

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

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

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

1 about .

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

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

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

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

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

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

15 Thank you.

16 (Applause.)

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

19 Let's do questions.

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

1 the satellite downlink.

2 MR . ELENGOLD: I really am sorry I had to
3 cut you, Lisa, but just for the record, CBER has
4 many -- not many -- yes, many approved new drug
5 applications. A product that has been in the
6 news quite recently, avicerokylese (sic), is
7 regulated as a new drug application, not a
8 license. A lot of the plasma expanders are
9 regulated as NDAs. So we use all of the
10 available tools under the FDAC Act. We have
11 drugs, we have biologics, we have PMAs, and a
12 510(K)S. So CBER has used every bit of the
13 flexibility given us by the Act to affect the
14 right products.

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

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

22 MS . RAINES : I should have been more
23 specific.

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

1 questions. John, do you have any questions?

2 MR . MARZILLI: I'm all set.

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

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

11 MR . ELENGOLD: Yes.

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

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

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

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

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

24 MR . ELENGOLD: I personally have been sued

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

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

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

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

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

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

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

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

21 MR . WESTON: Sure .

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

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

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

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

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

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

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

9 (Laughter.)

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

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

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

1 group .

2 MR . ELEGOLD: John, do you have any
3 questions?

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

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

23 MR . ELEGOLD: Steve, do you have anything?

24 MR . MASIELO: No.

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

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

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

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

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

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

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

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

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

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

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

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

15 MR . ELEGOLD: That was the purpose of my
16 question.

17 MS . JONES: Oh, I missed it.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 will let you do your presentation right now.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 unlicensed customers; for example, a hospital
2 customer. But the use of this same -- same --
3 identical instrument to an unlicensed customer
4 that we sell to a licensed blood or plasma
5 facility is routinely sowed with a second
6 application review, inspection, and approval
7 process. This means that even after a 510(K)
8 review process, which can take up to several
9 years for a device, and longer for NDA review of
10 a new anticoagulant or a storage solution, there
11 is a further delay for a year or more for
12 implementation of the new technologies by
13 licensed users. This translates to up to three
14 years between the time the new technology has
15 completed the R and D cycle and the time it may
16 be utilized by users.

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

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

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

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

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

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

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

1 compliance.

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

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

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

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

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

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

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

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

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

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

11 Thank you very much.

12 (Applause.)

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

18 (Noon recess.)

19 (Satellite Teleconference.)

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

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

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

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

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

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

24 Today FDA is faced with several challenges.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the least burdensome concept.

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

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

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

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

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

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

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

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

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

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

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

24 Some of the recommendations we're going to

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

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

24 We recommend the cosponsored educational

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

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

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

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

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

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

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

1 have a correct interaction in those up-front
2 meetings.

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

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

1 out a number of ways you can approach that.

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

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

24 The issue of educating the public on the

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

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

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

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

24 As far as training, industry training,

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

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

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

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

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

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

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

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

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

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

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

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

21 MS . JONES : Sure .

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

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

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

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

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

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

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

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

7 MR . ELENGOLD: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

21 Training you brought up, training the
22 trainer. I went to train-the-trainer school in
23 1971 or '72 back before we had project hiring and
24 a lot of the people here today were hired. We

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

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

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

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

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

17 MS . JONES : Okay .

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

1 overhead. We've cut travel just this year 25 to
2 30 percent. We're really interested, you know,
3 and again, you know, in what functions industry
4 thinks we can stop doing because we'd like to see
5 if we can stop doing them. But the rhetoric of
6 just, you know, "There are things you can stop
7 doing, " we think we've stopped, at least in CBER.
8 And I think Dr. Henney's proposed reorganization
9 of the Commissioner's office, which is
10 eliminating overhead and redundant things there,
11 has also gone a long way to doing that. So I'd
12 really be interested.

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

21 MR . ELEGOLD: Okay, thanks .

22 John, do you have anything?

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

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

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

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

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

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

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

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

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

24 MR . MARZILLI : Okay, David Fleming from

1 Genzyme had a comment.

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

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

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

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

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

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

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

23 MR . ELENGOLD: On a Friday night.

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

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

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

9 MR . MASIELO: Another thing I wanted to say,
10 we've heard a lot today about making more
11 information available through the Web and all
12 kinds of sources. One of the things that I'm
13 looking at is making sure information that's made
14 available through the recall process is useful
15 information. There's a lot of information that
16 gets out there, and you have to question: Well,
17 just how useful is this to the public? What is
18 the need to know this doing for them? And so
19 we're looking closely at that kind of information
20 to make sure that the stuff that gets out there
21 has some meaning to people and it's not just more
22 info. they've got to sift through to get
23 something useful. So that's something we're
24 looking closely at on that front, right? Yes, where,

1 that .

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

1 constructive and positive suggestions on how you
2 could reorient --

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

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

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

24 MR . ELENGOLD: You know, personally I'd

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

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

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

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

1 properly trained, then they do their work much
2 better.

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

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

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

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

1 government sometimes.

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

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

17 Anyone else?

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

1 from the lack of early and often communication
2 with stakeholders.

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

23 Thank you.

24 MR . ELENGOLD: Will you identify yourself

1 for the record, please?

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

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

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

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

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

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

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

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

24 And, John, thank you very much.

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

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

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

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

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

1 the meeting and spending the time with us.

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

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

8 (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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