minutes. Is that right?

MS. ZAGAME: I'll try and keep it short.

DR. BURLINGTON: Okay.

MS. ZAGAME: Good morning. I'm going to wander, too, if that's okay, if I can.

I'm Susan Zagame. I'm Vice President for Technology and Regulatory Affairs at the Health Industry Manufacturers Association. We represent over 800 manufacturers of medical devices and diagnostic instrumentation. It's a pleasure for us to be here today, and thank you very much for the opportunity to participate.

What I'm going to do is weave in some answers to the specific questions, but generally, I'm going to format my remarks based upon the six statutory requirements that you have.

If I could have the next slide, please?

Okay. There are lots of different themes of FDAMA. Dr. Burlington spoke about some of them. I chose a number of others. I believe that FDAMA really stood for the prospect that we are to collaborate more between the FDA and industry and consumer groups and all interested parties in the spirit of moving forward products to patients so that they can have access to these life-saving technologies. A more user-friendly FDA, the whole idea that we can meet with FDA is an important element of the act.

The Congress evidenced a serious commitment to time frames in the act specifically by requiring a plan by 1999 on mechanisms to meet the obligations of the act, and they were concerned about the delays in getting products to market. President Clinton in his signing statement for FDAMA cited specifically the reduction of regulatory burden and cutting red tape. And then, finally, we can't forget--and we in industry believe this is really an important element--that there is a focus on the promotion of public health. There's the protection of public health, which is a key element, but also promoting public health by allowing access to these devices to patients who are in need.

Please, next?

In looking up the statute, I couldn't help but go to the dictionary to look at what the definition of consultation is, and it says it's a meeting to discuss, decide, or plan. And this connotes more than just comments, in our view, and we hope that this will be an opportunity for an ongoing dialogue so that we can not only just give you our comments but brainstorm and go through the process of coming up with ideas, because we certainly don't have the answers. We don't have all the answers, and I'm sure you don't either.

We want to pay tribute to the FDA, Dr. Burlington in particular, for the enormous strides that have been made in the past few years, not only just with reengineering but also with implementation of FDAMA in a most timely way. And we believe that those improvements have been really for the better, obviously.

Now, we've seen this statutory language before, that the purpose of 406(b) is to develop a plan bringing the Secretary into compliance with each of the obligations under this act, and we've seen that list of obligations. I guess the point here is that there are a lot of things that are nice to do that are not obligations under the act, and I guess we would like to see a real focus on those strict obligations.

Again, we believe that there is a need for a strong FDA, that the industry is well served by a strong, focused FDA that does its job as efficiently and effectively as possible.

Next?

Okay. We have a series of general overall recommendations. First of all, we believe that each of the functions that FDA performs should be linked specifically to the risks to be prevented by that function, and that FDA should ask itself constantly what is the public health benefit of this function, and then determine the cost-benefit of that function. If the public health benefit is very small but the cost is very large, then perhaps some alternate mechanism should be looked at to see if there's some other way of performing that function. And if there is very little or no payoff, then that function should be stopped. I cite an example of what we call the reference list.

FDA went through a process where it determined that the cost of doing that particular function was simply too great for the benefit that was achieved, and we believe that same sort of exercise could be very productive for a number of other exercises that they perform.

Since we're talking about corporate reengineering,

I couldn't help but remember an old line from that Tom Peters book, "In Search of Excellence": "Stick to the knitting." Again, stick to the statutory functions. And align resources appropriately. Align the resources with those statutory functions.

Then, again, an allusion to the good work that has been done by the Center so far. There have been many, many initiatives that have only begun to be accepted by industry and used by industry, and we're hopeful that all of us will give these initiatives time to work.

Actually, this is a little bit out of order but the first area I would like to talk about is maximizing information about the review process. And in discussing this with my colleagues in industry and within HIMMA, we all agreed that one of the most important things would be to publish a flow chart of all of the internal processes that FDA has for all submissions--510(k)s, PMAs, IDEs--so that we know what happens when it goes into that black hole that sometimes characterizes the process.

And knowing that internal process could help us to better understand what FDA has to go through, could perhaps help us to ease the application through in a more timely way. Make available more templates, prototypes and examples. This is something that we've had some recent

experience with at our Device Submissions Workshop.

We worked with FDA and produced a prototype for the special 510(k) and for the abbreviated 510(K), and we are hopeful that with more examples of this type it will give industry a good outline, roadmap for how to satisfy the agency's expectations on good submissions.

And, again, as the gentleman from UL indicated, I think it's important to work with the industry to promote better understanding of those expectations.

The next area that I'm going to speak about is maximizing information about new products. We scratched our head on this. I guess that we thought that what happens here is that a lot of consumers call up Members of Congress and say, gee, I've heard about this great new device or this great new drug and I want to know more about it, where can I go?

And Congress imposed this requirement or at least asked FDA to come up with ways to maximize information about new products. And our feeling on this was that this is really not a function for FDA to promote new products. That being said, however, FDA's obligation would be to refer inquiries about new products, new drugs, et cetera, to the appropriate parties and that might be professional societies, physicians, medical device companies, drug

companies. And we would ask FDA to consider perhaps listing hyper-links to those different parties so that they would have an appropriate place to refer inquiries on matters of this nature.

The next area is implementing the inspection and monitoring provisions of the Act. And this was broken down into a couple of different areas. The inspections area, first of all, FDA is doing some triage in this area and we support that. We think it's important to stratify the inspections based upon past history of compliance of companies, the degree of risk of the product and various other elements that FDA has built into its plan.

FDA does have enforcement discretion and to exercise its enforcement discretion in a logical way maximizing resources for maximum protection of the public health is a good goal.

We believe that FDA should consider ISO certifications. The ISO-centric companies do have third parties coming into review their operations against the quality systems regulation and that should count for something in our view. And, so, a further triage element, if you will, would be companies that have ISO certifications.

FDA has gone from an individual element kind of an

inspection approach to a systemic approach with the quality system regulation. And that's good, that's an important step, to look at systems that companies maintain, and also as part of that is a pre-inspection preparation job that they do where they will ask companies to send documents that are key to determining whether they are in compliance with this systemic approach. And we believe that that's also a very positive element of how they are approaching inspections, one that should give some comfort to the public.

Another point about the fact that education and joint training are critical both for the inspector and for the company. So, the company has a better understanding of Food and Drug Administration's expectations so that they can be helped to come into compliance, which most companies want to do, believe me. And also it would serve the goal of more focused inspections. Everybody knows what is going to be looked at, everybody knows what is required and it should streamline those inspections so they would not take as long, consume fewer resources, FDA can do more of them during the course of a year.

Continuing in the post-market monitoring area. We support the sentinel system. I don't understand how FDA can make any sense out of 100,000 MDRs it receives on an annual

basis. We believe it has got great potential. We see it as a potentially very valuable tool for what we term synergistic learning among all three parties. It's just not an FDA user facility situation. It's not a two-way street, it should be a three-way street, because the industry that I represent wants to know what is going on in hospitals, wants to know where the user error is occurring, wants to know where the device problems are prevalent.

And in this area, we would like to recommend that an industry, FDA user facility working be convened so that we can look at the design of the program and even the funding issues. Because we really don't have any idea how to fund this thing but there might be some creative ways of doing it. And that's the sort of thing we would like to see in this area.

Resource shift. There may be a need to shift some resources that the agency has into this, scraping together a few dollars here and there might help to create some seed money for additional funding opportunities. And I guess our point here is that we think a clear vision is needed. What do you want this system to do? How do you want it to be structured? How can we make it work? Because it has got a tremendous amount of potential.

And then because of the great number of MDRs that

do come in we do believe that there should be greater use of summary reporting.

Post-market surveillance, how to make it work? Well, this is a program that has had its problems in the past and with the passage of FDAMA the Congress gave FDA discretion to determine what are the products that would benefit most from post-market surveillance? We believe that the program needs to be limited to an achievable purpose. There are many alternative ways of gathering information about a device after it's been on the market. Intricate, long, tedious, post-market surveillance studies are not always the answer. They are in some cases and they should be continued in certain cases.

The number of subject products should be reduced and I just have a question there, where is the rescission notice? Because there was a proposal to reduce the number of products subject to post-market surveillance, but it hasn't yet been finalized. So, we're still in a limbo state on some products that simply do not require tracking it or surveillance at this point.

And then finally we recommend that there be better communication between the Office of Surveillance and Biometrics and the Office of Device Evaluation because very often the OSB office just doesn't understand the device...

doesn't understand, for instance, with vascular graphs, the 20 years of safe history that existed with them. So, there was a lot of over-design of post-market surveillance studies and so forth. So, we think there needs to be a lot of communication among the experts that the agency is so fortunate to have.

And then I just wanted to make this point on this slide because it's part of the law and that is that the law says to use post-market tools to reduce pre-market requirements. And while that might not be the correct place to put it, it's important to realize that some resources can be saved by, on the front-end, by requiring studies on the back end.

I threw this slide in about tracking because I think that the same issues apply to a certain extent. We believe tracking should be limited to those products that really require it based upon a validated risk model. And, again, we would like to have the opportunity to comment on devices to be tracked prior to the order itself because we might be able to make some convincing arguments that a product isn't required to be tracked for whatever reason.

Okay. Now, this next area probably elicited some of the stronger comments from some of the companies that I spoke to. Ensuring access to scientific and technical

expertise. The first bullet says, appropriate human resource management. Hire good people, get rid of the ones that aren't so good. It is sort of a simple mantra but it's difficult to do in government and we understand that.

We also support the greater use of consultants and I know that sometimes the agency has said, well, it's difficult to use consultants because they have conflicts of interest and we believe that that can be dealt with through disclosure. Companies are really, really anxious and willing to provide tutorials and they do hire the cutting edge technology scientists and are perfectly willing and anxious to hold symposium and to come to FDA and to provide information and education.

We have done that a little bit through vendors days at FBI and they've been quite successful. And recently, over the past couple of years, anyway, there have been an increasing number of reviewer site visits. And that's been well received by both companies and Food and Drug Administration.

I believe that there does need to be greater communication with professional societies, and other organizations. An example, FDA and industry were working on blood glucose meter guidance document. Consultation with the American Diabetes would have been very useful on

something like that. And we, as industry, should bear some responsibility for making those liaisons as well.

Graduate student internships. Where else do you learn about what's happening, the latest in science than in graduate school, Ph.D. programs?

DR. BURLINGTON: Ms. Zagame, that is 20 minutes.

MS. ZAGAME: Okay. Can I just run through real quickly?

DR. BURLINGTON: Pleas.

MS. ZAGAME: Okay. I won't go through all of these in great detail because my time is up but I do have extra copies for everybody. I guess if I could just spend a minute or two on the establishing mechanisms for meeting submission time frames?

DR. BURLINGTON: Please.

MS. ZAGAME: I think that FDA has come up with a lot of those mechanisms already. And, letting these mechanisms work is really important. Third party review, let me just make a comment about that. That more devices should be added to that list antis the process for using third party review should be made clear.

Again, improved submissions through better communication of Food and Drug Administration's expectations, reemphasizing that. We believe that standards

should be emphasized, both for industry and the Food and Drug Administration. We would like to see industry/FDA working group, again, to come up with additional mechanisms to help you all meet time frames.

So, those are two areas that we would like to meet further with you about.

I am not going to get into the establishment of a registration device listing data base. I would like to simply conclude--if I can get to my concluding slide--by saying that I think that in order to meet these statutory obligations we need to use and evolve the FDAMA and the re-engineering tools. FDA needs to work synergistically with industry and others, including patient groups, professional societies to help meet its statutory obligations, and, again, to focus its activities on high payoffs for public health.

Thank you very much.

DR. BURLINGTON: Thank you very much.

And if you could join us, the other 2 percenters, and allow us a couple of minutes to ask questions and clarify points that may have come up.

Ms. Suydam?

MS. SUYDAM: I have a few questions. First of all, thank you all, three of you, for very thoughtful

presentations. My first question is for Mr. Fitzgerald. You focused a couple of times on redirecting resources from inspections to other activities. And we have already seen from Dr. Burlington's presentation, the diminution of our inspectional capability and where we are not meeting our mandatory inspection obligations and that clearly is something under FDAMA that we are intended to meet.

Can you give us some suggestions about how, whether you think should the biannual inspection obligation be changed because clearly that's one of the alternatives? Or should we have other mechanisms to meet the inspection requirement?

MR. FITZGERALD: My thoughts would fall broadly in line with the lady from HIMA who has just spoken that there should be, in the first place, partial credit perhaps awarded for appropriate ISO certifications in order to relieve the burden both technical and administrative of FDA inspectors. And that there should be, we should start now planning on a means by which the agency can control rather than do the inspection process.

And perhaps a mechanism for that control would be a suitable accreditation process. Does that answer your question?

MS. SUYDAM: Yes.

MS. GILL: I have got a question along those same lines. You mention on the inspection process slide that we should not discriminate against U.S.-based manufacturers and allow them, I understand, to become third parties.

Could you elaborate a little bit more on what you see as what they should be able to do?

MR. FITZGERALD: Well, as many of the folks in the room know there is a proposal for a mutual recognition agreement at the moment between--well, there are several actually that are out there--but the one, in particular, that concerns us is the United States and EU agreement.

There are some interesting byproducts if one studies the wording of the proposal that is issued in order to implement the MRA. There are some interesting byproducts of that wording and we have formally submitted those byproducts in our written comments, as a matter of fact.

But it seems at certainly the first reading, that European manufacturers may be advantaged by their ability to use one organization to achieve both European compliance and U.S. compliance.

Whereas, American manufacturers will need to use two organizations to get that same level of international global compliance. This sets both American manufacturers and the forthcoming American CABs at a disadvantage

vis-a-vis their European colleagues.

That may be unintentional. And we suggest that one method to overcome that would be to include in the accredited person program the partial credit for ISO certifications. This would level the playing field possibly.

There are a few other little byproducts and I think that merits some discussion.

DR. GARDNER: I guess I was interested to hear Susan Zagame talk about the sentinel program because it is one of the bigger items on my plate, day in and day out. And I haven't really had a lot of input from industry. And, in truth, we haven't gone out yet and asked a lot of questions.

But I wonder if you could elaborate just a little bit more on your comments about the idea of a working group and how industry might play in putting together this program?

MS. ZAGAME: When I spoke about this with the folks that are really interested they said, look, you know, the user facilities are our customers, too. We have a special relationship with them. And we believe that it would be important for us to get some of the same information that you're getting to try to assess whether the

program is functioning and what the problems are and so forth and so on.

But they didn't really have any exact concrete ideas for a design or funding. But they said, look, there may be some ways of contributing to this. Some ways of figuring out which facilities would be willing to participate and maybe self-fund the program.

So, again, we have had a lot of good experiences with FDA where we have sat down in a room and come up with some good ideas that have worked and so that the idea was to try to do that again. And there are people that are really good people that are willing to sit down and do that.

MS. MESSA: Brian, under question two, I would like you to elaborate. I believe you said to divert expert resources from non-critical inspection duties. Could you elaborate a little bit on that?

MR. FITZGERALD: Well, again, the non-critical inspection duties would be devices perhaps in the lower risk categories and the inspections to the QSR related to manufacturers of those devices, those inspections might be appropriate candidates for at least the first phases of devolution of inspection duties towards third parties in the accredited person program.

That was my view of that.

DR. BURLINGTON: Thank you.

Ms. Kono, you heard Mr. Fitzgerald tell us that we have approaching hundreds of recognized standards and he is correct, with the next round coming out, it will be over 400 and he said that's too many, it's bewildering.

You told us that you proudly, that ASTM sponsors 10,000 standards. There seems to be a little bit of a disconnect here. Can you help us reconcile how many standards should we have, how shall we keep current on them? The more there are, the harder it is to keep current. And that was obviously a theme you had, as well.

MS. KONO: We have 10,000 standards but we have 10,000 standards for 132 different industries. I believe that the standards that are available they should be decided upon by the users of the standards, the manufacturers and the customers, and they should be able to decide what standard they wish to use.

You know, it's hard for me to tell you that there are too many standards. I think it's nice to have the option of being able to use an appropriate standard and ASTM is proud of its portfolio of standards.

MR. FITZGERALD: What I intended to say from that is that the huge plethora of standards that is available to manufacturers is just that, it's available to manufacturers.

And they have every right and, indeed, they're encouraged in the European model which we would advocate, to use specifically recognized standards in order to have compliance with the regulation presumed.

It is, however, going to be an administrative monstrosity for FDA to be able to know whether such standards have actually been complied with. And perhaps that's another area in which third parties might be able to lend a hand.

I didn't intend to mean that there should be fewer standards, I meant FDA is going to have a problem with this plethora of standards.

MS. SUYDAM: I have a general question for Ms. Zagame. Obviously, the industry very strongly supports the FDAMA law and its variety of regulations that will have to be implemented and the kind of work that has to be done. I think even the CBO estimated that it would take $40 million to do this Act. And, obviously, nothing has been appropriated to meet the requirements of the Act.

And that is really not small change when you look at it in terms of the FDA budget and, in fact, in terms of the CDRH budget. Because I think most of--well, a large percentage of the work under FDAMA is falling on the Center for Devices. And we've had this reduction in resources.

How can you help us in accommodating this disconnect between having to implement all of these new provisions, do the kind of things we need to do, still meet the statutory time frames, try to improve processes and no new resources?

MS. ZAGAME: Well, I would like to wave a magic wand and make it happen for you.

DR. BURLINGTON: Please, be our guest.

MS. ZAGAME: Talk about a tough question.

I guess my reaction is that, first of all, I've never heard that figure before and I would be curious to see how much of that is CDRH specific. Second, I would again just point to the fact that Dr. Burlington and his staff have met, I think, all of the deadlines so far as far as implementing the provisions of the law and have managed to keep the time frames that they've achieved pretty well in tact.

And, so, they are balancing all of this. I don't know how they're doing it. Maybe Dr. Burlington could answer that question but I guess that from an industry perspective we would like to be able to assist in whatever way we can to make life easier for you. And we tried to do that by, for example, developing these prototypes and I would like to see us do more of that.

the answer doesn't look like it's going to be, yes.

You said many times, give the many initiatives that we have out a chance to work through, a chance to see whether industry will not participate and will not, in fact, reduce our pre-market review obligations. How can we get industry to participate more aggressively? How can we get industry to take advantage of this and give us the abbreviated submissions?

MS. ZAGAME: Well, I think that we've made a step forward in that regard by highlighting them at our device submissions workshop. I would like to see us put those prototypes on your Web site, for instance, and give clear instructions and encouragement to how to use them.

I think we, as a trade association, can continue to push them in our publications and in our communications with our members. And hopefully the trade press that is here will also make them known.

So, it's a combination of all parties trying to--and part of the problem is that you're not the only entity that is just over-worked. We are over-worked and over-burdened and our trade association and industry folks, one of the more common reactions has been, there's just so much going on that we haven't had a chance to keep up with it all.

So, hopefully as time goes by and as people get used to some of these new provisions and become more familiar with them, there will be greater usage and that will ease your burden.

DR. BURLINGTON: Thanks.

Other panel members?

[No response.]

DR. BURLINGTON: Okay. Well, thank you very much.

A number of good ideas have been put on the table. We appreciate your perspective and we will look forward to any additional written information supplied to the docket and review it.

I am hearing two messages. I have, number one, Dr. Anderson, did you wish to add a comment or--

DR. ANDERSON: Yes.

DR. BURLINGTON: Okay. We will take just a couple of minutes and let Dr. Anderson comment and then we will look for an early break and come to our second panel in a few minutes.

DR. ANDERSON: I'm one of those alumni that Dr. Burlington mentioned earlier. I'm here today representing NCCLS as the president-elect. NCCLS is an international group charged with developing consensus standards to improve the value of all of our medical testing. And we've been

working with FDA on the development of consensus standards that can be used in helping the review process.

We've been certainly talking with industry about standards that industry sees that would serve those same purposes.

I think there is an idea I would like to put on the table today that cuts across centers. There is an area of device evaluation that also involves the Center for Drugs Evaluation and Research and that is anti-microbial drugs.

Obviously, Drugs does the approval of the anti-microbial drug but Devices has the responsibility for the susceptibility testing. And NCCLS is in a position maybe to help out that entire process.

Our efforts to develop what are called break points are generally and pretty internationally recognized as what should be used in the practice of doing the actual testing.

If, in fact, the Center for Drugs Evaluation and Research wanted to relieve itself of some rather boring and burdensome work, it could simply rely on the NCCLS determination, as well. The other aspect of that that may turn out to be useful is how it relates to post-market surveillance. Emerging resistance is an issue. It simply is not possible for drug labeling to always keep up with

what is happening out there in emerging resistance.

Our group meets twice a year and is constantly factoring in the newest information in terms of what the latest break points ought to be given the current emerging resistance pattern.

So, as a suggestion of an area that Devices and Rad Health is already making use of in terms of the in vitro diagnostic side of it, but maybe there is an opportunity here to extend that over to Drugs and save them some resources, as well.

DR. BURLINGTON: Thank you very much for your comment.

Let's take a 12-minute break and then reassemble, and we have two more panels.

Thank you.

[Recess.]

SECTION TWO

DR. BURLINGTON: Ladies and gentlemen, can we reconvene?

Thanks very much. I owe an apology to Ms. Zagame. Apparently I cut her a few minutes short. I will try to pay more attention on my watch here and/or use the timer.

For our second panel we have Steven Collins as the first presenter.

MR. COLLINS: Thank you very much.

My name is Steve Collins. I am here today representing the Conference of Radiation Control Program Directors and I will say more about that in just a minute.

FDA seems to be hoodwinking the American public by maintaining the X-ray post-manufacture inspection program at a very low funding level. People think that X-ray machines, which are new from the manufacturer, are safe and put together just like the literature says. In fact, the FDA does not check up on enough of them to really know.

So, why not eliminate the inspection program and put the onus on the facility buying the equipment to hire a medical physicist to inspect it?

The physicist could report the results to FDA and the FDA could take action against manufacturers that have many deficiencies or assemblers.

Alternatively, FDA should return to an adequate inspection program so that it will meet its public health responsibilities in this area. Only the FDA has authority over the manufacturers and the assemblers of X-ray machines.

FDA should not say that it has an effective program when what it has is a minuscule program that is not credible. This is recent change.

Ask the consumer advocates how many spot checks

they would consider to be a credible sample? I bet they would say that 1-in-10 should be checked. How many does the FDA check? The cut-backs on inspection by the FDA and as a result of the consequences of contract reductions, also, the inspections of end-users, all of these result in manufacturers and assemblers not being held accountable in many cases and also results in FDA not meeting its public health responsibilities for X-ray machines.

As a matter of fact, Dr. Burlington has pointed some of this out in his slides and overheads.

On behalf of the board of directors of the Conference of Radiation Control Program Directors, I am here today to express concern regarding Food and Drug Administration's reduced funding for compliance testing to verify conformance with the Federal Radiation Safety Performance Standard on newly installed, diagnostic X-ray equipment.

For over 20 years FDA contracted with many State radiation control programs to perform these tests, to verify compliance by manufacturers and assemblers with the Federal standards for diagnostic X-ray systems, mainly because the States performed the inspections less expensively than FDA could with its own staff.

The States continue to work with FDA without

contracts but at a reduced level. The CRCPD is the national organization of professionals in State radiation control programs. Our members can attest to the fact that manufacturers and assemblers are keenly aware of Food and Drug Administration's testing program and are seriously concerned about receiving a deficiency letter from Food and Drug Administration.

Although State and local radiation control agencies always inspected some new installations, the mere fact that there is a possibility of our testing their equipment against Federal standards is extremely effective in increasingly the likelihood of compliance.

Additionally, we and that is 49 of the 50 States, our members or our organization, are concerned that reduced funding for the Federal Compliance Testing program may be indicative of the trend to reduce funding for the radiological health program of the CDRH.

This program has historically been most successful in contributing to a reduction of radiation exposures to the public and occupational sectors, and, also, in improving diagnostic image quality.

This has been achieved by the CDRH in establishing performance standards and developing X-ray equipment testing protocols, in training States' radiation control staff and

performing the testing, and providing necessary testing equipment.

Also, of concern is the reduced emphasis on reporting requirements either because of reduced compliance oversight or exemption. Specifically most States utilize the Food and Drug Administration's form 2579, report of assembly, to ensure that new X-ray equipment is properly registered within the State.

Without that registration and oversight, the State does not necessarily know for a long time where that equipment is at and is being used. And many installers may fail to complete this form without that continued oversight. We need this mechanism for locating the X-ray equipment.

We certainly hope that even though FDA has currently been required to reduce funding for the testing program that these other areas of support will still be provided. Radiation exposure of patients will increase without continued post-market surveillance.

Also, attention needs to be focused on improving X-ray image quality with lower radiation doses in areas other than mammography because the war to get quality mammograms has been won. The CRCPD is not suggesting another Federal Act like MQSA. We are suggesting that there are other areas of radiography for which similar

improvements can be made in image quality with a modest increase in FDA's funding in this area.

Regarding third-party reviews of new devices, the FDA should continue to offer its reviews as a service as an alternative to third-party reviews. And FDA should carefully review the third-party evaluation work product just as it would the work product of its own staff.

Use the dollars saved in this area for the increases that I have recommended. The FDA's past activities related to radiological health have withstood scrutiny by the scientific community and have provided added credence to the activities of the States' radiation control programs.

We request that you consider the State radiation control programs' needs and especially in information in the FDA-required reports in your re-engineering plans and encourage you to maintain the Federal Compliance Testing program for diagnostic X-ray systems.

Sufficient funding should be provided to assure continuation of the CDRH radiological health activities that have so positively impacted the public's health relative to radiation exposure.

Thank you.

DR. BURLINGTON: Thank you very much.

Now, Dr. Pentecost.

DR. PENTECOST: Thank you very much.

I am Michael Pentecost, and I am a practicing physician here in Washington and I'm speaking on behalf of the American College of Radiology.

I would like to--I have been associated with leadership in two different radiological societies for about 10 years now--and I would like to start out by saying that long before there was a Modernization Act, actually probably 5 or 6 years ago, it was fairly uniform that the radiologic community noticed a dramatic increase in responsiveness of the FDA just person-to-person return phone calls, interested in talking with us, interested in sharing meetings with us, sponsoring programs with us. And this has been greatly appreciated by the radiology and scientific community.

I would also like to say that we use your Web site a lot. I think it is really a standard in its ease of use and in the timeliness of its upgrades. So, I think from our point of view, the agency has become more responsive, not only mechanically but on a person-to-person basis, particularly over the last 5 to 6 years and we certainly appreciate that.

I wasn't aware of the budget numbers that you all showed earlier but it is clear, qualitatively from our

interactions with the FDA, that despite the fact that efficiencies have been built into the system and people are working smarter, re-engineering, whatever you want to call it, that the lack of resources is starting to hinder the people power in the agency and we would certainly be willing to volunteer our efforts in trying to articulate these budgetary needs to the appropriate people.

We were very proud in radiology to be a part of the Biomaterials Access Coalition which was passed by Congress and signed by President Clinton about two weeks ago. We certainly hope that in the implementation of the regulations associated with this legislation that the spirit of that is kept.

I think probably my most serious recommendation to the FDA is in the advisory panels and I appreciate what Ms. Zagame said about this. I think that with all due respect to many of my colleagues, who sit on these advisory panels, I don't think that the number and scope and breadth of the advisory panels has kept pace with progress in the field. And the number of the advisory panels is roughly what it's been since I've been familiar with the field and yet the field, as you saw by the numbers of the revenue of the companies et cetera, has really exploded.

I appreciate the fact that there has to be great

rigor in selecting people for the advisory panels based on conflicts of interest and I certainly applaud that. However, I think the whole idea of the advice from advisory panels, the scope of their work really needs to be revisited by the Food and Drug Administration.

And maybe through disclosure or some other mechanism we can open these up to a larger group of scientists and physicians whose input I think would be most worthwhile.

A model that I would look at and that I am personally familiar with is the United Study Sections which have many conflict of interests and they weave in and out of that field I think very nicely and I think the public is well served by the standard which this group uses.

So, I think this would also help, the idea of this being a science-based specialty, really needs to bring in a larger group of the scientific and professional community, who, I think would be proud and happy to serve in this role. So, I would urge you to maybe just start from ground-up and take a look at the advisory panels again.

My last comment is a little far afield and I appreciate that but I don't get a chance to talk at HHS very often. FDA obviously studies and oversees the safety and effectiveness of devices and the Health Care Financing

Administration looks at the reasonableness and the necessity of devices when they pay for them. I can tell you that, as a practitioner, that all of the excellence in manufacturing of devices which is certainly the standard, that the very good work of the agency, the skill and expertise of practitioners is frequently obviated by a failure of payments so that patients aren't served by these particular devices.

And, frequently, that's not even a HCFA central office decision so much as it is the medical director in an individual State and I think it is lamentable that after all the work that all these people do that really a capricious decision is made that prevents these devices from getting to our patients which is what we're all here for to start with.

Thanks.

DR. BURLINGTON: Thanks very much for your comments.

Actually I was going to ask if Dr. Rudolph would join us up here instead of Mr. Phillips for this panel, given your background and expertise in radiation programs.

And Phil will join us at the next panel.

Ms. Suydam, any questions?

MS. SUYDAM: I appreciated the comment that Dr. Pentecost made about the resources and would encourage you

to continue to be--and we will try to provide more information if your association, if you need additional information. I think this is a very real issue to the agency and it's one that, while we feel internally we've suffered in silence, perhaps it's time to stop that silence.

I do also have a question about the HCFA interaction. Is there anything that the agency can be doing, the FDA can be doing to change that or is that really a departmental question?

DR. PENTECOST: Well, I don't know this office well enough but I do think that collaboration within the HHS would be worthwhile. I mean we're all out here to see, you know, that devices be manufactured properly, be inserted properly by my colleagues to be regulated by you. But I think the job is not done until they are actually used with patients.

And as open as this process is and as open as information is through the FDA, through the Web site, and return phone calls et cetera, I think some of the other groups that are responsible, these are not as responsive and not as open in their decision making. And that I think is wrong. I think they should be open and clear about why they're not paying for these devices, once they are approved by the FDA.

MS. GILL: Dr. Collins, in your remarks, in your concern about the dwindling program for diagnostic X-ray equipment and assemblers, you mentioned three things that needed to be done. A continuation or resurrection of the States' program where they do the testing for us, a greater FDA presence and some mention of third party.

Is there a recommendation of which one you see is a better route for us to take?

DR. COLLINS: Which one of the program areas or clarify the question?

MS. GILL: Which one of the--of ways of addressing the shortage in covering the program, the States, FDA take on the role of more inspections? Or turning the program and the inspections over to third parties.

DR. COLLINS: Not being a State employee, naturally I would prefer that you make sure the States are available to do it. I did mention that second in my list of things that I mentioned.

Several of the States, including the one that I work for, in fact, have a program that is a combination of those already where, in fact, the physicists that are either consultants or employed in these larger facilities can do the inspections using our forms and according to our standards and send in the reports to us. We will evaluate

those reports. As a matter of fact, approximately half of the inspections done in the State I'm from are done by those private people and they send us in the reports.

So, that has allowed us to continue an inspection frequency at a frequent rate instead of having to drop off when we've had the same kind of cut-backs in the last few years that you're now undergoing.

DR. RUDOLPH: Can we clarify, Mr. Collins, one thing? This is State law that the facilities must be inspected and then the facilities must then pay a fee to be inspected or how does that work?

DR. COLLINS: It's either a law or a regulation that they must have an inspection at a certain interval. They get to choose who does the inspection, whether it is by their private contract individual or with the State.

And there is a fee associated with it. Every one of the forms that is turned in by the private contractor has to come with a small fee for us to do the review work. It is up to them to negotiate a price if they get a private physicist to do the work, whereas, the State has a firm, flat, fixed rate in it's regulations.

DR. RUDOLPH: Thank you.

DR. BURLINGTON: I heard a suggestion from Dr. Collins that we move to something like an MQSA approach,

perhaps at a more modest level, for other diagnostic tests. Can you comment from the perspective of the practicing radiologist, where, if any, additional Federal standards or Federal directives of a program like, MQSA, might be appropriate?

DR. PENTECOST: Well, we certainly think that there is room for increased credentialing or codifying practice of radiology or medical imaging in the United States. I am representing the American College of Radiology and we have a program which we think would serve that need, probably short of Federal regulation, very well. But the idea of applying more homogeneity to the market place so the public can sort of see, expect a more standardized approach to medical imaging, we think is laudable.

DR. COLLINS: Likewise. I very clearly stated we didn't want another Federal statute that would do this. But we do think working the States, working with the Food and Drug Administration, with the ACR, and with the American Association of Physicists in Medicine can work together to prioritize which one of these different radiographic procedures we can have the most benefit in terms of reducing dose to the public and improving image quality, the order being reversed. More important to improve image quality so that the doctor could get a much better chance of proper

diagnosis.

And so far all of our efforts to do that have simultaneously resulted in an actual lower exposure per exam. And that's what we would like to see. And not necessarily, like I said, by law or by regulation, but by a partnership effort.

DR. BURLINGTON: Are there any other questions?

I have one additional one and that is in terms of the call for an expanded use of the advisory panels or advisory committees, can you elaborate on, Dr. Pentecost, exactly are you thinking about more meetings? Are you thinking about larger panels? Are you thinking about a broader spectrum of activities that they would be challenged with?

DR. PENTECOST: Broader spectrum. I don't think that we could ask the individuals already on the advisory panels to probably meet much more often but I think a larger number of advisory panels, probably with a broader mission. You know, what is a successful outcome from an arteriograph procedure? These sort of things that are more generic to the field rather than less specific, specific about a certain issue.

DR. BURLINGTON: Okay.

Any comments from the floor for these two

panelists or presenters?

[No response.]

DR. BURLINGTON: All right, well, let's go on to our third panel.

Thank you very much, gentlemen.

We have Ms. Cohen, Griffith, Keeling, Russano, and Vogt.

Thank you very much for joining us. Ms. Cohen?

MS. COHEN: I wonder if I could say something to Dr. Pentecost, wherever you are. First of all, the study sessions in NIH, I don't know if you know, to a certain extent that's an old-boy network. Secondly, some of the people chosen for the study sessions don't really know the science that's being presented at those study sessions. So if you use a study session, make certain they understand the science that's being presented. My husband was at NIH for 42 years, and so I've been around science a lot, and I continue to hear a lot about NIH.

In terms of advisory panels, I have served on an advisory panel for four years, and I have some concerns. I would like to see another consumer member. I add a dimension that no one else could possibly add, and more than that, I'm always concerned when research is funded by a pharmaceutical company or a device manufacturer and someone

gets up and is the recipient of that funding, exactly the dichotomy he's caught in. He needs the funding because there isn't other money around, and is the presentation totally objective? That's a concern of mine in terms of science. And I'm not questioning people's honesty. I just always have this concern that when money comes from elsewhere and you're dependent upon it and grants are harder to get, what happens?

I think I have 10 minutes. I hope I can do it.

I have some concerns, and I'd like to just read a couple things, one I alluded to in another testimony I had done. One is this report that came from federal investigators who participated in clinical trials were often exposed to unsafe and unethical practices. And HHS participants often have no real protection because the review boards that supervise the clinical testing of experimental drugs and medical devices are overwhelmed with work. That is scary.

What is scary is everybody wants FDA to do everything, but they're not willing to fund them to do what needs to be done. Good science is good science, and you cannot substitute anything else, and I don't know where people come up with ideas that FDA has to do everything under the sun, but they don't understand what goes into

doing the right kind of work. And I have served now, as I said, for four years, and I have been tremendously impressed with the ability, the caring that I have seen the scientists doing, and to try and dilute or diminish their role I think is very, very sad. And I wish you luck, and I don't know how in the name of God you're going to do it, to tell you the truth.

The other thing that concerns me is also this new law that would prescribe--this is with off-label use of drugs, which prescribes new-use information the manufacturer may disseminate and discriminate the established procedure for a manufacturer's submission to FDA, and this is also devices, and this is also medication. The off-label use of drugs, this is going to make it so much easier for people with devices, no clinical history. They can prescribe it, and what's going to happen? I have tremendous concerns about that. This is all about consumers. This isn't about anybody else. The bottom line is consumers. Self-monitoring and privatization would be glorious in a perfect world, but we're not in a perfect world.

What price is modernization and who pays for it? I suggest it's the consumer. And when Dr. Collins talked about X-ray machines, I don't think I'm ever going to have another X-ray. I, like other consumers, thought that they

were going to be tested more often than they are. I do try and look and see what happens, but you don't always see. But what I want to know, can science, can politics, can profit for device industry and regulatory control be compatible with the mission of the FDA to guard and promote safe and effective devices for consumers? Can all these factors be successfully brought together and at the same time give consumers protection that is essential to their well-being? Can we allow device manufacturers to fail to fulfill their commitment to the FDA in a timely manner?

What I brought with me--and this happens to have something to do with a drug, but I think it's the same kind of thing. One of the things--I come from a consumer protection background, and as far as I'm concerned, compliance is compliance and it has to be done in a timely fashion. And I won't tell you what this was about, but this is a memo that went out on July 16th, and this is in reference to a pharmaceutical company that was to provide some information in September 1997 and still hasn't provided it. If someone has to provide information, it should be done in a timely fashion with a date. I think to wait until they get to do it is not appropriate. I think you have to set the limits on when they provide the information.

Can we fail to fund the FDA with adequate funds to

seriously monitor postmarketing devices? How can we put consumers' life at risk by not properly monitoring postmarketing of these devices? And I don't know and it probably is impossible, but I think physicians should be required to report any adverse effects they find from devices.

Is it safe for consumers to rely upon this kind of thing? And can we allow--I told you off-label drugs. I think that we need--as we get more complex and more new things come into the market and it becomes more sophisticated, where are the consumers in all of this? I've heard people say consumers can go to their Web sites. How many consumers in America have Web sites? How many consumers in America understand English very well? They're not--we have a lot of consumers that don't. We should be doing early education. We should start in the schools. We should be going to TV. If cigarette manufacturers can advertise, why can't FDA get on and say these are the things you need to ask your physician? And why can't we get more information?

We have in Montgomery County a health information library, and it's a very good library. Let's use libraries. Let's give talks in libraries. Use volunteers. Get people who are retired in the community to go out and give talks.

I'm a volunteer half the time. I do that.

I recently served on a panel on a highly controversial drug which was approved. The science was more historical than clinical, and the scientists on the panel had serious concerns. But the drug was passed. It was political. I am convinced it was more political than it was scientific. And I am seeing the nature of panels changing, and I'm very, very uncomfortable.

I don't think personally--this is in my opinion, of which I have many--that a drug or a device should be brought before a panel unless it's clinically sound, the clinical studies have been done, the work has been done, there's good information that it should be brought. I have now sat on at least two panels where I don't think the information ever should have been brought to the panel. It wasn't there. And on top of it, they didn't use diverse populations. They didn't use a culturally diverse population. They didn't use enough women in many cases. And I am concerned that we're not fulfilling the mission of the FDA, and that is to get a diverse population.

I think that we have to have large funding to provide adequate scientific investigation and monitoring. I think that we just have to only bring those things that are clinically sound before the panels, and I think you can

eliminate some of the extra work.

I am concerned about, again, conflict of interest. That is a real concern of mine. And I've often had this dream of having a general pool of money that manufacturers, pharmaceutical and device manufacturers, bring together, and this money is then given to the scientists to do the investigation, and they have no obligations to any manufacturer. But that's probably a dream more than a reality.

I am concerned about reaching the general consumer population. When I sit on a panel, I'm very advantaged. I've been near science. My son is a scientist. I have a lot more familiarity, but I'm not the typical and average person. And how are we going to help them be more intelligent in the questions they ask? How are we going to get them to be more intelligent and ask questions about devices when they go to an HMO and they see ten patients in an hour? How are we going to do that?

How are we going to--and I think we need more plain language. I think labeling needs to be better than it is. I would dearly love to see a label like the food labeling that goes on food, which I think is marvelous, and I think it can be devised, a very simple label with very, very plain information.

I think that the FDA also owns--and I was at a panel which I found fascinating. There was a difference of opinion as to how the FDA read the slides and how industry read the slides. And I think there has to be better clarification for industry to understand exactly what is needed and what is necessary. And there were some differences of opinion, and I think they were honest differences of opinion scientifically, between the industry and the FDA, but I don't think that's healthy for anybody. I think that there has to be--and if there is that misunderstanding, I don't think anything can be moved forward until the clarification is met.

I really support the FDA, and I think modernization or change for change's sake--as I said, man proposes and God disposes, and I don't know how FDA can be in the role of God. I think too much is asked, and I think you're going to have to prioritize, and maybe there are some things that just aren't going to be able to be done. Now, if this meets your needs or my comments, I don't know. But I am worried as a consumer member.

DR. BURLINGTON: Thank you very much.

Now, Ms. Griffith?

MS. GRIFFITH: Thank you. I found that very interesting. I mentioned to Dr. Burlington at the break

that I wish I had the exposure to the earlier comments before I wrote my remarks. I'm just your average consumer. I haven't had the benefit of the exposure that you've had. So here goes.

Dr. Burlington, panel members, ladies and gentlemen, my name is Diane Griffith. I am the congressional liaison for the national network of silicone breast implant support and information organizations. I want to assure you in the opening that most families residing outside the Washington area do not understand and could not possibly imagine the intricacies of political nuance in running of the FDA or, for that matter, the International Monetary Fund. These citizens must depend upon and trust in the good intention of their public servants who manage the details of public health for them.

For the past few years, these citizens have not received services to warrant this trust but, rather, have been given a circus. It is not general public knowledge that the Center for Devices or CBER's intramural research programs are being considered for elimination and reduction, despite loud protest from many defenders of public health.

As the victim of a grievous FDA regulatory crisis--or should I say fiasco--I, more than most citizens not directly affected, appreciate the reviewer research

model. Therefore, to engage in dismantling of the present reviewer research process without any viable alternative fills me with fear. It is completely unacceptable to suggest a wider open door to encourage and permit an increase in existing inappropriate industry influence of FDA research and review evaluations as a purported alternative while government funding for the FDA, on the other hand, is restricted. Such policy places public health, people's lives in great jeopardy. Political pressures applied within the agency which thereby can manipulate the decision of our highest ranking FDA officials must cease.

Of three relevant subjects I wish to explore with you, the first pertains to lack of adequate funding and support for the FDA's Office for Women. It is essential that the Office for Women be provided both funding and empowerment to develop an expanded outreach program. It would be this office instituted to serve women's health issues that can best accumulate and make available understandable information for consumers on adverse event/injury report. As technology and new product development advances to increase demands upon the agency, the Office for Women will surely experience the need of larger contributions to public health education, collaboration with professional organizations, consumer

groups, and regulatory counterparts.

As a second subject to introduce to you, it is most important that I express the public's strong interest in and advocacy groups' strong concern over the agency's ability to retain highly qualified scientists within the FDA. Quoting from Dr. C. Everett Koop's May 19, 1998, letter to Acting FDA Commissioner Dr. Michael Friedman, "Recent cuts in research budgets have had disproportionate effects on CBER, which is responsible for evaluating vaccines and blood products, leading to the loss of research scientists who provide crucial expertise to the regulatory process. If unchecked," Dr. Koop went on to state, "these cuts will lead to a dramatic reduction in the FDA's ability to fulfill its obligation to the American public health."

I ask, and adverse reporting statistics demand, that products be reviewed on the merit of scientific evidence, safety and effectiveness, and not on politics supported by industry lobby. I further ask, and public health responsibilities demand, that the FDA never again become concerned with the reputation and profit protection of the manufacturers than to inform the public of potential and well-recognized dangers.

The process for adverse event/injury report itself is my third subject and is perhaps the most urgent task

facing the FDA today. The consumer must be involved in this process. Consumer protection and education cannot be accomplished without the agency's conveyance of its collected adverse event/injury data to the public as warning issued. The FDA's own 800 number listed on manufacturers' included package information would certainly be advisable. However, the information volunteered by the industry through an 800 telephone advisory might not be expected to accurately reflect the industry risk and safety data. An FDA consumer advisory 800 number should be mandatory and, above all, in this manner, the adverse event statistics collected by the agency should be conveyed to the inquiring consumers. I believe it is critical that the agency work with consumers and physicians, not solely industry representatives, to assure the best quality of report and data conveyance.

What must be addressed is the process by which adverse injury report data be captured with its integrity preserved as well as how this data can be converted for efficient agency and consumer use. It is a prime consideration that all collected data must be reviewed not only by agency monitors, but also by clinicians who will be called upon to treat patients exhibiting these adverse events.

Though now a severely injured breast implant recipient, I had prior placed blind trust in physician and medical institution integrity, including manufacturer responsibility. With similar naivete, I had assumed that any drug or medical device allowed general market privilege under FDA regulatory law promised reasonable safety assurance. No more. Today I feel the same compelling obligation as author Pamela Stock Kendall, who wrote in her book "Torn Illusions" that she herself often wished to walk away from her own involvement in the silicone story, yet she knew she would not be able to go forward with her life without taking a stand for those women who had borne even worse losses.

Like her, I am also committed to keeping a vigilant watch over those in powerful positions who profit from the misery of others. As she stated, the breast implant industry leaves behind a legacy of desolation, destruction, and death. Without advocacy, without public oversight and justified outrage, is it possible that right will ever triumph over wrong?

Thank you.

DR. BURLINGTON: Thank you very much.

Ms. Keeling, now, you had indicated that you wished a somewhat longer time.

MS. KEELING: Yes.

DR. BURLINGTON: Are you down to 10 minutes or so, or how long do you need?

MS. KEELING: About 20.

DR. BURLINGTON: About 20. Well, I'd ask you to try and be as succinct as you can. Let's see if we can't--

MS. KEELING: All right. In 1978, after consulting with my personal physician, I made the decision to get breast implants. It was the worst decision of my life. My implants were ruptured in 1994, and the pathologist found they were ruptured. It was a silent rupture, which I understand gel-filled ruptures often are, and now I have been diagnosed with demyelinating neuropathy. Something is destroying the myelin sheath around my nerves. If both the FDA and the ASPRS both agree that ruptured implants should be removed immediately, but it can be a silent rupture with no symptoms and no reliable method to detect rupture, how can a woman protect herself? The purpose of my testimony today is to address the issues of informed consent, consumer protection, and adverse event reporting as it might apply to all medical devices.

I would like to read from M55376, a product report problem to the FDA. Husband asked: If implants rupture, what would the gel do? The doctor answered: Do you think

the government would allow them on the market if they would cause harm?

Many women were told by doctors, who take an oath to do no harm, implants were safe and would last a lifetime. Many consumers trusted that the FDA was protecting them as consumers. Our trust has been broken.

A recent survey of 23 plastic surgeons' offices, when asked this question, Are saline implants FDA-approved for safety?, every one but one said absolutely, they are FDA-approved for safety.

Recommendation number one: Mandate that every breast implant informed consent includes the following: The FDA has not formally approved these devices as safe and effective because the manufacturers have not provided to FDA adequate scientific evidence to prove their safety and effectiveness. The FDA is concerned about possible health problems from the use of these devices. This information should be included with different wording for every device that has not been approved by the FDA so that consumers will recognize they are part of an experiment and the risk they are taking.

The FDA is mandated to make sure that medical devices are safe, effective, and accurately labeled. The FDA, manufacturers, and the plastic surgeons have an ethical

and moral responsibility not to mislead the public into using harmful toxic devices. Tom Talcott, a former Dow Corning scientist specializing in polymers and silicone elastomers, states that almost all silicone elastomers contain extractable silicone oils, catalyst residues such as PCBs and heavy metals such as tin and platinum.

Recommendation number two: Mandate that all chemicals and catalyst residues used in implantable devices be listed in the informed consent along with toxicity information. Some of the findings in the 1992 congressional report on the FDA's regulation of silicone breast implants are as follows:

One, in 1992, Dow Corning disclosed that the company sold implants to doctors before they were shown to be safe in animals, failed to disclose problems with the implants, and submitted fabricated information about quality control.

Two, patients have been misled about the safety of breast implants for at least the last 15 years.

Three, patients continue to be misled by the FDA-approved informed consent form.

Four, FDA's public statements about breast implants minimize the risk.

In 1996, I became a founding director of

Chemically Associated Neurological Disorders after networking with thousands of women with implants and hearing many similar diagnoses, including peripheral neuropathy, demyelinating neuropathy, organic brain disease, reduced blood flow to the brain from spec scans, MRIs showing white lesions on the brain, abnormal nerve conduction tests, dementia, cognitive dysfunction, and memory loss.

Mentor's current product insert states the following regarding immunological and neurological responses: The medical literature has raised the possibility that there may be an association between certain immunologically based diseases and silicone breast implants. The diseases most commonly mentioned include scleroderma, rheumatoid arthritis, and syndromes which mimic lupus.

Available information does not permit precise quantification of risk. Neurological problems have been reported in a small number of breast implant patients who also exhibit immunological symptoms. Nowhere is this information mentioned in the informed consent given a patient. Nowhere does it state in either the informed consent or the product insert that the Manual of Allergy ad Immunology reports scleroderma-related disorders superficial to the subcutaneous tissues can be induced by silicone breast implants.

Mentor states that they rely on the surgeon to advise the patient of all potential complications and risks associated with the use of mammary prostheses. Women do not realize that they need to ask to see a product insert. The reality is an unethical surgeon can downplay the risk because he has a conflict of interest and could lose one-third of his income from breast implants and the repeat surgeries they require if he tells the truth.

In some cases, surgeons have stated that 30 years of use in large studies by Mayo and Harvard prove implants are safe. They further state that informed consents are merely a formality caused by hysterical media and greedy trial lawyers. In some cases, the informed consent was given to the patient only a few minutes before the surgery process started.

Recommendation number three: Mandate that informed consent forms must be given to potential implant candidates at initial consultation along with the mandatory FDA breast implant information update with consumer and patient information so that a potential implant candidate can obtained balanced information, if desired. Mandate a seven-day cooling-off period between initial visit and date of surgery to give patient adequate time to receive information by mail. In order to have true informed

consent, mandate that accurate percentages of complication rates and disease rates be included.

The Wall Street Journal, in an article dated July 14, 1998, states that 122,285 women got breast implants for cosmetic reasons in 1997, approaching the '90 peak. We believe this is due to a false sense of safety encouraged by the following statements in the current so-called informed consent:

Page 1, most women implanted have had satisfactory results. My reply: What percentage? After what period of time? Six months? One year?

Informed consent: this data will be used to collect short-term five-year data about possible health problems associated with breast implants. This data will be used to help determine if these implants are both safe and effective. My response: With the latency factor of approximately 5 to 15 years for symptoms to appear, 5 years is not long enough to prove implants to be either safe or effective. Tobias Meeker with St. John's Hospital sent a fax to the FDA in 1992 concerning a serious reservation of the protocols of the phase II Mentor study and quoted a surgeon as saying the protocol was designed to give the illusion of a study. St. John's currently has patients sign an addendum to Mentor's informed consent, stating their

patients receiving gel-filled implants are not in a strictly controlled scientific study to help determine if implants are safe. I have copies of both of these documents.

I could go on in that area, but in the interest of time, I will go on to the most egregious false and misleading statement made in the Mentor package insert, which is: Our product history indicates an overall reporting average rupture rate of approximately 1 percent. The FDA estimates that rupture rates are generally between 1 to 4 percent. Protocol violations have been reported to Mentor, the IRBs, and the FDA that have allowed Mentor to make this statement. Research published in the Annals of Internal Medicine April 1996 titled "Reported Complications of Silicone Gel Breast Implants" states: 71 percent of the women in this series had either frank rupture or severe silicone bleed at explanation. Eleven recent research articles documented in Plastic and Reconstructive Surgery states--reports of failure rate of 50 percent at eight years predicted from their analysis of results for explanted silicone gel prostheses from many different research groups. The authors state that the failure master curve shows a significant direct correlation of failure curve with implant time and a failure rate so high that one must seriously question the safety of this device for general clinical use

due to biomechanical failure problems alone. Fraud on the part of the manufacturers in underreporting of complications is serious and cannot be tolerated, along with other protocol violations.

This brings me to the subject of adverse event reporting. Dr. Lori Brown told a recent IOM Committee on the safety of silicone breast implants: The FDA has received 115,920 adverse event reports on breast implants. Who at the FDA is looking at the long-term consequences of breast implants? With a reported latency factor of an average 5 to 15 years for symptoms to appear, the current MedWatch system is inadequate. It appears it was designed as an early-warning system only.

Recommendation number four: Design and implement a supplemental information checklist on frequent complications and diagnosis on devices suspected of having a long latency period for ease of reporting and collection of data for statistical analysis. I have brought with me a supplemental MedWatch form for breast implants that I would like to leave for your suggestions or implementation. If this would take additional funds from Congress to implement, I am willing to help approach the appropriate committees.

The Wall Street Journal on June 24, 1998, in an article titled "MedWatch system comes under fire" quotes

Brian Strom, chairman of the University of Pennsylvania's Biostatistics and Epidemiology Department as saying: Basically, nobody is looking for problems. The system has turned into a big waste basket. It's convenient for industry and the FDA because no one is looking over their shoulders.

Well, I'm here to tell you, Dr. Burlington, I'm looking over your shoulder. We have many documents showing how the breast implant manufacturers and ASPRS agree to act in concert to keep these devices on the market. I only hope the FDA is not the third part of this unholy alliance. I hold you personally responsible for allowing the experimentation of women for over 30 years to continue. When I tried to make an appointment with you regarding valid concerns that I and the thousands of implanted women whose health has been destroyed by the toxic effects that silicone have, I was denied in spite of congressional intervention on my behalf.

Tell me what to say to the young medical student who tells me her implants are 5 years old and her lymph nodes stay swollen after many rounds of antibiotics. She reports she is fatigued all the time and doesn't have the **money to** get her implants removed. Should I reveal to her that Mentor changed their informed consent 002AS-01 to

002AS-02 and added the wording, "Rat studies have suggested that silicone gel similar to that in the implant may have an abnormal effect on the immune system, but the relevance of these tests to humans has not yet been established"? Should I tell her that while under your leadership at the FDA, Mentor was allowed to sell implants that Dr. Pierre Blay (ph), a noted Canadian scientist, called "dirty aquariums filled with decaying tissue, dead blood cells, and in some cases bacteria" because of fundamental design flaws?

Recommendation number five: Mandate all manufacturers to halt marketing and require recalls, much like the automobile industry, when good manufacturing practices are violated and until they are corrected.

On October 15, 1997, in response to my citizens petition, Dr. Michael Friedman stated that the FDA did not have sufficient information to change the current regulatory policy on silicone gel-filled breast implants at this time and that the public interest is not well served in your current situation. Your response in a letter dated December 2, 1997, to the president of the ASPRS was to ask for their help in finding additional plastic surgeons to put more gel-filled implants in women. May I remind you, Dr. Burlington, that the Nuremberg Code states the following:

One, the voluntary consent of the human subject is

absolutely essential. The person involved should have free power of choice without any element of fraud, deceit, overreaching, and other ulterior form of constraint, and should have sufficient knowledge and comprehension of the elements involved to be able to make an enlightened decision.

Two, no experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur, except perhaps in those experiments where the experimental physicians also serve as subjects.

Three, during the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage if he has probable cause to believe in the exercise of good faith, superior skill, and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death of the experimental subject.

You, Dr. Burlington, are that scientist in charge, and I leave with you an Alabama death certificate dated April 12, 1994, that states: Cause of death, colitis due to or as a consequence of autoimmune disease due to or as a consequence of lupus due to silicone gel implants.

Thank you.

DR. BURLINGTON: Thank you for your remarks and

for conservation of time as well.

Now, Ms. Russano?

MS. RUSSANO: Yes. I'm going to need about 15 minutes, and I'll try not to rush too much.

Thank you to the committee for allowing me to speak. My name is Jaima Russano. I live in Northport, New York. I have a background in marketing and sales for consumer products for over 20 years. I will be addressing the silicone issue relating to medical devices and will recommend improvements in the reporting system to help identify problems in the future.

I was born with a hemangioma tumor on my right breast at age 14. I had a Dow Corning silicone silastic gel breast implant on my right side to correct the deformity. My first implant remained in my body for 19 years. In 1989, I had the old implant replaced with the "new, better" silastic 2 breast implant. I was never given a package insert, which was by law by then.

I had a myriad of health problems from esophageal motility disorder, chronic pancreatitis, autoimmune autonomic orthostatic tachycardia, systemic sclerosis, and a rare bone cyst on my femur bone and one on my S2 spine, migraine headaches, and, worst of all, allergies to silicone.

I gave birth to two sons, now age 15 and 13. At the time I gave birth with my first child, my implant was over 12 years old. I breastfed both my children, not knowing that there were never proper studies to prove the safety of breast feeding with breast implants. Now my children suffer from a variety of unusual disorders, from esophageal motility disorder, renal infections, which is rare in boys, bone cysts in the back of my older son's head that I had to make sure that when they replaced it that they did not replace it with silicone products or use silicone sutures due to his allergies, which was very difficult to do, synovitis, headaches, rashes, fatigues, and, again, allergies to silicone.

My children are not alone with problems related to exposures of silicone and saline breast implants. In 1992, I felt that there had to be a better method of reporting adverse symptoms to the FDA on all products or devices. I started a foundation, Children Afflicted by Toxic Substances, and have heard from over 7,000 families with children born to mothers with breast implants as well as with other children--with other silicone devices, and this is just a sampling of some of the pictures of the children that we have collected data on and some unusual bone deformities.

Could you go to the next slide, please?

We started ranking children and taking pictures. Again, I am funding this. I have been collecting the data.

Could you go to the next one, please?

We're finding, again, a myriad of deformities from large head, distended stomach, esophageal motility disorder, rashes.

The next slide, please?

And these are just a list of some of the symptoms that we have found in children, and it ranges from abdominal allergies, asthma, cancer, endocrine problems, infections, lymphoadenopathy, motility disorders, neurologic, orthopedic, rheumotological, renal rashes in sica(?).

Unfortunately--I'm sorry. There are over 85,000 children listed now in the Dow bankruptcy to date, with no funding of any--there's not even enough money in that system to give them medical monitoring. There is not even enough money--$50 million would not even pay for each child to be monitored, for blood tests, urine tests, and any other type of testing that's possibly needed, to see how far this silicone disease has gone.

Unfortunately, I had another bad experience with a product that was not approved by the FDA until a few years ago. This product is not a medical device but relates to

this issue. I was part of a clinical trial for the drug Sessapride (ph). Before taking the drug, I had to fill out all types of forms. I went through extensive testing and had my insurance company pay for them, and I was added to the clinical trial. I was on the drug for approximately two months and developed enlarged lymph nodes all over my body. I went off the drug, and my lymph nodes went down. I went back on the drug for four weeks, and my lymph nodes swelled up again. Finally, I was taken off the drug and out of the protocol study.

To this day, I have never been contacted by the doctor who conducted the study nor Jansen Pharmaceutical Corporation to see if I was green, blue, if my arms fell of, or if I was still alive. I contacted the FDA to make a complaint, and I was told the FDA had no control over drugs and devices in protocol studies. The drug was approved, and now there are various problems being reported.

Today, saline and silicone breast implants are being implanted in--could you go to the next slide, please? Today, saline and--next one, please. Sorry. Keep going.

Today, saline and silicone breast implants are being implanted in women as young as 13. In 40 years of implants on the market, manufacturers have never tracked the safety of implants in young women or young developing women,

nor has proper data been collected on the risk of pregnancy and breastfeeding. A young woman may not know if she wants to breastfeed a baby and cannot make an informed choice at such a time. Vital data such as the impact of miscarriages, infertility, allergies, hormonal changes, along with other related disorders, have not been properly collected or conveyed to the consumer.

Next slide, please?

Breast implant manufacturers have and continue to this today to target young women of child-bearing age. It is against the law to conduct experiments on children and pregnant women, yet the FDA has done nothing to stop the ads, required doctors to state that there are no studies on young women and exposure to the fetus. President Clinton signed on April 23, 1997, an executive order stating that every federal agency must protect the health and safety of children in America.

Silicone devices and all breast implants have, for some strange reason, been the exception of the rule when it comes to devices that are allowed to remain on the market. For example, the PDR and OTC for every product warns and identifies contradictions published yearly which includes information on the safety of pregnancy and breastfeeding. If products were never tested for safety, there are clear

warnings listed or states "not known." This information is also included on package inserts, outer packaging, and PDR and OTC products across the board. Herbal cough drops have more information on the safety of pregnancy and breastfeeding than a breast implant package insert.

Chemicals like toluene, benzene formaldehyde, lead, platinum, and latex, just to name a few, are additives or catalysts in implants. These same chemicals have been ordered by the FDA to be removed from cosmetics and nail polishes.

Most products carry an expiration date. Breast implants and other medical devices do not. Today I brought a saline solution used to pump up an implant that shows that the expiration date which saline lasts approximately two years. The saline IV container states: Store unit in moisture barrier overwrap at room temperature, 77 degrees Fahrenheit, until ready to use. Avoid excessive heat.

What happens when the saline expires in a breast implant? Does the heat of the body at 98.6 degrees shorten the life of the saline, causing it to become contaminated? These are simple questions, and in 40 years, manufacturers and doctors have been shown to sell the implants and these devices along with testicular implants and other devices carrying the same type of solution, without answering any of

these questions.

In 1997--the next slide, please?--I gathered patents on breast implants, silicone gels, tissue expanders from 1940 to 1996 with a total of 246 patents. These patents were turned over to Dr. Marietta Anthony, Office of Women's Health, FDA, last June.

In 1954, Dr. Pangman (ph) invented the first surgical breast implants, Avalon (ph) foam, Patent No. 2,842,775. Pangman describes how tissue, blood vessels, and fluid grew into the implant. Column 2 shows that the material of the sponge is characterized by numerous small sponge-like openings which are normally invaded by the surrounding blood vessels and fibrous tissue of the patient. Such invasion, as previously pointed out, is normally described in that it securely retains the device to the proper position. Too much invasion or absorption of body fluids, however, result in hardening and eventually atrophying of the sponge.

Cronin's patent in 1963, Patent No. 3,293,663, identifies the problem of Pangman's patents and further states: This invention relates to a breast prosthesis comprising: one, a flexible container approximating the shape of the human breast; two, a soft gel filling said container; and, three, a layer of porous material attached

to one side of the said container so that tissue can grow into said porous material to anchor the prosthesis to the chest wall.

In 1969, Dow Corning patented the 3,652,628 cyclotetracyloxin which impart alteration of genital functions in mammals. This patent identifies certain phenyl and methyl-containing cyclotetracyloxin compounds which exhibit androgen-depressant effects. It has been shown that one can alter the genital function, which includes reproductive capacity, as well as androgenetic and estrogenetic capacity of mammals. This should have been a wake-up call to Dow Corning. But to this day, cyclotetracyloxins are used widely in a variety of consumer products.

In 1987, Dr. Frank Joreau (ph), plastic surgeon at the Baylor College, and Thomas Cronin, partner of the Cronin implant, designed a new breast implant that identifies fold fault. He writes in his patent that silicone fluid has been associated with more generalized potentially fatal tissue response which varied depending upon a tissue or structure the agent migrated. Human adjuvant disease may be a systemic effect of paraffin or silicone fluid installation and is apparently an autoimmune connective tissue disorder that manifests as connective tissue disease, rheumatoid

arthritis, systemic scleroderma, or systemic lupus. He also writes that 16 percent of the plastic surgeons' income is derived from breast implants.

In the mid-1980s, Dr. Joreau refused to place silicone breast implants in women. Unfortunately, his implant warning device was ignored by breast implant manufacturers.

Next slide, please?

Virtually every patent identified major problems with silicone breast implants and saline breast implants. These patents were written by people skilled in the art of silicone polymers and medical devices. This slide happens to show a cosmetic from Estee Lauder that is now on the market. It's about a $40 item. There lists in the very first at least six different types of silicone, and cyclotetracyloxin is the first one listed.

Silicone is used in thousands of medical devices. In some cases, the benefit outweighs the risk. But what happens to a person who has a device for cosmetic reasons and develops an allergic reaction to silicone, gets sick, and needs, for example, a pacemaker? Because that person now has an adverse reaction, they can no longer have the devices that might save their life. That is the situation I and my children, as well as many others with implants, are

in. Doctors do not even know what products contain silicone, what puts a patient with silicone allergies at great risk.

Silicone is the Titanic of medical devices. It was touted as the answer to all. But we have learned we cannot fool Mother Nature. Government health agencies, doctors, manufacturers, and consumers need to learn from the past and go forward to improve informed consent, testing, and research on medical devices, as well as other consumable products.

There are many issues that need to be addressed by cannot be expanded on in 15 minutes. However, I will briefly touch upon them and the changes that are needed outside government agencies to truly incorporate safe devices.

Could you go to the next slide, please?

DR. BURLINGTON: Ms. Russano, if you could wrap up in the next minute or two? If you have additional remarks, we will be glad to receive them for the record and make sure that they're fully considered.

MS. RUSSANO: How much time have I gone through--

DR. BURLINGTON: A couple minutes, could you--

MS. RUSSANO: Yes, I'd just like to know how much time have I--

DR. BURLINGTON: Two minutes.

MS. RUSSANO: No. I wanted to know how much time have I used.

DR. BURLINGTON: I make it that you're at 13 minutes now.

MS. RUSSANO: Okay. I'll do my best.

One is to create a round-robin approach with grants from universities and research centers. Example: To date, a manufacturer comes to a university with a grant for $5 million to conduct research for a new pacemaker. At that point the study is biased. The researcher knows that he and she must come up with the information the manufacturer wants, or he and she loses a grant for the next project for the university. He and she loses their reputation as a player. He or she could lose earning potential. The round-robin would give hospitals and universities equal opportunity to conduct research. This time it may be Harvard School of Medicine. Next time it may be Washington University. Small companies would greatly benefit from it as well.

Medical journals should no longer accept advertising dollars from pharmaceutical companies and devices manufacturers. Subscriptions should be the main source of income.

Health insurance companies could collect data on many devices that were implanted and problems associated with these devices if they occur. This data-collecting system could be used to follow adverse reactions on drugs. After a specific number of devices fail, the health insurance companies would be required to inform appropriate agencies.

Limit the amount of funds for giveaways to doctors, hospitals, and institutions. Items from trinkets, trips, lunches, tapes, to manufacturers' samples are given to doctors and med students. Most corporations today limit the receiving of gifts to $25 or less to their employees. The medical industry should follow this example.

The ideas that I have for the FDA are:

An application fee should be submitted to ensure the FDA has appropriate funds to conduct testing on the product submitted for the FDA approval to independent labs. Also, fines should be enforced, maybe more fines should be enforced, to help establish those funds.

All products grandfathered in should be restricted, new sales should be halted, and only replacement devices should be allowed to be used. Follow-up studies should be conducted on persons who have had these devices to help identify any problems or symptoms associated. The FDA

should have names of persons who participated in the studies. The FDA should contact randomly throughout the years these persons. The FDA should engage large fines to those who do not abide by these regulations.

The FDA should mandate to all departments a basic outline. The FDA should calculate the quantity of any given chemical used in various products. Silicone is used in thousands of products from shampoos, hair sprays, to fried chicken. At this time there are no guidelines as to how much a person should ingest on any given day.

I have many more ideas, and I would be happy to work with any agency. And, again, I brought a saline bag that shows the expiration date, and if you'd like to see it, I'll be happy to turn it over.

Thank you for your time.

DR. BURLINGTON: Thank you very much.

And now our last speaker, Ms. Vogt of the National Patient Safety Foundation.

DR. VOGT: Good morning. I'm Eleanor Vogt, senior fellow with the National Patient Safety Foundation. The foundation is an independent, not-for-profit, educational association. It was originally started by the American Medical Association and since has invited to the table partners from all stakeholders in medicine--consumers,

providers, and manufacturers. And I'm very happy to say the FDA is at the table as well, and Dr. Burlington serves on our board.

I'm here to talk with you this morning about the issue of patient safety, and particularly your first issue of concern, which is incident reporting.

We are doing regional forums around the country, and what we're hearing from particularly providers is they want to be able to speak about what's happening in health care. They want to be able to speak about not only the accidents but the near misses as well. And they need a forum for doing this.

Everything in our culture works against sharing this information. Our legal system, our cultural system, our organizational and professional systems work against this. They are asking us for a forum, a safe harbor, to share this information, and it is from that framework that I encourage you to explore an incident reporting system alongside and in addition to your sentinel reporting system. And I know as I say that you see those figures of all those reports that are coming in fast and furious and however will you address them. Hear me out for just two minutes, and I have a suggestion for you.

One of the suggestions or one of the areas that we

are learning from is other high-risk industries, and in particular, aviation. As you probably are aware, aviation does have a safety reporting system, the Aviation Safety Reporting System, which actually is administered by NASA, not by the FAA. And that's one of the suggestions we have to you as you consider an incident reporting system, that the administration be by an agency outside of the regulatory agency.

As you may know, when the FAA originally set up their system, it was not a success because it was administered by the FAA, and reports were not that swift in coming. That has now been reversed, and the system now gets something like 30,000 reports a year.

The other key element there, of course--and this is one that may help address your resource issue--is that the reports are analyzed not by technicians but by hands-on people. In this case, it's retired pilots, retired air traffic controllers, and I wonder--and I hope you are exploring the idea of using real practitioners and ultimate end users, consumers in every form, to help evaluate the reports.

Another key element of the Aviation Safety Reporting System is that--we talked about summary reports with sentinel reporting, but that you go the other way. You

go for the full story, you go for the full anecdote so that you can pick up, start analyzing the patterns within the full story that are available--that could be available to us.

So perhaps there is a whole resource available to us--we were talking before about we're all in it together--of practitioners and consumers working together, perhaps even as volunteers, to analyze this data, to look at the patterns, what the scientists call the genotype, you know, the underlying music, the underlying themes in these patterns, then to make recommendations to the regulatory bodies and the policy bodies. This is a model that is in existence that we can learn from, and I know you, in fact, have been looking at that. I want to encourage you to continue to look at that and to give consideration to other forums in which we can move beyond blame for everyone involved--manufacturers, providers, and consumers--so that we can move to solving the problem.

So thank you very much for allowing us to come, and I want you to know that our resources and our expertise is fully available to the FDA.

MS. COHEN: May I have just a couple minutes?

DR. BURLINGTON: Sure.

MS. COHEN: I just wanted to say that MedWatch--

DR. BURLINGTON: Could you use the microphone?

MS. COHEN: MedWatch has a budget of $148,000. I don't have to say anything more about that.

Also, the user fees, PDUFA has been very successful, and I see nothing wrong with the price of paying something to perhaps speed some things along.

Manufacturers pay for witnesses all the time to come before the advisory boards. I think there should be a fund for public citizens to come and testify before the advisory panels, and you're really going to get citizenry to come and speak.

Lastly, another thing that I found very troubling was consistent protocols. There was a large protocol that went across the country, but when I started to question how the protocol was done in one part of the country, it was different than any other. So there has to be consistency in protocols.

I am so deeply touched by these ladies, I can't tell you. This is America. This is what it's about. And we have to listen to them. I can do my part, but this is so significant, I can't tell you. I am truly touched.

MS. KEELING: There's three generations of my family affected by this issue. We're going to have many more.

MS. COHEN: Yes, it's--I think they've said everything, but I have to say, in all honesty, I think everybody is trying and we have to find our way.

DR. BURLINGTON: Thank you.

Can I ask our FDA panel--Ms. Suydam?

MS. SUYDAM: No questions.

Ms. MESSA: No questions.

DR. GARDNER: No questions.

MS. GILL: No questions.

MR. PHILLIPS: No questions.

DR. BURLINGTON: We heard from some of the earlier speakers a call for expanded use of advisory committees. It seemed to be suggested that they do a different type of job than they have been doing in the past, that perhaps FDA take some of the work that we currently are using our in-house professional staff to do and use the advisory committees to do that work instead. I wonder if you would care to comment on that suggestion. At least I thought I heard that suggestion between the lines.

MS. COHEN: I have a comment, and it's a mixed blessing, because it becomes single issue, and one of the hardest things as a consumer member is to sit on an AIDS panel and have the AIDS representatives sitting next to you, as a matter of fact, and hearing their needs versus the kind

of science that's being done. It's very difficult. And when you become single issue, you sometimes forget the overall picture, and I think you have to have that balance. And it's easy for me to say because I don't have--I have a cousin who is a plastic surgeon in Boston who wouldn't touch silicone, by the way. So I knew enough to stay away from it. But I am concerned about single issues, and I'm concerned about balancing out the general need with specific needs. And that's very hard to do.

MS. RUSSANO: I think one thing that I would like to see is a medical device manual like the PDR that lists different devices and has to be updated yearly, because it is very difficult for consumers. You know, you have to go to the Web to get this information? And it is unfortunate, because I happen to be in a position where I know many salesmen. In fact, I was sitting on a plane with a gentleman that was in pharmaceuticals, and you know what he said to me? Money buys the best science.

And I think that--you know, I'm sorry, but that is wrong. I mean, you know, the ultimate goal is not to utilize a product so we can go and sue somebody. Nobody wants to do that. I didn't have a breast implant so I could go sue Dow Corning. I would rather have my career.

So it has to be a blend, and patients need to be

informed. They need to understand if the risk out-benefits--or outweighs, you know, the cause or the cause being worse--the cure being worse than the cause.

DR. BURLINGTON: Your comment raises a question for me in that a theme I heard was that consumers need more information presented in a more digestible, understandable form. And yet there's a counter-balance in terms of how does one completely inform without increasing the confusion.

MS. RUSSANO: There are very many simple ways, and I think that corporations would really need to work with various consumers, and as you said, that we need more consumers on panels. You know, on the FDA hearing in 1992, there was one woman that was a consumer on that entire panel. That is not enough.

You know, I was--in fact, I received a letter asking to be on one of the panels, and at that time I was so upset with the FDA, I just put it aside. And a friend of mine told me, Well, you know how drugs are proved? They go through animal studies first. That's the panel that you should choose. And I thought, well, you know what? Until they change things, I just can't be a part of that. And I really--I have to tell you, I have manufacturers in my background that--I worked for Revlon. I worked for the cosmetic industry. This is what we need. We need more

information and better organization with consumers. And you know what? The manufacturers have to digest the problems. They need to say, okay, we're willing to deal with that.

DR. BURLINGTON: If I could interrupt, and also ask our other panel members if they have any suggestions about how FDA can do a better job in getting the information available to consumers?

MS. COHEN: I think that--

DR. BURLINGTON: I would point out, the PDR is published privately by Medical Economics. It's not an FDA organ, and it's done through revenues obtained from the pharmaceutical manufacturers.

MS. COHEN: And it is the exact information that the pharmaceutical industry gives them that goes into the PDR.

DR. BURLINGTON: Right.

MS. COHEN: Yes, part of the problem is not all advisory panels like consumer members, I have to tell you. Not all exec secretaries like us either. So you have to recognize it's not an easy road all the time. But I would like to, on this study, on more thing that I think I have to say, the review boards that review the clinical trials are often deluged with reports of drug harmful side effects but cannot allow follow-up. Such reports are mainly spent one

or two minutes of review per study. In some cases, a review board supervises more than 2,000 research protocols and cannot do more than a perfunctory review of serious problems.

DR. BURLINGTON: For clarification of a point, I believe that's a discussion of the Institutional Review Board system in institutions which are supervising--

MS. COHEN: The protocol, yes.

DR. BURLINGTON: Research, right.

MS. RUSSANO: Can I make one more suggestion? I think one thing that is very confusing to the average consumer outside, first of all, they really don't understand how the FDA works or even--you know, I find going to various meetings that everything is given--you know, it's HHS or, you know, CDHS, you know, something like that. And it's very hard for people to grasp. And I think that there can be some type of volunteer system, an ethical volunteer system that can truly help the FDA and help manufacturers reach the ultimate goal, and that is to put safe products on the market.

DR. VOGT: I strongly support that last point. I happen to have the distinction of being the first consumer representative on an FDA technical advisory panel. It was the Bureau of Drugs. It was the committee on arthritis

seven or eight years ago now, I guess. And what I experienced then and I still see now is the lack of preparation for a consumer member on a technical advisory committee. Not only do they have to overcome the science barrier, but the cultural barrier of not being in the inside network. And I'm sure you're addressing that as well.

But the other thing, I think the underlying theme is that too much of this consumer orientation seems to be an add-on and not an integral part of the process, and I think that's what you're hearing from all of us, is that it needs to be integral from the very beginning in the ultimate design so that it's not seen as add-on.

MS. COHEN: One of my specialties in consumer protection was advertising, and Fosamex, I was on the panel that approved Fosamex. And I've been following the advertising in Fosamex. In the very beginning, it was pure, it was nice. But I can tell you it's deteriorating.

I often think, though, that I know FTC has part responsible for advertising practices, but you've got to monitor better what pharmaceutical industries put out and what they monitor. It isn't monitored adequately, and I see stuff on television, and I collect things, and I keep sending it in. A lot of it is blatant deceptive practices, and they do not monitor themselves.

How you do all these things with the limited amount of money--that's why you mentioned volunteer, I mentioned volunteer. I know a lot about advertising practices. You can find other people like me. And we as private citizens should be monitoring what goes in our inserts, what we don't get, and what goes on the box. And I think we all have a responsibility to do that.

MS. RUSSANO: Manufacturers today complain that either they have to change a label, you know, it's going to cost them XYZ because the FDA says, okay, now we have to put this label on and I've got a warehouse full of product.

If we could save money for manufacturers on other ends of some of these trinkets that I had mentioned and put a limit, put caps, then manufacturers would have the right money to be able to fund some of these other vital issues. I mean, those are more important.

And I have to tell you one last thing. A medical student that I was with received a tape, an audiotape, which they get all the time, on how to avoid a lawsuit. I thought for a medical student that is absolutely despicable. Yes, how to avoid a lawsuit when utilizing their drug. That's what this videotape was. It was turned over to the appropriate persons, but you know what? They get tapes like this all the time.

I think that kind of information has to stop, and the funds--don't tell me that there's no funds to do this stuff when there's funds to do other things, and those funds need to be appropriately administered in the right direction.

MS. COHEN: The Japanese--and I hate to bring them up because of their economy, but they have a very different kind of system in terms of salaries and money. They don't try to make their money immediately in terms of the sale of their drugs, and the salaries of the executives are not like the salaries of this country. So we have to really re-evaluate our value system and what is essential. You can't tell a company how much they can earn, but you can certainly let the public know what the salaries are versus what they're not doing.

DR. BURLINGTON: We have one final comment, and then I want to see if there are comments from the floor.

MS. KEELING: I'd just like to ask what standard of risk for devices does the FDA have. Is the current standard--as long as it is mentioned in the product insert, it is an acceptable risk. Has the standard become buyer beware? It is an unworkable society that must do medical research in order to make health decisions and then wonder who financed the research and for what motives.

DR. BURLINGTON: Okay. I especially want to thank the members of this panel for their heartfelt concerns. We've heard you. You have an important message for us. And I would like to ask if there are any comments from the floor at the close of the meeting here.

[No response.]

DR. BURLINGTON: Okay. Thank you very much. We appreciate it. We have received many suggestions today. We look forward to additional suggestions to the docket, and remember there is the overall agency meeting coming up September 14th if there are additional points of view that folks wish to make clear for the record.

Thank you.

[Whereupon, at 12:23 p.m., the meeting was adjourned.]