will also get regulated as a drug, even though if that second-generation product was developed first, it would be regulated as a biologic.

So as these examples show, and there are many others that will be in the more extensive paper that we've prepared for you and that's just going through all our MBC review process, these general principles don't always have general applicability. It's not always possible to predict whether a product will be regulated as a drug or as a biologic. Even where it can be predicted, there can be unfairness.

I remember two companies, neither of which was mine, developing products for ALS. Both were common proteins. One was regulated as a drug; one was as a biologic. It turned out both products failed in the clinic. But to put competitors in different centers with different review groups, with different standards, and with different implications for whether there was going to be a generic version of their product that would be substitutable at the drugstore in the future, creates a competitive issue that competitors are, I think, legitimately concerned

about .

Here are a couple of further exceptions to the rule. Erythropoietin is a hormone produced in the kidney. It's regulated as a biologic. It did predate the Intercenter Agreement, but Amgen has told me that they went to see Harry Meyer, and Harry said, "Do you want it regulated as a drug or do you want it regulated as a biologic?" And Amgen says, "Well, we like the people in biologics. They know the science. We'd like it regulated as a biologic. " And Harry turned to Elaine Esper and said, "Okay, keep those biologic. "

That is not the way policies should be made, and it has implications that even Amgen didn't. anticipate at the time. Similarly, the fact that Genzyme decided to develop a non-recombinant GCR product means that our recombinant product was regulated as a drug. Had we gone directly to recombinant, it would have been regulated as a biologic. That has profound implications for whether companies choose to develop first-generation products and whether the patients have access to those products earlier.

And, finally, the Intercenter Agreement recognizes, and we agree, that if there's one division in the agency that knows a lot about a particular disease, it probably makes sense for that division to do the review. But each center has the authority to issue a license of either kind, an NDA or BLA. I'm not aware of either center having ever issued the type of license that is typically provided by the other center, and that may be something that's worth exploring further. I'm going to go into that. That will be a one-minute thing.

Given the fact that there's some randomness on whether a biotech product is regulated as a drug or a biologic, we believe that there should be consistency with respect to whether such products are subject to any kind of abbreviated or truncated approval system. I won't go into further detail on this, but YOU will see the detail in our paper. There are good public health reasons to say that minor differences in a molecule should be demonstrated to be clinically irrelevant before assumed to be clinically irrelevant for that purpose.

If you move on to pediatrics, the pediatric provision of FDAMA provides for a six-month extension of market exclusivity if you do an FDA-requested study and get the results before your exclusivity expires. This extension only applies to drugs.

Now, the only kind of exclusivity that biologics get is orphan drug exclusivity, and we have proposed and we would encourage FDA to support legislation that amends FDAMA so that orphan products, regardless of whether they are drugs or biologics, are equally eligible under the same circumstances for six-month exclusivity extensions .

Thank you.

(Applause.)

MR . ELENGOLD: Just for the record, in case you didn't notice, we're skipping the break.

Let's do questions.

MS . FAIRFIELD: Oh, you want to do questions? Okay . After questions and answers, we're really running late, so what we'll do is break for lunch. And then the last two speakers, Ms . Lopez and Ms. Jones , we'll have present after

the satellite downlink.

MR. ELENGOLD: I really am sorry I had to cut you, Lisa, but just for the record, CBER has many -- not many -- yes, many approved new drug applications. A product that has been in the news quite recently, avicerokylese (sic), is regulated as a new drug application, not a license. A lot of the plasma expanders are regulated as NDAs. So we use all of the available tools under the FDAC Act. We have drugs, we have biologics, we have PMAs, and a 510(K)S. So CBER has used every bit of the flexibility given us by the Act to affect the right products.

MS. RAINES: Has CDER? I guess I should have been more specific.

MR. ELENGOLD: Let me put it this way. I worked there twelve years, and I don't remember anything other than new drug applications, the abbreviated new drug applications, Form 5s and Form 6s, which don't exist anymore.

MS. RAINES: I should have been more specific.

MR. ELENGOLD: Okay, I just have a couple of

questions. John, do you have any questions?

MR. MARZILLI: I'm all set.

MR. ELENGOLD: Okay, I just have a couple of questions for Janice. One of the things you had on your list was to use closed advisory committees. How do you think that impacts on the requirements we're under under the Federal Advisory Committee Act?

MS. BOURQUE: In terms of making it an open public forum?

MR. ELENGOLD: Yes.

MS. BOURQUE: I know that when I reviewed the description of how that was going to be conducted, I think we'll have to think about how we can do this. It's really challenging, I think, for our industry, where it's open to large groups of individuals that we think don't lend any kind of benefit to the meeting itself, but I know it's challenging. You want to have an open forum with people; there's nothing hidden. And at the same time, there are some real challenges as to why are the people there that are there?

MR. ELENGOLD: Yes, I've worked for FDA long enough to remember the point in the early '80s

where the advisory committees changed from being virtually empty rooms to lots of guys with at that time briefcase-size cell phones. You know, I remember that change. And I know somebody mutters something, and we've actually had to clear rooms because there were so many cell phones ringing.

But it is a challenge. It is a requirement that we're under under the law, and what I did last year, and 1'11 request it again, where people make suggestions like that, where it appears to go against the legal advice we have been given by our counsel, is say that we'd be happy, if you want to have your counsel prepare, you know, a justification and reason for that, that we can present to our lawyers and committee management people. That , we can do. But absent that, I'm afraid, you know, that's one where we're stuck with living with the law. We're not only the law enforcers. We're the recipients of law enforcement.

MS . BOURQUE: Right, and I think we'd be willing to pursue that.

MR . ELENGOLD: I personally have been sued

by Sid Wolf for closing an advisory committee, so. . .

MS. RAINES: Yes, if I can just add to that, I think you're correct about the Advisory Committee Act requiring open meetings. However, proprietary information can be discussed in executive session and is discussed by panels in executive session. And the law provides that our applications are confidential information, including the data therein. And I think that there is a way. Maybe you don't even call it an Advisory Panel. Maybe you call it a meeting of consultants. But there are mechanisms like the executive session --

MR. ELENGOLD: Meeting of consultants is defined as a Advisory Committee by FACA. See, that's the problem, but I don't want to get into a lot of it, but I'm just saying, you know, we'd be willing to consider it. And in fact, last year after one of the things that FARMA brought up at the 406(B) meeting, they did provide us with a legal justification, and we have changed some policies. So I'm just going to point that out.

On the training issue, we have been working with large groups over the years. One of the problems we had is when we cosponsor with a group, generally we're required to make that open to anyone. And I'm just wondering if you have a problem if we cosponsor something with you, that we would have, you know, everybody flying in from the West Coast as well.

MS. BOURQUE: No. I mean, no, no.

MR. ELENGOLD: Well, 1'11 invite you or anybody else that's interested to get in contact with Gail and work that out.

And, finally, we'd be willing, under some changes made in the department policy, we can now go into partnership agreements for those kinds of things, even with specific regulating company. And we have exercised that, and we encourage you to do that.

Jim, the risk/benefit communications, I have two questions for you on that.

MR. WESTON: Sure.

MR. ELENGOLD: The first one is, we agree that that's a very important thing that FDA should be doing. The problem is, when we're

competing for resources -- and in my old job as Director of the Communications office, I was constantly fighting for resources to do that. Everybody has a simple answer: "Put it on the Web, put it on the Web, put it on the Web." And having, you know, one person in our office who's responsible for both our inter- and our intranet -- in fact, we just doubled our staff to two -- does the industry believe that would be a cost that is either acceptable under PDUFA or that a PDUFA amendment or agreement could be made so that PDUFA resources could be used for that? Because as I showed in that slide, the non-PDUFA resources is that little blue box.

MR. WESTON: In response to that, I think that's something we could certainly consider. I think in the past couple of years, we've all seen the validity of the Internet being a communications tool, and particularly a two-way communications tool, and I think that's something we could take a look at, yes.

MR. ELENGOLD: Okay, so that's that. And given the priorities that we're all faced with making people in companies as well as the FDA,

where do you think that putting that effort is in priority to some of the other tasks we have?

MR. WESTON: I think it has a relatively high priority, but I wouldn't necessarily put it above, you know, the approval process. Obviously that's where you --

MR. ELENGOLD: But you would put it slightly above enforcement actions, right?

(Laughter.)

MR. WESTON: I don't think I dare to comment.

MR. ELENGOLD: Okay, that's another thing. You know, since you've made the suggestion, either to the docket or, you know, just in a communication to us you could address, we'd appreciate that.

MR. WESTON: We'd be glad to do that. It's the type of thing which I think we'd be willing to look at as part of a partnership too. It's the type of thing where you don't have to necessarily share the entire burden. It's the type of thing which, with the industry or the industry groups, a partnership could be formed because we both came to see the values of these

group .

MR . ELENGOLD: John, do you have any questions?

MR . MARZILLI: No. I was just going to add, in terms of any of the training and cooperative efforts with Mass. Biotech, surely call the District Office and you can discuss things with us, and coordinate with Gail and the folks in Mark's office as well. So you know we're always available.

MS . BOURQUE: Great, and, I mean, in terms of what those presentations will look like, what the science ought to be, I think surely that we just need to sit down and say: What are the areas the reviewers are interested in? What are the areas the industry thinks we should do some more work on? And like I said, finding a site, and this is one facility that I think is a natural, but we can explore that further with UMass. And I think it would be received well from both sides. It's very exciting for us to be able to do something like that.

MR . ELENGOLD: Steve, do you have anything?

MR . MASIELO: No.

MR. ELENGOLD: Okay, does anybody in the audience have any questions for these speakers?

One thing, as we go through this, if you either ask a question or later when we get to the open part, if you make a statement, state your name, who you represent, if anybody. And after you speak, at some point, either on a break or afterward, go over to the Reporter over there and give her a card or identify yourself, because we are transcribing this, and that way it will appear correctly in the record.

MR. PIGNATO: Yes, my name is Bill Pignato. I'm with -- the new name now of my company is Bayer Diagnostics, and we manufacture a wide variety of in vitro diagnostics, some of which have had to go before CBER, and our experience with CBER has always been a lot more frustrating than those of CDRH. So I'm certainly encouraged by the initiative of the Device Action Plan, and I'd like to offer a couple of suggestions. And that is, I notice that part of the activity with the Device Action Plan is the development of a number of guidance documents, and I'd like to suggest a different approach in terms of

development of the guidance documents. That is, the experience that I have had with CDRH in participating in the development of a couple of their documents, in fact, a modification document, the working document, and that is that forming working groups in the development of these guidance documents as opposed to the traditional approach of issuing the guidance document and asking for comments.

I think that those participants, myself and other people that participated in these working groups with FDA, I think that both parties, both FDA and the industry, were both satisfied with the outcomes in the final product; and I would clearly encourage the agency to give that consideration as well.

MR. ELENGOLD: As some here know, we've actually had meetings with the HIMA Board and the Device folks, and I guess Carolyn will get to some of that when she speaks.

Anyone else, questions for this panel? Yes, sir?

MR. SCHUBERT: Thank you. My name is Dave Schubert. I'm with Genzyme Corporation. I'd

like you to comment on a question that Lisa asked with respect to the Intercenter training on the fast track and accelerated approval process, and where is CBER on that continuum?

MR. ELENGOLD: Gail? Yes, we have not started our training on that. It is going to be a module in the revised reviewer training. We have coordinated with CDER as much as we could. They are, you know, on their own initiative doing things. We get the materials. We try and leverage it. Quite frankly, with the device interest right now, we have been concentrating our joint reviewer training with CDRH. But we have talked to Nancy and some of the folks over there, and we would like to leverage it. But right now, we are in the process of completely redoing our reviewer training, and that's why the suggestion on working with Mass. Biotech is so interesting to us, because it does provide us with a current opportunity. But that is something that's interesting, and we'll put it in the record and we'll look at it.

Carolyn? You're talking. You can't ask any questions.

MS. JONES: I think it's an interesting concept that Mass. Bio discussed about the reviewer training; but coming from a broader perspective than just a regional trade association, I think it's also important that if you consider that, that there may be issues from biotech companies in California that may not be appropriately totally addressed in anything that's done in a regional setting. So I would say that if you're going to do anything that involves reviewer training where, you know, that might impact companies that aren't going to be present or in the development of that process, that you consider making it a broad training --

MR. ELENGOLD: That was the purpose of my question.

MS. JONES: Oh, I missed it.

MR. ELENGOLD: Yes, I'm sorry, Carolyn. I asked that. I said, would it be expected to be a regional thing? Because generally when we have partnerships, we put them in the Federal Register, and quite frequently people come from all over, in fact, all over the world, to do that.

MS. JONES: One other question for you, Mark. You talked about budgetary constraints on travel and so on. How would traveling around the country to training programs like that, how would FDA review staff handle that?

MR. ELENGOLD: Well, we have two options. The most common option is: We pay for it out of our appropriated funds. It is possible, if a sponsoring group is a group that is eligible for what we call 348 cash-in-kind reimbursement, that we could allow the group.

Now, several of the groups -- we have just been working with the Commissioner's office and the Department and have gotten those types of groups extended. It pretty much used to be universities and certain groups that had no membership of companies but only individuals. We've gotten that changed a little bit; and in fact to accommodate that, the PDA has changed their charter to eliminate company memberships so they will qualify. So if an organization like DIA was the sponsor, DIA could provide reimbursement to the government. The way it works is: We cut the travel letter. We turn our

voucher into the FDA, and the FDA then sends a bill to the eligible group.

And so that would be the mechanism, but, for example, that would not be available to Mass. Biotech. It would be if DIA or the Parental Drug Association or RAPS, I think RAPS is eligible now, Regulatory Affairs Professionals.

So that is one avenue, but again we think the importance is such that we have done a fair amount of allocating travel funds to that. In fact, one of the things we did in CBER this year is, we imposed a percentage travel cut over last year's, and we have that as a reserve fund so it's available so that we in the Director's office can fund travel to important meetings where our message is getting out, and we're hearing what industry folks in academia and industry are telling us.

MS. JONES: One final question. Regarding the issue of disseminating information to the public on risks, in your response or in your question, you asked whether PDUFA funds or the priority that MBC would attach to that, Is that an area where the agency would be willing to use

the CRADA concept to allow industry to contribute to it to disseminate the appropriate information if it's not already budgeted for?

MR. ELENGOLD: That's something that I was the pet transfer CRADA person for CBER in my last life, so I guess I have a fair amount of knowledge about that. It's an issue I hadn't ever really thought about, Carolyn. And again 1'11 say the same thing I've said, that anybody who would like to propose such a new mechanism, give us the proposal, the legal background from your counsel's viewpoint, and either submit it to the record or just in a communication to us, and we'll consider it and get back to you or answer it for the record, either way. That's an interesting concept.

MR. MARZILLI: Lisa Lopez, okay, Lisa, the microphone .

MS. LOPEZ: Lisa Lopez, Vice President and General Counsel of Haemonetics Corporation, and I am on the program later this afternoon. And I apologize, I'm not going to be able to stay. I have a flight.

MR. ELENGOLD: Okay, I tell you what. We

will let you do your presentation right now.

MS. LOPEZ: Well, I have the remarks that I've left. I did, however, want to ask a question about something that you've said earlier. I know that you're on a tight deadline.

MR. ELENGOLD: No, that's okay, that's okay.

MS. LOPEZ: You mentioned, Mark, that two years ago there was a crisis of confidence in the blood supply that gave the FDA a real sense of urgency to jump start very, very quick decisions. And my question is that certainly many of us in industry perceive that there is a similar seriousness. I wouldn't characterize it necessarily as a crisis of confidence, but whether it be CJD or EEHP or a proliferation of donor, you know, all of the above, there is the same very strong sense of seriousness attached to issues of blood that we believe give us a great sense of urgency to direct our engineers and our scientists to act quickly, to innovate, to create very, very quickly. And I'm hoping that you will say that the FDA sees the same kind of sense of urgency to make quick decisions. I mean, do you think that we're still in that same similar

period of time that requires of the agency the same sense of urgency that you referred to a couple of years ago?

MR. ELENGOLD: Well, if you look at Dr. Henney's priorities for the FDA -- I don't have the list in front of me right here but it's in your pact -- I believe the safety and confidence of the public in the blood supply is one of the five. And therefore we have as our marching orders in implementing the Commissioner's priority anything we can do to increase the safety of and the public confidence in the blood supply. That is one of the major driving forces for the Device Action Plan because we believe that better tests and better devices for processing blood lead to better safety and more confidence. So, yes, that is one of our goals, and it is right on the radar screen.

MS. LOPEZ: And my only comment there would be: We would certainly like to see added to that safety and availability of blood.

MR. ELENGOLD: Yes, well, that's -- you know, I don't go home one night without hearing a donor request on the radio. And on the NIH

campus where our office is, there's also a sign when you pull in of what type of blood the bank needs. So we're very aware of that, and the availability of blood products is a major concern to us. There's a chronic GG shortage. There's, you know, chronic shortages of component blood, and we realize that the equipment used to process it and the devices used to test it are important .

Are you sure you don't want to just take five minutes and summarize your --

MS. LOPEZ: I don't know that I'd be able to do so.

MR. MARZILLI: Lisa, are there any comments you want to come up and make?

MR. ELENGOLD: Yes, I feel bad about that. Time is not a problem. We'll just cut it out of everybody's lunch. I mean, we're only going up stairs. It's just that we want to make sure people have enough time to take care of their needs, make their phone calls, return the pages they've got.

MS. LOPEZ: I apologize. I was directed to actually have prepared written comments. I don't

usually speak this way, but I'll do my best to summarize. As I mentioned, I do represent Haemonetics Corporation. We're a medical device company born in Boston over twenty-five years ago. We're now global with customers throughout the United States, Europe, and Asia, but our headquarters is here, a landmark on Route 128 in Braintree right up the road.

Haemonetics has always been associated with invention and innovation, pioneering the collection of specific blood components from healthy donors in the '70s and the '80s, pioneering blood salvage and reinfusion for patients in hospital operating rooms, and most recently we introduced a system for the safe collection of two units of red cells for transfusion from a single donor. This advance will, in our view, improve both the availability and the safety of transfusion medicine practices.

Haemonetics is grateful for this opportunity to talk with CBER's leadership. We are profoundly encouraged by the responses FDA has made to FDAMA. We believe that the benefits of

these fundamental changes and the way that FDA interacts with industry will reap benefits for the agency, for industry, and most important, to all of us in this room today, the public.

The questions posed to this meeting center around the challenging environment that we in industry share with the FDA, and that's one of unavoidable risk and imperfect science, one where the pressures of cost containment, competition, and technology are fundamentally altering the architecture of our blood products delivery systems.

Now, in addition to sharing environmental challenges, we also share a public that is quick to find fault and slow to forgive; and perhaps because of these mutual challenges, industry and FDA are motivated by many of the same goals: Number one, the desire to make devices as safe as possible for patients, donors, and operators. Number two, the need to make sure that our products meet customers needs and expectations. Number three, genuinely, the desire to make the world a better place. And that is FDA and industry's mutual goal. And, number four, the

need to improve operations by adopting what I think we're all comfortable calling so-called "best practices" to meet, in industry's case, the expectations of our shareholders, and in FDA's case, the expectations of its stakeholders.

These shared goals are too often overlooked by the media and external constituencies that we also share, patients and their families, blood oversight bodies and other arms of federal and state governments. Because we have shared constituencies, we will improve our communications with them if we send a consistent message, one that says we are doing the best that we can. But we are not perfect. We must be prepared to say that we're sorry when we make a mistake and avoid setting unrealistic zero-risk expectations for our products and services.

Because several of the questions for this meeting involve FDA's responsibilities throughout a Product's life cycle, I would like to spend just a few moments and explain the unique environment in which Haemonetics operates in the United States with our licensed blood and plasma

customers. The bullets after Premarket Clearance list the channels of communication with the FDA that already exist for Haemonetics and our customers during a product's life cycle. The information gathered via these mechanisms provide an important resource for scientific staff involved in risk-based decision making.

Parenthetically, we hope that the information is available to the scientists who could benefit from this exposure, and not just limited to the administrative staff charged with reaching a review and the gathering of these statistics.

Before leaving this slide, however, I would like to mention the two-tiered premarket approval process that exists for Haemonetics and our licensed blood plasmal customers because it's unique in the U.S. public health regulatory scheme, and I think in most of the world. Although device or drug manufacturers in other medical fields need only obtain premarket clearance to introduce their products in the United States, this scheme applies to Haemonetics only insofar as our sale of instruments to

unlicensed customers; for example, a hospital customer. But the use of this same -- same -- identical instrument to an unlicensed customer that we sell to a licensed blood or plasma facility is routinely sowed with a second application review, inspection, and approval process. This means that even after a 51O(K) review process, which can take up to several years for a device, and longer for NDA review of a new anticoagulant or a storage solution, there is a further delay for a year or more for implementation of the new technologies by licensed users. This translates to up to three years between the time the new technology has completed the R and D cycle and the time it may be utilized by users.

We spoke of this a moment ago, but in balancing the public policy considerations of regulating blood in the world we share after AIDS, we almost acknowledge that the risk of indecision or and an unduly delayed decision may be just as dangerous to the public health as a poor decision. And certainly I think all of us in industry would agree with Mark, your remarks,

that a poor product is not one for which we want to expedite approval. But given the worldwide need for safer, higher quality, and sufficiently available blood products, industry must be encouraged to direct all of its resources to be more innovative, to be more creative, to be less constrained by conventional approaches to product design. But for these efforts to result in the kinds of extraordinary public health improvements demanded by the public's sense of urgency about blood safety and availability, they must be coupled with less burdensome paths to regulatory approval .

A good example, we believe, was the less burdensome approaches for blood testing which were used very successfully by CBER when it was recognized that the public's urgency for improvements demanded no less. And, similarly, less burdensome approaches for blood collection equipment users could save FDA what we've spoken about today are admittedly very scarce resources without compromising public health.

I think we need to remember that in our case, automated blood collection devices have had

a good track record for twenty-five years. That gives FDA a good basis to make informed decisions.

Haemonetics would welcome the opportunity to communicate with FDA scientists in a less formal manner outside the context of application review, inspections, or enforcement actions. We would be willing to host scientific visitors from the FDA or come to FDA to demonstrate our technologies and to assist in general training and exchange of ideas and expertise.

In addition to improving the scientific knowledge base upon which FDA's decisions are made, we believe that this interaction would prevent misunderstandings, reduce the number of cycles during application review, and foster a more constructive climate for problem-solving. I think these sentiments echo what you've heard from several other speakers. We are genuinely interested in sharing our technology so that FDA staff, whether they be reviewers or enforcement, have hands-on opportunities to really understand the technology out of the context in which there is some question about enforcement or

compliance.

FDA's efforts toward harmonization with regulatory authorities in other countries have been encouraging to us, and we hope that they will continue until a -- you know, let's think about this -- single dossier is accepted worldwide. That would be truly extraordinary, and we think that it is possible to do that.

Signs of the internal harmonization that have been referred to this morning between CDRH and CBER, as exhibited by the CBER Device Action Plan and what I picked up on the Internet Monday and the Federal Register, are also very, very encouraging .

It's also been gratifying to see the comments from the stakeholders meeting last fall now being introduced into working groups at CBER . Everyone inevitably will benefit from these plans.

We spoke or I spoke earlier about the layers of regulation. While it may not be possible to eliminate totally the redundancies in premarket clearance for blood technologies and the blood products they manufacture, FDA could make some

approval routes less burdensome for itself and industry by reexamining traditional approaches to regulation, with an eye toward integrating some premarket approval processes and streamlining data submission requirements where the risk is low and the track records have been established.

Third-party reviews are being used by CDRH, but to the best of our knowledge, have not been tried in the blood devices sector, and we think that they could be.

Finally, thank you very much, FDA, for beginning to move away from the zero risk rhetoric . Particularly for those of us in the blood sector, what I think we remember as a decision paralysis resulting from those years is just beginning to subside, and now it's just decision anxiety for all of us. We think that's a little bit easier to deal with. But perhaps now we can move forward to educate the public and other external constituencies about patient decision making and risk acceptance.

In this light, prompting media stories about risk, even TV show story lines, as is being planned for the Hepatitis C campaign, would reap

benefits. But these efforts must be ongoing, and maybe with ongoing efforts, we'll get through to the physicians and, an even tougher act, to the lawyers.

In conclusion, thanks for this opportunity to speak today and for the improved communications that we've seen on the Internet, Again, I echo the comments of others. That's a tool that we all utilize daily, and we applaud you for being a leader in that area.

Thank you very much.

(Applause.)

MR. MARZILLI: Okay, thank you very much, folks. I've got a caterer who's been hounding my heels, so if you'd please exit, and people will escort you immediately to the 14th floor for where lunch is being served.

(Noon recess.)

(Satellite Teleconference.)

MR. ELENGOLD: We appreciate everybody coming, and, again, what we had done was figured that we could put any slippage, not that we really anticipated any, in on this end and finish up. And the last speaker we have, and then we'll

open up the floor for questions and comments, is Carolyn Wilson from HIMA.

What did I just say? What did I say? I'm sorry. I'm having a real rough day. Anyway, Carolyn is here for HIMA. They are at two of our meetings and somebody there. That shows the way that devices are intrusive into everything we do.

Anyway, Carolyn is a former FDA CBER employee, so that's why we're glad she's here.

MS. JONES: Thanks, Mark. It's often hard to be sort of the last speaker of the day, so I have been sitting there trying to pare down my comments so that I won't hold you here longer than necessary.

I want to thank FDA for the opportunity to comment on the progress in implementing FDAMA. And I'm not going to go into the usual spiel about who HIMA is and what we do and all of that. Needless to say, we represent the medical device industry, a large portion of it, and for a number of our companies, CBER issues are very important.

Today FDA is faced with several challenges.

It is charged with implementing a complex and demanding statute. It also wields enormous economic power over a substantial portion of the marketplace. Public expectation of the agency's ability to provide the most technologically advanced products risk-free and immediately can be unrealistic, and the agency is under constant scrutiny by Congress, the public, and we, the stakeholders.

And Mark reminded me this morning in his presentation that CBER is faced with an additional challenge because the products that it regulates sort of cross all center bounds. They regulate products that would be considered drugs as well as devices and traditional biologics.

I have some overall general comments that apply not specifically to CBER but just to the agency in general. We feel that faced with shrinking resources, increased statutory obligations, and public expectations, we recommend that the agency devote its resources to its core statutory obligations. It needs to focus resources on the highest risk products. It needs to maximize the tools provided by FDAMA.

It needs to continue to seek improvements through re-engineering and management initiatives. It needs to leverage its resources in both the public and private sector. It needs to cease activities that are not essential to carrying out the law, and to seek additional resources from Congress to address the ever-increasing number of issues it needs to deal with, particularly from our perspective, device reviews.

We have some ongoing general concerns, and then I'm going to specifically answer the questions that FDA posed in its March Federal Register notices.

While the majority of the devices are regulated by CDRH, there have been a number of devices that are regulated by CBER. The device provisions of FDAMA apply to those products as well. Not surprisingly, industry's ongoing concerns with device reviews conducted by CBER don't differ significantly from the concerns we express with the products reviewed by CDRH.

Product review times top the list of concerns for manufacturers. Until very recently, because CBER's focus is not primarily devices,

little attention had been paid to medical devices industry's concerns about the ever-increasing product backlogs.

Changes are in progress. Mark talked today about the Device Action Plan, and a number of you probably picked up copies of it off the back table. We are really happy to note that the concerns expressed at earlier stakeholders meetings as well as the December Device Action Plan meeting were taken to heart, and FDA has put this Device Action Plan in place. We think it's long overdue and needed to address a broad range of device industry concerns, and we look forward to reading it and providing comments to the agency, and probably meeting with them to discuss our particular concerns with the plan.

One of the things before we knew that the plan was going to be issued, we had a concern about the input provided into developing a plan. We wanted to remind CBER of a necessity to communicate, collaborate, and consult with the stakeholders in the development of the plan and with the plan's implementation. We feel it's a challenge for CBER to involve industry as a

partner in the development and implementation, and part of that challenge will be for CBER to think beyond its traditional ways of doing things and allow the stakeholders, both in industry and the blood banking community, to help CBER set realistic science-based goals for its device-related functions.

One of the questions put by one of my co-workers had to do with product development times, and I'm not going to go through the aspects of the FDAMA regulations that address product development times, but needless to say, product development times are an important issue for the device industry. As review times go down at CDRH, the product development times go up. We don't want to see the same thing happen at CBER.

We have put together what we call a Least Burdensome Industry Task Force and sent some proposals to CDRH on how we feel that least burdensome issues should be addressed, and we urge the agency to consider these proposals, but we also urge CBER to be involved in that process. CBER needs to insure that its reviewers are adequately trained to make appropriate use of

the least burdensome concept.

One of the things that we found in trying to gather information from our industry constituents is that a complaint has been that CBER asks for extensive studies when other less burdensome studies could demonstrate the same safety and effectiveness. This often discourages manufacturers, who will often develop and market products that could improve the safety of the nation's blood supply, to market these products outside of the U.S.

Again, we recommend that CBER participate in any meetings that the Device Center has with the industry to work out issues related to least burdensome .

Although long product review times remain the issue of primary concern, manufacturers also note an apparent disconnect between what manufacturers submit or what they think CBER wants in the product submissions and what CBER actually wants in the submissions. And I'm going to explain a little bit by saying, the example we have been given in-house is that after waiting about six months to receive the first round of

questions on a submission, on average, it will take a manufacturer three to six months to respond to CBER's queries.

In our discussions, we found that CBER believes the problem was based on poor product submissions, and that's not borne out by the fact that CBER has refused to file any of these things or anything of that nature. So we sort of think it's based in the idea that maybe there's a lack of guidance out there on CBER's expectations of industry. And so we need to, as industry, to work with CBER to develop guidance so it's very clear on both our parts what's going to be expected and what's going to be the outcome. If CBER is looking for A and we give them B, of course we're not giving them what they need, so we need to be on the same page.

Any good plan, one of the things that we talked about in our industry groups, needs some way to measure progress. Traditionally industry has measured FDA progress from origin product review time. Complete timely data on CBER review times is generally not available. CBER should publish its review time metrics on a regular

basis to provide the agency and the industry a yardstick to gauge the progress made. And I was listening to Mark's presentation this morning, and he was talking about how you routinely have those meetings internally to see where the reviews are in-house and, you know, give suggestions to the various divisions on how to improve that process. We'd like to have some access to those review times quarterly, every six months , but some kind of metric so that we know how we're doing and how you're doing.

Now, with respect to the specific questions that CBER asked, we will be submitting comments to the docket, a combined set of responses, because we don't think the answers to these questions significantly differ whether you're talking to a CBER audience or whether you're talking to a CDRH audience, so there will be comments submitted to the docket.

On the issue of the capacity or capability to incorporate state-of-the-art science into its risk-based decision making, we think one of the issues this question raises as a general matter is the need for FDA to be vigilant in insuring

that it is incorporating the appropriate level of science in its decision-making processes. For instance, the regulatory requirements for a PMA approval incorporate a reasonable assurance of safety and effectiveness standard, not an absolute assurance of safety and effectiveness. FDA must insure that whatever quantum of science it applies to its decision making, it must be within the regulatory construct of the law. Scientifically based conclusions must represent a balance between risks to the public and benefits to the public.

In addition, as a government agency there will always be a financial constraint on FDA's ability to hire experts. The agency will seldom be able to compete with the resources of academia or industry. However, the key to incorporating state-of-the-art science into FDA's decision-making process lies in the ability of its reviewers to understand data, interpret results, and ask appropriate questions. FDA should focus on developing and cultivating these skills in its reviewers.

Some of the recommendations we're going to

make were addressed in Dr. Henney's presentation, and I was encouraged by that. The specific recommendations we have in those areas consist of: FDA should leverage the industry resources, company tutorials, vendor days, cosponsored educational workshops, et cetera. HIMA proposes that FDA take advantage of industry resources to expand its own scientific knowledge.

Dr. Henney addressed the issue of vendor days. Most of the vendor days that we've helped work on have been directed toward CDRH. We would like to see a vendor day that's directed toward CBER, and we would be willing to work with the CBER in the same way we've worked with CDRH to come and set up a vendor day so that your review staff can actually see the technology that they review. It's important to understand that FDA's review is a paper review; and in a non-confrontational environment of a vendor day when you get to talk to the company, you're not reviewing product, it's a relaxed environment, I think the CBER staff would benefit greatly from that interaction.

We recommend the cosponsored educational

workshops be another vehicle for dissemination of information, and we at HIMA are working with the agency to develop CRADAS to fund such workshops.

We also agree with Dr. Henney that outside experts, government agencies, academia, the private sector, and even the scientific advisory committees, could be used to help build your science base. You know, again, due to the budgetary constrictions, you are not going to be able to compete with industry to obtain the disciplines that you need to do your product reviews . FDA needs to strengthen its use and relationships with its sister organizations, such as the NIH, NSF, and the other organizations that have a scientific base or laboratories and so on to help it through this process.

We should also find ways of using consultants and contracting outside the agency to bring in the scientific expertise,

We also looked at your conflict of interest policy. We think the current conflict of interest policy prevents FDA from gaining the input from the private sector or using those resources in a way, and we think that FDA should

sort of consider reevaluating the conflict of interest policy to provide a little greater flexibility in your use of outside entities to help you build that science base.

We also agree that continuing education is important for your medical staff, for your scientific reviewers; that FDA should at least encourage, if not require, scientists to keep current in the field by taking advantage of seminars or other educational opportunities.

One of the other things that we think in industry that we can do is to make use of the collaborative meetings, to make that a learning tool as well, to bring the important people, the experts, the statisticians to these meetings so that these meetings can be productive and provide additional information on the way technology is moving with regard to a particular company submission. Oftentimes I'm hearing from the FDA, and even from industry, that these meetings aren't always as productive as they could be. I think industry needs to take part of the gauntlet here and provide and bring the appropriate people to those meetings, too, so that FDA can learn and

have a correct interaction in those up-front meetings.

Another opportunity for FDA to gain the scientific knowledge that it needs is standards development activities. Many scientific experts, including some of FDA's own experts, are involved in developing standards, and it's a really good opportunity for groups to get together their FDA base, their academic base, or their industry base to debate issues in the development of standards . And I think that brings out a lot of information on the technologies that are being addressed, that FDA also has another opportunity for a learning experience there. We would recommend both industry and FDA continue to participate in standards development opportunities .

As for question two, what actions do we propose to continue the exchange of information throughout a product's life cycle? This question first asks for ways to improve FDA's access to scientific information. We think the access to scientific information, that issue was addressed in that first question, and we've already listed

out a number of ways you can approach that.

I was glad to hear Dr. Henney mention the use of FDA staff, college and training institutions, as an additional mechanism for keeping abreast of what's going on. We recommend that the agency adopt, if it hasn't already done so, something that' s used in the industry which is called "train the trainer. " Industry, too, has financial constraints often, and they send people to training seminars and standards development activities, and that individual has the responsibility to go back and train the folks who weren't able to attend the meeting, to relay the information that was obtained. FDA needs to make use of that if there are still constraints on traveling to meetings and to different functions.

Also, information on product life cycles, manufacturers and companies have annual reports. That's a way of continually tracking information on products and so on. There are more specific recommendations in our written comments. I don't want to keep you here any longer than necessary.

The issue of educating the public on the

concept of risk, consumers are increasingly becoming better educated about their own health and their personal medical problems. The availability of the Internet resources can result in patients having sometimes more information than their physicians about a particular device or drug or whatever. This creates a demand in the marketplace for additional information by both consumers and physicians, a demand that will largely be met by the marketplace and not a government agency like FDA.

There's no magic bullet that will fully educate the public about how to balance risks and benefits. For CBER, this is particularly difficult because some consumers believe that products, including the nation's blood supply, should be completely risk-free. FDA can play a useful role in educating the public generally about the risks and benefits of the product it regulates and about continuing efforts to reduce those risks. FDA can also work with the medical community to discuss ways of adequately informing patients about the risks and benefits of the products that they proscribe.

Another opportunity for FDA, and I guess industry as well, to provide information to patients about the risks are the use of the various Web sites, and that also is resource-intensive , but, again, that's not a burden FDA must bear alone. Companies also have a responsibility to put important information on their Web sites, or at least FDA could possibly link to some of the company Web sites so that they don't have to provide the information.

How to focus resources on the areas of greatest risk to public health? CBER should continue to implement the tools of FDAMA and to adopt, where appropriate, CDRH's re-engineering tools. We think this will free up some of your resources. This includes taking a critical look at ways to expand the list of recognized standards and increase their use by industry, to make optimal use of early collaboration meetings, and to harmonize the regulatory requirements. In perusing your Device Action Plan, these are some of the same things that the plan addresses, and we're glad to see that.

As far as training, industry training,

education and communication, in order to maximize the tools at FDAMA and to create the most efficient system possible, FDA staff must be adequately trained in their application. It's not enough for Linda to sit in a stakeholders meeting and outline what's contained in FDAMA. Your front-line reviewers, your inspectional staff, the district offices, need to be thoroughly versed in what's contained in FDAMA and how it should be applied. The industry must also be educated on the tools available as well as the agency expectations.

We also look at focusing resources. We've all got to in belt-tightening situations eliminate unnecessary or redundant functions. FDA should closely examine all of its functions and determine which are not essential to carrying out its core statutory obligations. FDA should look to rid itself of all but absolutely necessary functions mandated by law.

On the inspectional side, HIMA has participated in several initiatives to improve FDA's device functions. Those comments or testimony with regard to those initiatives are

included in our written comments, and we think that CBER should review those comments and look to see what aspects of those initiatives can be adopted by CBER to enhance its inspectional program as well.

On Question 5, enhancing the communication process and allowing ongoing feedback, the statute uses the term "consultation" in connection with FDA's 406(B) obligation. This means more than just listening or reading comments . If Congress had intended the FDA to only seek public comments, it would have said so. Webster defines "consultation" as "Meeting to discuss, decide, or plan." Discussions, decision making, and planning all involve brainstorming and a give-and-take kind of activity. We urge the agency to engage in consultation with its stakeholders that may be more meaningful and productive than the type of consultation exemplified by most of the meetings that we've had with the agency.

The other thing that the agency can do is that -- 1 know HIMA has commented extensively on the regulations, notices, and guidance documents

developed by CDRH to implement FDAMA. It's unclear on our part what input CBER has actually had in the development of a number of these documents, and we'd like to know what your input has been. But the problem is, in some cases it appears that our comments go unacknowledged. While we do not expect that all of our comments would be adopted, we do believe, especially on key issues, the process would benefit from a true dialogue with industry and other interested parties. A true dialogue is especially important when there are documents, from CBER's perspective, that they may be reluctant to adopt. It is important for industry to understand the basis for CBER's reluctance to adopt specific documents.

And, again, that goes back to the point: If we had a true consultation, a true dialogue, each of us would know up-front why there's a reluctance. But because of the process that's used currently, we don't.

The one thing that we've done at HIMA -- and at some point, Mark, when we have future discussions on CBER'S Device Action Plan, we'd

like to be able to share this information -- we sent out a questionnaire to our member companies on their experiences with FDAMA, and we're in the process of collecting those surveys and collating the data. And, again, we will share the results of this questionnaire with the agency, and particularly we want to share the specific questions related to CBER with the CBER folks.

In conclusion, we want to thank the agency for this opportunity to provide our ideas and our comments. We look forward to working with CBER to implement the appropriate provisions of FDAMA, to utilize the relevant CDRH re-engineering initiatives, to develop and implement the Device Action Plan that appropriately focuses CBER'S device-related functions, so that together we can eliminate the product review backlog and significantly reduce product review times.

MR. ELENGOLD: Thank you. I've got a couple questions.

MS. JONES: Sure.

MR. ELENGOLD: I've got a couple questions. One of the ways that CDRH -- and I'll be fast, too, because I know everybody wants to catch a

plane -- that one of the things CDRH did was down-classify devices. We've looked pretty hard at our inventory of regulated devices, and many of them are treating either people with fatal nontreatable diseases, like in cell separation, or in safety of the blood supply. Could you give me an example that HIMA might think might be a CBER-regulated device that would be eligible for down-classification, what we say in our vernacular as the "tongue depressor bedpan"? I remember when the device amendments were implemented in '76, a lot of things that were relatively simple were classified too high; and in down-classifying them, that's one of the ways CDRH lessened their review workload. But we've had extensive internal discussions over the years, and we, frankly, can see one or two things that might be down-classifiable; but I'm sure that HIMA has had the same discussion. Do yOU have any ideas on that?

MS. JONES: Honestly, we haven't had the discussion about the list of products that could be down-classified. That is a discussion that we can have with our CBER steering committee. We do

feel -- I guess in Lisa Lopez's presentation, she talked about some of the products that you've had extensive experience with in triaging your reviews that may not get to the level of actual down-classification, but the amount of time and effort spent in the review of the products that you have had extensive experience may be lessened.

We realize CBER's discomfort with down-classification of instrumentation associated with some of the IVDS and so on; whereas CDRH has down-classified or exempted, really, the instrumentation . And in discussions with Dr. Epstein and his staff, we realized their discomfort with that, and --

MR . ELENGOLD: You have to keep in mind that I've spent the past ten years dealing with four different oversight committees on the safety of the blood supply. The Secretary of the Department of Health and Human Services has publicly stated that the safety of the blood supply is one of her priorities, and Dr. Henney gave it to you as three or four, depending on how you count today. And something as simple as

recently a filter that's been in use for many years, an acceptable manufacturing change was made that led to severe adverse reactions across the country. So we've got to keep in mind --

MS. JONES: But you reviewed that product, didn't you?

MR. ELENGOLD: Yes.

MS. JONES: And it didn't stop that?

MR. ELENGOLD: Yes, that's right, that's right. And that's the problem. So maybe we need more controls and extensive clinical trials before allowing manufacturing changes. I'm just giving you the questions that we get on those issues,

MS. JONES: I understand, I understand, but --

MR. ELENGOLD: And we have to strike a balance.

MS. JONES: We do have to strike a balance, and we understand that you're not going to catch everything, even in an extensive premarket review.

MR. ELENGOLD: That's right, but the reality is, the public has demanded through their elected

representatives that we devote additional resources and additional controls. And that's something that FDA has to face in its life.

Let me go on. You've said we've changed our conflict of interest. That's a major concern to us. One of my previous jobs was dealing with what we like to call the "generic events."

Now, the problem as I see it and the one I've dealt with is: We go to seek an outside expert that's been to a hypothetical school like Boston University to come into our Advisory Committee as an expert, and we find out that the main expert in the field at BU has been a consultant to another company, and the conflict of interest prohibits us from doing that. Does HIMA believe that its members are willing to waive that type of conflict of interest?

MS. JONES: I think on certain levels, yes. The discussions we've had in developing our answers to the questions posed by FDA, the companies indicated that they would be, and that in certain instances, the public disclosure of that information that you have had some dealing with the company, and so on, is what we thought

was more important than waiving, you know, the company rights there. And as long as the conflict or the involvement with the company was adequately disclosed and everybody was singing from the same song sheet, that it would be appropriate.

MR. ELENGOLD: Well, perhaps we can work on a pilot on that, and when your members are bringing products to our Advisory Committees, they could suggest experts along with their agreement to waive any conflict, because everybody knows who's working on the alternative products, and I encourage HIMA to back up that with some examples and some working with us because, you know, we don't invent the ethics laws or the conflict of interest requirements. For the main, they are either imposed upon us or demanded by companies to protect their own rights, and that's just another thing that I'd like to see,

Training you brought up, training the trainer. I went to train-the-trainer school in 1971 or '72 back before we had project hiring and a lot of the people here today were hired. We

have embraced that concept. The problem that we face is that every training that we do, including that type of thing, takes away from review and investigational time. And that's one of the reasons we are really interested in partnering because having our people do the training takes away even more time, and that's one of our concerns with that. We have looked at that.

And, finally, you made the comment twice that you think we should stop doing things we don't need to do. My experience over the years is: Anything someone thinks we shouldn't be doing is something that somebody else is demanding we're doing it. And the tautology of that is, you know, we don't need Consumer Affairs people, we don't need Web engineers. And yet all this morning and all last year we heard: "Put it on the Web, expand the Web, increase the Web." So I would just like, you know, as an example one function that we have in CBER that HIMA thinks we could eliminate.

MS. JONES: Mark, I did preface my comments by saying that the answers to the question may not specifically relate to CBER, that they are

answers that we think go across FDA quite broadly. We're asking your agency to be quite introspective and to look at things that it thinks, you know, that you're doing. I didn't come prepared today to list out the things that we think are totally unnecessary. I mean, I'm sure that if I got an industry group together, they could probably give me a list. But we're asking the agency to do a self-check and look at those things that you think really don't add a great deal of benefit to the process or those things that are redundant of other things that could be collapsed into one.

MR. ELENGOLD: Well, again, I'd really appreciate either a submission or an off-line conversation.

MS. JONES: Okay.

MR. ELENGOLD: Because the budget situation has really forced us into doing that. I didn't show one of the slides that I usually do show that shows we're spending 40 percent less than our laboratory function in actual dollars, not adjusted dollars, than we were four years ago. We have eliminated a lot of our management

overhead. We've cut travel just this year 25 to 30 percent. We're really interested, you know, and again, you know, in what functions industry thinks we can stop doing because we'd like to see if we can stop doing them. But the rhetoric of just, you know, "There are things you can stop doing," we think we've stopped, at least in CBER. And I think Dr. Henney's proposed reorganization of the Commissioner's office, which is eliminating overhead and redundant things there, has also gone a long way to doing that. So I'd really be interested.

MS. JONES: I think part of the problem, Mark, as you've seen at earlier stakeholders meetings, is the issue of transparency that you stressed in your presentation. Maybe it's evident to the agency some of the things that you've stopped doing, but because of the lack of transparency, it's not evident to us some of the things you've stopped doing.

MR. ELENGOLD: Okay, thanks.

John, do you have anything?

MR. MARZILLI: As we're getting a mike down to David, I'd just like to make a couple of

comments . One of the things that I think CBER should be applauded on in terms of increasing the science base of the agency and really focusing our resources, and you did mention it earlier, Mark, and that is Team Biologics. I think for the first time in a long time this agency has had a highly focused, well-trained work force to go out there nationwide and to do the fieldwork for CBER, and I know you've played an active role in that, and it's an important aspect.

For those of you that have had members of Team Biologics come out, we've really been able to focus our training opportunities on a devoted cadre that are devoted to these products. And Mark has taken a leadership role in that from the Center for Biologics; and as a District Director, I've seen that it's been a tremendous resource boost to me in terms of trying to get my work done in the field organization. I want to compliment you on that.

MR . ELENGOLD: Thanks . I was quoted in one of the meetings as saying, "Team Biologics is either way above high technology regulation of the future or something we're going to look back

on as a massive failure, " and so far, I've been really happy that I think it is the wave of the future for high-tech regulation.

MR. MARZILLI: And the other thing I'd like to add, the technology that we've seen here today in terms of satellite training, and Al Levitt sitting over there is my training officer for the New England District. We have at least two satellite broadcasts a week related to training opportunities within FDA, either seminars that are given by the various centers or other areas of interest to our folks that are usually broadcast in each of the twenty district offices and five regional offices across the country. Locally we record them on videotape and get them out to our district offices, so there is a multiplier effect, and I think we're doing a lot of innovative things. And I'm excited about this Webcast that we saw today. That's the first time I've seen that, and I think that would be an excellent training opportunity for us in the field to get the message out.

And most recently our blood bank inspection cadre has an interactive CD-ROM training program

with a little Hector-Hector guy over there that tells you whether or not you did your blood bank inspection right. And there's a lot of high-tech training, and CBER has taken a leadership role in developing that with the field organization, and I really wanted to compliment you guys on it.

MR. ELENGOLD: What we did, in fact, to do that was we leveraged -- the CDRH folks have this Tech Center where you saw that satellite broadcast from today, and that is a state-of-the-art network grade facility. And rather than try to develop any of our own, we decided to leverage that, and rather than spend a lot of money on satellite technology, we paid Bell Atlantic to put a fiber line in that runs from the Tech Center to all four of our buildings. And again, at least two, three times a week we use our system to have them down-link to us educational opportunities, NIH grand rounds, association things; and our people can get their continuing medical or pharmacy education by just going down to a conference room.

MR. MARZILLI: Okay, David Fleming from

Genzyme had a comment.

MR. FLEMING: Mark, let me try to pose one possible issue of one area where possibly CBER and industry can work together, and I guess that's the first point. I think industry, I'm hearing today, wants some more open collaborative dialogue and better communication with CBER, and I think it's improving, but we want to improve it more. And one example is just, again, the long review times. I think we might have different perspectives as to what the issues are. And I think industry sometimes believes that there's a disconnect, there continues to be a disconnect, in that we see it on the submission side between what we feel CBER wants in a submission and what CBER feels that it wants. And what happens is, you end up having six months while CBER is reviewing, and then it comes back to the manufacturer, but it's three to six months to get back because there are unanticipated issues. So I think -- Bill Pignato mentioned it earlier -- I think there's a great interest in working collaboratively on guidance and on guidance documents, and not for industry to go away and do

it, not for CBER to go away and do it, but for both to sit down in some manner that's acceptable and to work these out so that there is a clear commonality that goes into the submission process so that we bring down the review time, bring down the number of rounds, and really get down to where not only is the product going through faster, but you are able to use your resources more effectively.

MR. ELENGOLD: Yes, I agree with that. You know, extra rounds of review do cost us money too, and we don't see any great benefit from those. And had I been answering this about a week ago, I would have said I would suggest you put a proposal together and submit it to Becky Devine, our Associate Director for Policy, on a proposed pilot to do that. Unfortunately, Becky has decided to leave the government in June; so in the interim, until someone takes her place, 1'11 suggest you put a pilot suggestion together, pick a topic, and send it to me, and 1'11 get it worked on.

One other thing that Carolyn Jones brought up, the review metrics issue. We acknowledge

that that's something industry has asked for. We, frankly, do not have a mechanism in place to do the kind of a review metric analysis that I remember doing in the new drug report from twenty years ago and we do in our review performance. We put together a pilot and we're refining it to get the system to work right, and I did present some of those figures out at the HIMA meeting back -- was that a month or so ago? I can't remember . And those are posted on the Web, and they give you the last year's performance, and we will be posting those at least on a quarterly basis. We heard that last year. We're working on it, and we will start doing that. You saw those when I did those.

And Steve just wanted to say something just before we get to the next question.

MR . MASIELO: I just wanted to mention that, you know, when you talked about scaling back the regulation of various products, something as simple as a pipet tip came into the forefront not too long ago.

MR . ELENGOLD: On a Friday night.

MR . MASIELO: On a Friday night, yes, where,

you know, a manufacturer's pipet tips weren't picking up enough sample, and that had an impact across the blood industry with some really severe potential consequences. So, you know, even though on its face it might appear like a simple device, it has major impact.

MR. ELENGOLD: Nothing but a piece of blown glass, but it was sampling too small an amount.

MR. MASIELO: Another thing I wanted to say, we've heard a lot today about making more information available through the Web and all kinds of sources. One of the things that I'm looking at is making sure information that's made available through the recall process is useful information. There's a lot of information that gets out there, and you have to question: Well, just how useful is this to the public? What is the need to know this doing for them? And so we're looking closely at that kind of information to make sure that the stuff that gets out there has some meaning to people and it's not just more info. they've got to sift through to get something useful. So that's something we're looking closely at in our guidance to ensure,

that .

MS. DeMARINIS: Hi, Anna DeMarinis from bioMerieux and a former CBER person, so please take what I say with a grain of levity. I have two issues on which I want to take issue with you, Mark, two comments that you made. One was, you sort of gently chided Carolyn on her remark that “What would you have us cut out for us to be able to better utilize our existing resources?” And I think Carolyn’s response to look within yourself first is a very important one. You said, "What would you have US do? Get rid of consumer affairs, public affairs?" And I know some of those people, and I know that they are very scientifically and technically capable. And I would submit those individuals could be cross-trained to conduct inspections, to be reviewing applications when there’s a backlog. Within your organization there are quite a few very talented people that may not be utilized at the present time as effectively as they could be, so I would certainly support Carolyn’s suggestion that we would be very happy as an industry group to give you some instructions, some very

constructive and positive suggestions on how you could reorient --

MR. ELENGOLD: Well, that wasn't my point. I mean, folks in ACMA, I mean, Mike Hooten who just retired last month, had done the plague inspection just about every year, even though he was mainly answering Congressionals, and Mary Myers, who's now the office director, was doing prelicense blood bank inspections up to three years ago. I even did one. They even let me do one.

The point is: If they do that, then they are not doing the consumer affairs work. I'm not saying that the people couldn't be reprogrammed, but if we stop doing the Web work, the consumer affairs work, you heard the people this morning say: It's FDA's job to post more information. It isn't the matter that we can't reprogram the people. It's that whatever they stop doing, one of our stakeholders will object to. That was the point to that.

MS. DeMARINIS: And I think that's a very valid point.

MR. ELENGOLD: You know, personally I'd

rather be a full-time compliance officer and write warning letters, something I'm very capable of doing; but most of the time they have me in meetings on budget, you know, so. . .

So that was the point. It wasn't that the people aren't multi-talented. It was that anything anybody has ever suggested to us that we stop doing or have stopped doing, we are immediately chided by somebody else: Why did you stop doing that?

MS. DeMARINIS: And I think that that further supports the whole notion that we need to meet with all stakeholders regularly and frequently to hash out these issues, because we in industry, we do have to do more with less sometimes. It's a reality of life, so we have to work on it.

The other comment that I wanted to make was in response to your comment that if we're sending someone to training, they are not reviewing an application. And I was a former teacher, so again, to me, the whole notion of training being an unnecessary or a frivolous activity is very unsatisfactory because I think if individuals are

properly trained, then they do their work much better.

I would throw back the comment to you: Research is another activity that if individuals are doing research, they are not reviewing applications; and yet research, as you shown in your own slides, is a very important training function. So, again, I would submit again that a number of these kinds of issues that. tend to fall on the fringes need to be kept in the mix and used as effectively as possible.

MR. ELENGOLD: I hope no one took that as belittling training. At the period when I became responsible for the training operation, I don't know, what was that Gail, about four years ago? No, no, I've been in this job two years. What? What? Was it only two and a half? Man! The reorganization for training into my organization, the staffing has increased about 30 percent. The budget has probably tripled. We have gone to the on-line learning. We have gone to orientations by videotape.

I think we need much more training. I just meant to say that by having trained the trainer

and -- you know, the joke I hear constantly at -- we have been doing internal stakeholders meetings. We call them “voice your opinion meetings, " and it’s basically an opportunity for the staff at CBER one office at a time to get up and yell at me. And the one thing I keep hearing is: “The reward for good work is more work. " And the problem that we’re faced with is, if we put our best people in more training -- I mean, we have been trying to set up this vaccine training course, to give you an idea, with ORA’s Team Biologics transfers to the inspections on October 1. And one week is a VERPAC meeting; one week is a religious holiday; one week is a professional association meeting. And that was the point, that we can only spread our people -- and we’d really, rather than train the trainer, to have our line people do it, one option we have to explore is, rather than using line people and training the trainer, is to get full-time training people that can do the technical training. And that’s all. I did not mean to belittle the need for training, I am perhaps one of the most overtrained employees in the federal

government sometimes.

MS. DeMARINIS: If you hire full-time trainers, how do you keep the trainers -- you say that you'd only send the trainers to the seminars?

MR. ELENGOLD: No, no. No, I mean full-time training people so they can work with the actual product experts and not have to do their own overheads. As I said, we have been doing that more and more, because the training, anybody's who's ever done training, is really the smallest part of your time. It's the logistics, the prep. work, the follow-up work. So that was all I meant by that. I'm sorry, I did not mean to belittle training. I am probably the greatest supporter that we have of it.

Anyone else?

MR. RIDER: Yes, I'd like to thank all of you for bringing the stakeholders here. As one who represents a stakeholder group, I enjoyed hearing the "early and often" comment on the video in relation to communication. I think that adverse reactions are bad publicity. Loss of market share on products, all of that results

from the lack of early and often communication with stakeholders.

I'd also like to encourage, as one that's interested in blood safety, working for a group that has a direct stake in that issue, the involvement of ethicists in relation to the risk, potential risk, and how not only the physical impacts of adverse reactions but psychological, mental health reactions. I deal full time with the impact that that has on families all over this country, and, of course, that impacts on our industry and our bottom line in terms of productivity, because when you decimate family systems' mental health, you have unfortunate spin-off consequences to the economy. But in relation to that, I would say that you have good scientific data base that you can tap into in many professional nonprofit associations for scientific review, such as Physicians for Social Responsibility, who have the empirical training and knowledge and also an ethical basis for which to do some peer review.

Thank you.

MR. ELENGOLD: Will you identify yourself

for the record, please?

MR. RIDER: I am John Rider. I work for the Committee of 10,000. I am an advocate nationally for that organization.

MR. ELENGOLD: Thank you. Anyone else? Well, then I will do my thank-yous and then turn it over to John. I just want to thank everyone for coming, first off, and participating. The only way we're going to get where we all want to go is by working together. You know, reasonable people can disagree, and the basis of progress is getting together and reaching compromises and doing what we need to do.

I particularly want to thank Paula Fairfield, John, the folks here at BU who have just been wonderful, the AD folks. I do this probably at least once every ten days or so, and this is the most professional, best organized group I've dealt with in probably fifteen, twenty years, and I do appreciate that.

I want to thank the folks back in Rockville who did the work, the folks who came up here, Gail and all of her people, Lorrie Harrison, who some of you spoke to in registering for this,

Steve, John, the folks from Winchester, and Bob Miller who have been the butt of several of my jokes just because when I need money, he's the one I give the bank.

I appreciate it, and this is not the end of this process. We will be continuing it.

One other thing I'll mention is if you look at our Web site, one of the things that I set up that I'm fairly proud of is our automated e-mail system. You can subscribe to those automatically and then get notices of all our guidance documents, meetings, workshops, new initiatives, things we're posting, and I would urge everyone to look and consider signing up for that.

It's easy to find me. If anybody wants to contact me, my number is (301)827-0372, and I'm never there because I'm always in budget meetings, so the best way to do it is to send me an e-mail. It's Elengold @CBER.FDA.Gov. I usually try to answer things within a day or two, or get it to the right place, so if you don't know where to start, you're always free to send it to me.

And, John, thank you very much.

MR. MARZILLI: Okay, Mark, thank you as well. And I do want to salute the BU staff. I think they did an excellent job. And once again I want to say a special thank-you to Paula Fairfield who has handled this from the very beginning. Paula, my appreciation for the hard work that you've done in putting this whole thing together.

Again, we passed out some brochures. They are available in the back of the room. If yOU want to reach the District Office, we talked about consumer complaints, we have a 1-800 number for consumer complaints, et cetera.

Again I want to thank our representatives from CBER who came down today. And in the times of diminishing resources, I want everyone to know that they got up at the crack of dawn and took a flight in and came here from the airport and will be leaving promptly. So we want to --

MR. ELENGOLD: We came in last night. I don't want to go on any false pretenses. We got in at what, 8:00 o'clock last night?

MR. MARZILLI: Okay, okay. But I do want to thank you all for coming in and making it into

the meeting and spending the time with us.

MR. ELENGOLD: We have done it in one day. Boston is pushing it.

MR. MARZILLI: And, folks, your parking stickers should be validated with the word "FDA," and thank you once again for coming and thank you for spending some time with us.

(Applause.)

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C E R T I F I C A T E

I, Lee A. Marzilli, Registered Professional Reporter, do hereby certify that the foregoing transcript, Pages 1 through 153 inclusive, was recorded by me stenographically and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings to the best of my skill and ability.

Dated this 3rd day of May, 1999, at Lexington, Massachusetts.

LEE A. MARZILLI
REGISTERED PROFESSIONAL REPORTER
CERTIFIED REALTIME REPORTER

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