

ORIGINAL

TRANSCRIPT OF PROCEEDINGS -8 P12:52

FOOD AND DRUG ADMINISTRATION

CONSUMER ROUNDTABLE ON
CONSUMER PROTECTION PRIORITIES

Pages 1 through 217

Washington, D.C.
December 13, 2000

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FOOD AND DRUG ADMINISTRATION

CONSUMER ROUNDTABLE ON
CONSUMER PROTECTION PRIORITIES

Wednesday, December 13, 2000

9:17 a.m.

Hubert Humphrey Building
Penthouse Conference Room
200 Independence Avenue, S.W.
Washington, D.C.

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P R O C E E D I N G S**OPENING**

1
2
3 MR. BARNETT: If everyone is seated, I think we'll
4 start the meeting. I want to welcome you to this consumer
5 roundtable meeting. I'm Mark Barnett with the Food and Drug
6 Administration and I'll be serving as your moderator this
7 morning and this afternoon. Seated with me is someone who
8 needs no introduction for most of you. She's Dr. Jane
9 Henney, Commissioner of the Food and Drug Administration.

10 Before we hear from Dr. Henney, let me just say in
11 a very simple way that the purpose of this meeting is to be
12 sure or help be sure that consumers have a say in what FDA
13 does and how it spends its money. Now, obviously, this
14 agency doesn't have complete flexibility in what it does.
15 We are constrained by the mandates of the laws that we
16 enforce and by the Congress. But within that mandate, we
17 do, in fact, set priorities, priorities in our research
18 efforts, our education, in the way we enforce the law, in
19 the way we approve products before they're marketed, and in
20 the way we monitor them after they're marked, and, of
21 course, that's where this meeting comes in because it gives
22 you the opportunity to affect that priority-setting process
23 and let us know what you think we should be doing.

24 A couple of housekeeping things. Is there anyone
25 here, and let me have your hand, who would need the services

1 of a sign language interpreter. I see no hands? Okay,
2 fine.

3 The other bit of housekeeping is the usual thing
4 you hear about cell phones and beepers. Put them on
5 "vibrate" or turn them off, if you would.

6 Dr. Henney, let's begin by talking about the
7 purpose of the meeting. As I stated it and as it's in the
8 Federal Register, it says something about getting input from
9 consumers about the direction FDA takes in its planning
10 process, but that's the input part of it. There's an output
11 part, too, I would think, and that is getting consumer
12 groups to work with the agency in getting the job done. How
13 important is that?

14 DR. HENNEY: Well, Mark, it's very important, but
15 let me back up and just say a few things about consumer
16 engagement with this agency. Even though we're almost on
17 the verge of celebrating our 100th birthday--that will
18 happen in 2006, so it's coming fairly close--this is one of
19 the oldest consumer protection agencies in the government,
20 and so I think both our history in terms of--and pride in
21 our organization comes from our mission of consumer
22 protection and public health promotion. It's also written
23 very clearly in the mission statement of this agency.

24 I think that some of the ways in which the agency
25 over time, over the course of this last century, has tried

1 to actively engage consumers in the business of the agency
2 has been in a number of ways. One was we were the first
3 agency to really open up the advisory committee process, not
4 just to the technical experts but to the public, as well,
5 and to have open public meetings where anyone could comment
6 on the business under consideration at that point. We've
7 done our business by open comment rulemaking. And I think
8 the other thing that we feel is very important in our own
9 history is that we were one of the first agencies in the
10 Federal Government to have an Office of Consumer Affairs.

11 But even with that history, I think over the
12 course of the last two years, although I've seen many of the
13 faces that are here in this audience today, I think that we
14 need to have even more and better ways in which we can
15 engage consumers and the public in the business of the
16 agency, and one of the most important parts of engagement is
17 in our planning process.

18 We are just on the verge of starting that
19 internally, that budget planning process within the agency,
20 so at this point in time, we wanted to hear from consumers
21 and from consumer groups. I know that over the course of
22 the past year you've attended many stakeholders' meetings,
23 but we wanted to have a meeting really just for you, to hear
24 your voice in this. I think we want to not only do this
25 today but keep doing this in an effort to keep increasing

1 our transparency as an organization about what we do and why
2 our decisions are made in the way that they are and include
3 your voices in that process. And third, we're looking for
4 projects, quite frankly, that can advance our shared vision
5 of the promotion of public health and the protection of
6 consumers through cooperative projects.

7 So if we hear some of those kinds of ideas today,
8 either projects, ways in which we can increase our
9 transparency, and things that you think that we need to
10 consider as we inside the agency go into our internal
11 planning process for the subsequent year's budget, those are
12 the kind of things that we would particularly like to hear.

13 MR. BARNETT: And shared projects is one of the
14 things that you've stressed the most in terms of priorities,
15 not just with consumers but with other stakeholders, as
16 well, and one of your favorite words there is the old word--

17 DR. HENNEY: Leveraging.

18 MR. BARNETT: --leveraging, right. Say a little
19 bit about leveraging.

20 DR. HENNEY: This is something that's not
21 necessarily new to the agency, but I think our emphasis on
22 it is. It goes back to way before my time when Archimedes
23 once said, give me a place to stand and I can move the
24 world, and he was talking about being able to move the world
25 with a lever, a strong position and effort against what

1 would seem like forces that are immovable.

2 I think with the vast amount of products under our
3 jurisdiction, with the kind of mandate that FDA has, and the
4 resource limitations that we have both in terms of our own
5 staff and others, we need to look for ways in which we can,
6 through leveraging also the mission of other agencies or
7 organizations who have like goals, to get our cooperative
8 work together, get us more emphasis in terms of improving
9 the public health. That's what we're looking for.

10 MR. BARNETT: Is your stress on leveraging really
11 because of budget constraints? I mean, if the FDA doesn't
12 have enough people and dollars to do everything it could do,
13 then obviously working with others is important. But
14 suppose we had more money and more people. Would you still
15 be talking about this?

16 DR. HENNEY: It's my belief that we will always
17 need others in order to do our work, and let me give you a
18 simple example, although it would be nice to have more
19 money, Mark. I wouldn't give that option away.

20 But even if we had all of the resources
21 imaginable, I think that there are still things that we
22 could never hire into the agency or we would never have
23 access to. Some of those kind of things are the
24 intellectual capital that resides in different pockets of
25 different organizations across this country that we may need

1 periodically, but not full time, and there are certainly
2 groups--I'm sure that many of them are represented in this
3 room--that can reach other people with messages in ways we
4 could never do, even if we had a vast amount of money,
5 because their credibility with those memberships or those
6 groups is far greater than a government agency. While we
7 have our own credibility, in part, people that work at the
8 grassroots who have either a similar kind of diseases or
9 similar interests can reach people in ways that we can't.

10 And so even if we had a vast amount of resources,
11 I think that we still need to be looking for opportunities
12 in which our work can be maximized by working with others.

13 MR. BARNETT: Another big word in your priority
14 list is the "S" word and that is science and improving the
15 science base of the FDA. If you went out and did a survey
16 of people on the street and you said, tell me the first
17 thing that comes into your minds when you think about health
18 science and the Federal Government, probably FDA wouldn't be
19 first. They may say NIH and so on. But FDA is a science
20 organization. Why do you think it's that important to keep
21 the science base as strong as possible?

22 DR. HENNEY: My emphasis on science is because we
23 use scientific evidence to ground all of our decisions, and
24 if we aren't well skilled in interpreting and knowing what
25 strong scientific evidence is, our decisions will either be

1 slow because they'll be very risk adverse or they'll be
2 wrong. And so keeping at the top of our game
3 scientifically, I believe is very important.

4 I do think it's interesting, one thing you brought
5 up about how well known this agency is. When Research
6 America conducted some of their surveys a few years ago, 80
7 percent of Americans can identify FDA as the place where new
8 drugs and devices are approved. They don't associate that
9 necessarily with science in the NIH sense.

10 I think the other surveys that have been conducted
11 that have been particularly interesting that also connect
12 this science issue is one done by the Pew Foundation this
13 past spring and it was done of all Federal regulatory
14 agencies, asking different groups--consumers, patients,
15 health professionals, and regulatory officers of much of our
16 regulated industry--what kind of confidence do you have in
17 this particular agency? And remember, this was done of a
18 wide variety of Federal regulatory agencies. The confidence
19 level there was somewhere between 75 and 80-some percent for
20 this agency of all of those diverse groups. They had
21 confidence in our decision making.

22 The other thing in that survey that they asked
23 was, do you believe that the agency makes its decisions
24 based on science? Again, same kind of percentages, 75 to
25 roughly 83 or 84 percent believe that FDA used science in

1 its decision making process. So the linkage there of trust
2 and confidence and using the evidence of science to ground
3 decision making, it doesn't mean that other considerations
4 don't at some times get melded into the mix. But the
5 grounding for all decision making being in science is very
6 tightly linked to the trust and the credibility people have
7 in an agency.

8 MR. BARNETT: The role of consumers in affecting
9 the health care system and in their own health care is
10 certainly changing a great deal. It's changed over the past
11 decade or so. Talk a little bit, if you would, about how
12 that affects the FDA and the FDA's interaction with
13 consumers and the FDA's role.

14 DR. HENNEY: Well, I think that the activism by
15 consumers is a very healthy sign, but it also means that we
16 have got to shift some of our emphasis on what we do as an
17 agency. The consumers desire for information, wanting to be
18 involved in their own care, having access through the
19 Internet to all kinds of facts and figures, means we need to
20 be better in our outreach efforts, we need to be better in
21 terms of signaling what is quality information, we need to
22 be engaged in a different kind of way than we have been in
23 the past, which has been much more paternalistic, I would
24 say, in terms of saying, we'll tell you what you need to
25 know and you'd better believe us. I don't think that that's

1 going to be a right position to be in going forward.

2 MR. BARNETT: Do you view the FDA as helping
3 people to sift through the tremendous amount of information
4 that they have available, the Internet, for example?

5 DR. HENNEY: Well, one way we do that is by our
6 own website, in terms of posting information. We also have
7 much on our website to try to help consumers in terms of
8 discerning other information that's on the Internet or
9 information about a variety of products that they might want
10 to take into their physician and say, here are all these
11 products that may be used for this particular operation. He
12 seems to have pros and cons. Tell me about it. So we're
13 trying to provide both identifiers for quality information
14 and also prompters for the consumer or the patient to be
15 helpful in engagement with their health professionals.

16 MR. BARNETT: I know you're going to be listening
17 very carefully to what people say today, but beyond that,
18 how committed are you to actually acting on what you hear,
19 using people's ideas in developing the FDA's plans?

20 DR. HENNEY: I think that we don't take scheduling
21 a meeting like this lightly. We don't take having all of
22 the senior staff here to make not only presentations but
23 really to be present to listen to you and then intend to
24 turn a deaf ear. We intend to take what you say, see how we
25 can use it. I can't make the promise that everything that

1 we hear today, we'll be able to act on or do, but you
2 certainly have our sincere desire to hear what's on your
3 mind, and as we can, work it into our planning process. And
4 I would also say that we don't intend for this to be the
5 last time that we have engagement with you.

6 MR. BARNETT: I think many people, consumers and
7 consumer groups, look upon the FDA planning process as
8 something that's the FDA's business, something that's kind
9 of internal to the agency. Is it important, though, that
10 folks on the outside understand that process in order to
11 most effectively be able to work with the agency?

12 DR. HENNEY: Well, I don't think that we're
13 different than any other Federal agency or any other
14 organization that people have dealt with. The more you know
15 about an organization's working, the more successful you are
16 at understanding what's going on.

17 So writing one letter or saying one thing or
18 waving an issue before an agency may have a moment's notice,
19 but I think your trying to understand what we do on a day-
20 to-day basis and when and how we make our decisions will be
21 very helpful to you to know how to move the issues that are
22 important to you forward. I worked at the NIH for nine
23 years and know very well that the groups that are very
24 effective in terms of dealing with an organization, be it a
25 health organization or a Commerce Department or anybody, are

1 the people who really understand the processes all through
2 the year.

3 MR. BARNETT: Thanks for setting the stage for
4 this meeting, and now let me explain a little bit about the
5 format we're going to use today. We're going to ask the
6 director of each of the FDA centers to present that center's
7 priorities for the coming year or years. Those
8 presentations will take about 15 minutes.

9 Then after that, I'm going to ask the
10 representative of a consumer organization with a particular
11 interest in that topic to respond to what the center
12 director said and to make suggestions about what that
13 organization believes the center should be doing, and that
14 should take about another 15 minutes.

15 Then in the time remaining before we go to the
16 next center, I'll open the floor to questions and comments
17 from the audience, and I'm going to give priority to
18 consumer groups and consumers because this is, after all, a
19 consumer meeting.

20 So at this point, I was going to say I'll call up,
21 but you're here already, and Dr. Henney and I will move over
22 so that you can see what's on the screen, and our first
23 center is the Center for Biologics Evaluation and Research

1 the Center for Medical Consumer and Health Care Information.
2 So I'll ask Dr. Zoon to take over.

3 I'm going to issue a gentle reminder to both
4 presenters in all cases when the 15-minute mark is about to
5 come up. The weatherman says there's going to be an ice
6 storm this afternoon, so we're impelled or we're motivated
7 to actually close this meeting at the prescribed time.

8 Dr. Zoon?

9 **CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

10 DR. ZOON: Thank you, Mark, thank you, Dr. Henney,
11 and thank you, Art, for coming. I'm just going to stand up
12 a minute and say hi because I know many of you are in the
13 back and can't see very well, so I want you to see who's
14 talking up here. I appreciate the opportunity to be here
15 today.

16 I'm really very pleased that the agency has put
17 together such a wonderful program and asked me to
18 participate. Particularly with the great deal of topics
19 today, biologics will also present themselves in a way that
20 I will explain to you, because sometimes people ask me, what
21 is a biologic?

22 But I'll start out, if I could have the next
23 slide, please, is to just give you the mission of the Center
24 for Biologics. The mission of the Center for Biologics is
25 to protect and enhance the public health through the

1 regulation of biological products, including blood,
2 vaccines, therapeutics, and related drugs and devices,
3 according to statutory authorities. The regulation of these
4 products is founded on science and law to ensure their
5 purity, potency, safety, efficacy, and availability. And
6 I'll start out with that because that's the fundamental
7 premise upon which we act.

8 I'm going to sit down now, and hopefully everybody
9 will be able to see the slides. Please don't hesitate at
10 the end when we're done to ask questions. If I could have
11 the next slide, please.

12 What is a biologic? Well, biologic encompasses
13 many types of products, many of which you in the room have
14 experience with on a day-to-day basis, and these include
15 vaccines. All of us, or many of us as parents or recipients
16 of vaccines to protect children, to protect us against adult
17 diseases, have a great deal of interaction and experience
18 with these products. Allergenic extracts, which are another
19 product, these are very traditional products, as is blood
20 and blood safety and blood-derived products. Our center has
21 responsibility for these.

22 Devices related to blood safety and biological
23 product safety are under the purview of CBER, and more
24 recently the biotechnology products, including monoclonal
25 antibodies, recombinant DNA-derived proteins, new thing such

1 as somatic cell and gene therapies, xenotransplantation, and
2 more recently, embarking in tissue products.

3 So this is a large portfolio. Biotechnology
4 actually cross-cuts all our products and has been integral
5 into the availability of many products that in the past have
6 not been present.

7 The next slide just gives the concepts. We call
8 these our Olympic rings of regulation, and I like that
9 always in an Olympic year, but they include science and law
10 throughout our evaluation with the eye toward public health
11 impacts. And these include review, review of documents such
12 as investigational new drug applications, license
13 applications, looking over adverse events, looking over
14 labeling for products, materials that go out to private
15 citizens or to doctors to make sure they have the right
16 information in them.

17 We do regulatory research to ensure product safety
18 or to develop new guidances to ensure that--to facilitate
19 the advance of new technology.

20 Surveillance is a very important part of our
21 program. This is looking at adverse events, making sure
22 that we have our fingers on the pulse of what the safety
23 parameters of our products are, both pre- and post-
24 marketing.

25 Policy development is very important, making sure

1 that there's a clear understanding of FDA's roles and
2 responsibilities and how we interpret those, as well as the
3 scientific concepts behind the expectations of the industry
4 and our sponsors in getting products into and through the
5 agency.

6 And, of course, compliance. There, we have our
7 education and enforcement roles to ensure not only that
8 sponsors of products understand what we want them to do, but
9 in cases where those rules and regulations are not being
10 adhered to, that we take appropriate action.

11 The next slide presents what I think are some of
12 the forces shaping biological products in this century, and
13 this is really driven by a number of parameters. Some of
14 these include new discovery biomedical research. Billions
15 of dollars are being invested through the government,
16 predominately the National Institutes of Health. Large
17 quantities of R&D money are being put in by the industry for
18 the development of new products for future health and safety
19 of the public. Well, FDA is a recipient of many of those
20 new technologies, and the ability to have the scientific
21 underpinning as well as the networking with the scientific
22 community and through the use of our advisory committees to
23 properly handle these products is very important for the
24 agency doing the very best job.

25 The demand for these new products and faster

1 access is also paramount. Many diseases today still don't
2 have cures or even treatments to help mitigate their
3 effects. So the need to have the development of these new
4 products and faster access is, we recognize, very important,
5 but again, not at the expense of the safety of these
6 products. And again, safety has to be looked at in the
7 context of risk-benefit. Any medicine has a benefit and a
8 risk factor. So as we go through both a development process
9 as well as once we license those products, those have to be
10 constantly assessed.

11 Ethical issues--new biological products raise a
12 variety of issues, be they gene therapy,
13 xenotransplantation, which is the use of animal tissue or
14 replacement tissues where human tissues may not be available
15 because of limited supply or need, and these are critical
16 issues that go just beyond the science piece of what we do
17 at the agency but really touch on some very basic elements
18 of society and those things come into play accordingly.

19 The next slide shows the changing health care
20 environment. The constant evaluation of where we are with
21 medical care in this country also impacts on the
22 availability and development of new biological products.

23 Globalization is key. Our world is shrinking.
24 The ability for us to interface with the rest of the world,
25 looking at common standards and understanding for accessing

1 new technology products as well as existing technology
2 products is important, as well as standards for overseeing
3 their safety.

4 Information technology, there is a boom and the
5 agency recognizes the importance of this. Access of
6 information into the agency as well as out of the agency is
7 critical.

8 And for us at biologics, counter-bioterrorism,
9 looking at new agents, vaccines in the event of a bio or
10 terrorist attack has clear importance as well as other
11 biological therapeutic products.

12 Our priorities for this current year are currently
13 underway for reevaluation for next year, but I will put up
14 the list under which we have been working over the past year
15 and are continuing until we complete our new list. And
16 these include, to ensure the safety and efficacy of
17 biological products while facilitating their development and
18 meeting the goals of the Prescription Drug User Fee Act,
19 ensuring a strong science base supported by excellence in
20 research that's directly targeted to the evaluation and
21 regulation of biological products.

22 Next slide. To ensure the safety and public
23 confidence in the nation's blood supply, and to facilitate
24 the development and approval of significant vaccines, blood,
25 and therapeutic products through review, policy formulation,

1 regulation development, guidance, and workshops and
2 meetings, such as this.

3 The next slide shows, to improve automated systems
4 to support review and evaluation of our products, and also
5 to continue to develop and support a high quality diverse
6 workforce. And I am happy to say CBER has completed the
7 lead task that it's had on FDA modernization, so this is one
8 that'll come off our list.

9 Some of our challenges, one of which is shown in
10 the next slide, is a continuing decline in our operating
11 budget, particularly in the areas that are not augmented by
12 the Prescription Drug User Fee resources. We continue to
13 look at methods in our own center to maximize our
14 effectiveness by looking at our procedures to make sure
15 we're getting the most out of our processes and our
16 scientific expertise, but in this light, it still makes
17 enormous challenges for the agency.

18 This is why, well, if you look at the data in the
19 next slide, you will see that the number of products coming
20 into the Center for Biologics are increasing. This has been
21 a trend over the past five years. Particularly, that trend
22 is driven by biotechnology products, and I think this is
23 important for the agency and for the public to understand
24 that we're in a dynamic where workload is increasing and our
25 resources in terms of the programs are static, if not

1 decreasing, in some areas.

2 But this has not stopped us from proceeding and
3 moving with vigilance. Some of the new approvals that we
4 have affected deal with new heart attack medicines,
5 medicines for bladder cancer, bone disease, hemophilia,
6 pneumonia for babies, and new products for rheumatoid
7 arthritis.

8 What are our challenges for the future? Well,
9 there are many. Many of you who read the newspapers
10 probably see these in there almost daily. Some of the
11 issues regarding gene therapy and some of the challenges of
12 approximately a year ago with the death of a young man named
13 Jesse Gelsinger opened up areas of concern along oversight
14 and what are we doing with human subject protection. And
15 this opened up a broader issue in human subject protection
16 overall, looking at the roles of our IRBs, institutional
17 review boards that overlook clinical trials, issues of
18 informed consents for human subjects in clinical trials.
19 These are all important issues that not only FDA but the
20 Department of Health and Human Services takes very seriously
21 in moving towards finding better approaches to deal with
22 these complex issues.

23 Again, using animal organs, tissues, and cells for
24 therapy is another challenging area. Looking at the balance
25 of access to lifesaving treatment versus risks of infectious

1 diseases is one that clearly we're constantly having to look
2 at the science to balance these. The promise of new stem
3 cell products that may be able to have replacement tissues,
4 replacement organs from our own cells is clearly something
5 that provides enormous promise but raises important
6 scientific questions that need to be answered, guidance to
7 be developed that we can go forward in the appropriate way.

8 We need to be vigilant with regarding emerging
9 infectious diseases, making sure that we're doing our very
10 best to make sure that all our products, particularly the
11 blood supply, does not harbor new agents that can be
12 transmitted to millions of people, similarly with tissues
13 and other biological products which are just wonderful
14 growth mediums for the possibility of organisms. And we
15 need to take care in that, whether it be infectious agents
16 or things such as BSE-like agents are very important that we
17 look at carefully.

18 The human genomic project clearly is going to
19 provide enormous potential for new products and new
20 approaches that touch every element of the FDA, including
21 the Center for Biologics. The opportunity for new medicines
22 and new treatments, new diagnoses, all of which--and new
23 discovery of medicines will clearly impact on the agency and
24 what we get, and the opportunity to understand the science
25 and be prepared to meet those challenges is extremely

1 important.

2 The Prescription Drug User Fee program, again, we
3 are going to begin going into a program where we're now
4 going to be looking at the next phase of this. It's on our
5 agenda for the next year.

6 Biological product safety, again, of paramount
7 importance both for the product and for the population
8 taking biological products, making sure we do a good job in
9 our surveillance and action, if necessary, with those.

10 I mentioned counter-bioterrorism and ethical
11 issues earlier.

12 I just want to close in my last couple of slides
13 to talk about our current outreach activities. In CBER, we
14 have a consumer hotline. We pride ourselves on having a
15 real person you can talk to to help you with your issues,
16 your problems. Please take advantage of it, use it. We
17 have a website, as well, that has a lot of important
18 information on biological products.

19 Vaccines, in particular, the Vaccine Event
20 Reporting System is a very important system for getting
21 input. This touches on all kinds of folks. It touches on
22 consumers that have issues with vaccines. If they think
23 there's an event either they or their child has had with
24 relationship to the vaccine, it should be reported. We try
25 to do a lot of outreach. We have a little booth at the back

1 of the room with information on that for you today, so
2 anybody in the audience interested, please feel free to go
3 back there.

4 Fax information system, e-mail distribution list,
5 that will send out documents, information on blood and
6 plasma, and we try to go and be out at meetings and do a lot
7 of outreach at exhibits to reach you.

8 But we want to hear today, what can we do more for
9 you, so we're here to listen today and to learn what's
10 important to you and really try to be responsive.

11 And just in closing, the last slide, again, some
12 information on our Internet and how you can reach us at our
13 web page, and I'll close there. Thank you.

14 MR. BARNETT: Thank you, Dr. Zoon. That was a lot
15 of information in 16-and-a-half minutes. That was great.

16 I'll ask for a response now from Mr. Levin.

17 MR. LEVIN: Good morning, everyone. I've been
18 asked to respond to Dr. Zoon's presentation, although I must
19 admit I'm not particularly expert in biologics. But this
20 format was an attempt to have a sort of lead respondent to
21 try to get discussion underway, so I'll try to make my
22 remarks as quickly as possible, and as a New Yorker, I can
23 do it in an "under-a-15-minute" New York minute, hopefully.

24 So, first, some general remarks. I certainly want
25 to thank the Commissioner, Dr. Zoon, all the other center

1 directors, Mark, and the FDA staff who were involved in
2 making today's roundtable a reality. This is the first
3 time, I've been told, that all the center directors have met
4 with consumers and patients under one roof at one time.

5 The idea for this event, if my memory serves me
6 well, began during discussions that occurred during the FDA
7 consumer consortium meeting some time ago, and I want to
8 especially thank the Office of Consumer Affairs for helping
9 make today a reality. For those of you who may not know
10 what the Consumer Coalition does, it advises the FDA on the
11 selection of consumer representatives who sit on advisory
12 committees, as Dr. Henney referred to earlier.

13 I also want to mention another organization, the
14 Patients and Consumers Coalition, which is a group
15 represented by a lot of people here today that's come
16 together to work for consumer and patient issues in the FDA
17 policy arena, and Travis Plunkett, I think, will be here
18 later this morning, and for those of you who don't know
19 about the coalition and are interested, you can see him or
20 myself or Abby Meyers or anybody else, or Larry Sassick, to
21 learn more. And that's an attempt to put our voices
22 together to be heard with a louder voice in the process.

23 I'm pleased to see such a large turnout today, but
24 I worry that the format may not permit the level of dialogue
25 that I think we envisioned when we first started to talk

1 about this kind of meeting. Therefore, I respectfully
2 suggest today should be considered as sort of a plenary
3 session, to be followed in the not-too-distant future by
4 breakout meetings, which would involve consumers and patient
5 advocates and a particular center, a smaller number of
6 discussants, perhaps, and a greater amount of time to permit
7 more in-depth and focused discussion to go forward. And the
8 process, and I'm glad to hear that the FDA feels the same
9 way, this process should be fully integrated into FDA's
10 internal planning process for now and all time.

11 One rationale behind today's meeting was that
12 consumer and patient advocates as a group are probably the
13 most supportive, although to be perfectly frank, at the same
14 time often critical of the regulatory process administered
15 by the FDA and supportive of the agency. But they've not
16 traditionally been invited into the agency's planning
17 process, or at least not at a meaningful stage of that
18 process.

19 For example, I believe one glaring example is our
20 recent experience with FDAMA, when the opportunity for
21 public participation was a frustrating effort to make
22 advocates' concerns heard above the roar of the legislative
23 process. We weren't involved early on in discussions around
24 the shape that FDAMA was taking.

25 And now, I think another example of a problem is

1 when we hear from Dr. Zoon that CBER's workload in the
2 future is trended up and their budget is trended down. So
3 this is another example of why there is a pressing need to
4 involve consumers and patients in the planning process to
5 become allies of the agency as well as critics and to help
6 work to make things better for all of us.

7 The fact that consumers and patients haven't been
8 involved seems to me to be a startling omission historically
9 on the part of the agency, and I want to press that despite
10 new language that's crept into the agency's dictionary, we
11 don't view ourselves as stakeholders. I think most
12 consumers and patients would view themselves, at minimum, as
13 clients of the FDA. Many of us would go further and suggest
14 that the public is the ultimate boss of the agency, which
15 is, after all, still largely funded out of the public purse,
16 with the notable exception of user fee income. It is the
17 public's health and safety that the agency is statutorily
18 charged with protecting, not that of any other interest
19 group or sector. But as a result of not being invited into
20 the planning process, advocates have had little or no
21 influence in helping to shape agency policy in the past.

22 I would be remiss if I didn't mention that there
23 are some pleasing signs, this roundtable today for one, that
24 the FDA is starting to reach out, and this year's public
25 meeting to discuss PDUFA III did have a lot of advocate

1 participation in talking about that important policy issue
2 coming down the pike in 2002.

3 Let me turn quickly to some general responses to
4 Dr. Zoon's presentation and try to go through some concerns
5 that I have in regard to the responsibilities of CBER in the
6 future. There's no question that we're experiencing the
7 beginning of what is likely to be a rapid increase in the
8 development and diffusion of biologic products, including
9 gene and cell therapies, other biotech-derived treatments
10 for injury, disease, and disability, xenotransplantation,
11 and more. All of these are extremely complex scientifically
12 and most have a thorny ethical component, as well.

13 So one concern I have is this. If the predictions
14 are correct, how has the center built into its planning
15 process for 2003-2004, or how will it build into its
16 planning process, such a vastly increased workload,
17 particularly when we hear of the budgetary constraints that
18 CBER is going to face?

19 The chart that we saw of total and biotech
20 IND/IDEs for the period fiscal year 1987 to 2000 shows in
21 recent years a relatively sharp trendline upwards. How
22 would you trend that out over the next five years? What's
23 the estimate of the resources that CBER really needs to have
24 to effectively monitor the safety and efficacy of new
25 biologics? What plans does CBER have to attract the staff

1 with the scientific expertise necessary to monitor biologic
2 products during development and in the post-marketing
3 period?

4 And what about the staff needs for factoring in
5 the ethical concerns that arise in gene therapy and
6 xenotransplantation and other biologic-derived therapies?
7 How is that going to be factored in? That ethical component
8 is relatively new and it's a very large one that needs to be
9 taken into account.

10 Is CBER concerned about PDUFA III? We've had a
11 discussion of that already earlier in the year. Does CBER
12 have any specific thoughts about the wisdom of continuing to
13 increase the dependence of the agency on user fees rather
14 than the traditional method of paying for a regulated
15 agency's activities, which is out of general revenues?

16 You point out that one of the future challenges
17 for both CBER and the agency is human subjects protection in
18 the brave new world of biotech. We have read a lot about
19 the failures of the IRB system in general, that is, that the
20 several decades old system, I think, is generally agreed
21 upon to be in need of repair, that it hasn't done an
22 adequate job of protecting the research subjects enrolled in
23 clinical trials. So again I would ask, what sort of are
24 CBER's plans in this regard? It's one thing to say we need
25 to monitor human subject safety in clinical trials. It's

1 another thing to recognize that the system we have in place
2 needs fixing, and the question is, what is the role that
3 CBER sees for itself in moving that process forward?

4 For example, the agency has taken an action in
5 response to the death that you mentioned in a gene therapy
6 trial. On March 7, 2000, the agency announced new
7 initiatives to protect patients in gene therapy trials in
8 collaboration with NCI. A gene therapy clinical trial
9 monitoring plan appears to be very resource intensive on the
10 part of the responsibilities of the FDA. How will this be
11 funded? What's its priority, and will its priority, if it's
12 high, take away from other CBER activities and
13 responsibilities?

14 The center has had a blood action plan in place
15 since July 1997, or 1987?

16 DR. ZOON: Ninety-seven.

17 MR. LEVIN: Ninety-seven, to, in the center's own
18 words, "increase the effectiveness of its scientific and
19 regulatory actions and to ensure greater coordination with
20 our public health partners." The FDA has recently filed
21 documents in U.S. District Court in Washington alleging
22 serious violations on the part of the American Red Cross
23 that supplies half of the nation's blood supply.

24 What can we do, consumers and patients, to help
25 you create a climate that says, we don't care whether it's

1 the American Red Cross or who it is. There are standards,
2 there are regulations, they're to be enforced, and we're
3 going to enforce them. And if the American Red Cross can't
4 get its act together, it shouldn't be in the business of
5 supplying our nation's blood and blood products.

6 We can be helpful in that, because we recognize
7 the political sensitivity with an organization like the
8 American Red Cross and the dependency on the American Red
9 Cross of supplying 50 percent of the nation's blood supply.
10 I think this is something paramount as a public safety issue
11 and we can be mobilized, I hope we would all agree, to help
12 you create an environment that says it's okay for the FDA to
13 enforce statute. That's not a bad thing. That's what
14 they're there to do.

15 I'd like to, in talking about blood products, I'd
16 like to refer back to the IOM report of a year ago, "To Err
17 is Human." I was a member of the IOM committee that
18 released that report. Now, we know that one of the
19 categories of errors that occur in hospitals is related to
20 blood and blood products, so I'd like to ask the question,
21 what's CBER's response? Is CBER doing anything to address
22 the issue of the challenge of the IOM report and the
23 challenge that President Clinton issued in his press
24 conference last February to reduce medical errors in this
25 country by 50 percent by the year 2005? Has CBER

1 specifically looked at the kinds of errors that occur
2 related to blood and blood products in hospitals and is
3 there any planning to take a further look or a more in-depth
4 look at that and then begin to suggest to the health care
5 delivery system ways in which those errors could be reduced,
6 and hopefully eventually eliminated?

7 On the agency's website--not CBER but the agency's
8 website--is a report on the Rezulin experience. This is the
9 first time the agency has posted such a sort of internal
10 review of a bad experience on its website. One of the
11 things that comes out of the report on the part of the
12 agency is the thought that members of advisory committees as
13 they're presently constituted may not have enough experience
14 and expertise in risk management and risk assessment. I
15 think that concern is going to be heightened when it comes
16 to issues related to biologics and I just wonder what
17 thought CBER has given to how they're going to be able to
18 find the advisory committee expertise in risk assessment and
19 risk management to deal with these very, very complicated
20 products.

21 As mentioned earlier, and I think it's something
22 that we talked about after the meeting on PDUFA, what about
23 PDUFA III? What do we think about this? Does the center
24 have a particular point of view on whether continuing to let
25 this dependency grow on industry-provided user fees is good

1 or bad for its objectives? What would happen if there was
2 no PDUFA III? We need to have some discussion of that.

3 Lastly, on vaccines, I think as the number of
4 vaccines that are administered to infants continues to
5 aggregate, I think there is growing concern about what we
6 don't know about that aggregation in the short and long
7 term. And also as we hear vaccines being suggested for
8 dealing with a whole host of other kinds of problems that we
9 haven't dealt with before, vaccines as the ultimate weapon
10 against the spread of HIV and AIDS, vaccines to inoculate
11 people against heart disease, vaccines to inoculate people
12 against periodontal disease, we probably are going to see a
13 real gold rush in terms of vaccine development to treat all
14 kinds of things that they haven't been used for in previous
15 years.

16 So the question is, again, how is CBER planning,
17 how is it going to look down the road to this great increase
18 in vaccine development? How is it going to be able to
19 monitor both pre- and post-approval the safety and
20 effectiveness of vaccines? Has CBER taken a look at how
21 valid the Vaccine Adverse Event Reporting System is? We all
22 know that adverse event reporting systems notoriously have
23 under-reporting. If we're relying on that system to give us
24 signals of problems with safety or to document known
25 problems with safety, are we relying on a good system? Has

1 anybody gone back and validated that system and thought
2 about how to increase reporting?

3 I'm going to stop here because I really think we
4 want to hear from other consumers and patients who are in
5 the audience and who were invited here today. I want to
6 thank Dr. Zoon again for her presentation, and again, I want
7 to emphasize that I would hope this is but the first in a
8 number of opportunities to have this dialogue between the
9 agency and, I think, your best friend, consumers and
10 patients. Thank you.

11 MR. BARNETT: Thank you, Mr. Levin.

12 I noticed that Dr. Zoon was busy scribbling away
13 during that entire presentation, which leads me to let you
14 know that at the end of this meeting, we're going to have
15 all the center directors come on back up here and respond to
16 what they heard today from their responders up here and from
17 you in the audience.

18 So now it's time to, in fact, open the floor for
19 questions, and so if I see a hand--okay, one right up here.

20 **DISCUSSION**

21 MS. MEYERS: I have two questions, first of all
22 for--

23 MR. BARNETT: Could you identify yourself?

24 MS. MEYERS: Abby Meyers from NORD, National
25 Organization for Rare Disorders. This confusion about when

1 a biologic product goes to the FDA for approval, whether it
2 goes through the drug division or the biologic division.
3 For example, human growth hormone, which is really a
4 biologic, was approved as a drug. And so it's very
5 confusing to us because nobody really understands what the
6 parameters are, and when a manufacturer applies for approval
7 of a product like that, they don't know if it's going to go
8 through biologics or drugs. Isn't there a way just to merge
9 the drug division with the biologic division because they're
10 really the same thing?

11 And the second question is, on the ethical side,
12 this is the first time I've heard FDA talk about ethics.
13 You don't have one bioethicist on staff, not one. So if a
14 horrendous informed consent document comes in front of you,
15 you really don't have any legal authority or any regulations
16 to say, this is unacceptable. So do you intend to get
17 bioethicists on staff?

18 MR. BARNETT: Okay.

19 DR. ZON: Thank you, Abby. The issue you raised
20 on product jurisdiction currently is managed through a
21 series of inter-center agreements. Dr. Henney has asked the
22 centers to work on those inter-center agreements, which we
23 currently are doing.

24 The question of whether or not to merge different
25 groups or different organizations is always a complex issue.

1 You know, there's different product responsibilities besides
2 therapeutics and biologics, such as vaccines and blood and
3 tissue and things of that nature. So you're looking at
4 complex organizations and complex responsibilities, but
5 certainly those things can be looked at and are looked at
6 over time to look at what might be best.

7 But I would say that looking at having a clear set
8 of standards that products are regulated by are very
9 important. There shouldn't be different standards for
10 protein molecules that have biological action that are
11 regulated by two different centers. The standards should be
12 the same.

13 And, in fact, Dr. Henney has been very supportive
14 in fostering the interaction of the two centers to work
15 together to develop common standards. We've been doing this
16 routinely now for the past five years. We've worked very
17 closely, not only on just FDA documents but also in the
18 International Conference of Harmonization, which is a
19 process where they're looking at standardization of elements
20 for different products and types of products have been
21 looked at. So a lot of work has gone on in that area and I
22 think very successfully. There's a lot of agreement in
23 those standards.

24 I think working on the inter-center agreement to
25 have better lines of clarification is important, and as I

1 said, we are working on that.

2 With respect to ethics, right now, we don't have a
3 bioethicist on staff. However, we do have a number of
4 bioethicists that we have participate in our advisory
5 committees right now, plus we interact very closely with
6 staff at the National Institutes of Health, who do have a
7 bioethics staff. Zeke Emmanuel is one of the persons that
8 has a group over there that we also work with.

9 I think it's an important suggestion and I
10 certainly will take that under discussion with my
11 organization and look at whether or not it's appropriate to
12 have somebody on staff in there or use outside experts with
13 different experience in different ethical issues. But I
14 think it's certainly a legitimate area and one that we
15 should look at.

16 MR. BARNETT: Okay. Anyone else out here with a
17 question? Up front?

18 MR. SASSICK: Larry Sassick, Public Citizens
19 Health Research Group. Two quick questions, perhaps the
20 Commissioner and Dr. Zoon could respond, and I suppose this
21 shows my political naivete, but in an era of increasing new
22 applications for biologics, and drugs, for that matter, and
23 the other responsibilities that are being put on the agency,
24 why over the last half-decade have we seen funding for the
25 agency remain level or decline?

1 Could you tell us--maybe this is an unfair
2 question, but could you tell us what the Congress of the
3 United States is thinking when this is happening? There
4 seems to be a big disconnect here. They have the
5 responsibility for oversight of this particular agency. It
6 looks like they're not aware of what the agency does and how
7 important it is.

8 The second question is, I'd like to touch back on
9 the issue of the Red Cross. I think the original consent
10 decree was signed back in 1993, if I'm not mistaken. It's
11 an inordinate length of time to be playing roulette with the
12 blood supply. I mean, it's almost seven years. Could you
13 tell us what you might need from a regulatory authority's
14 standpoint to be able to deal with problems like the Red
15 Cross and, say, other producers from being out of compliance
16 for such an inordinate length of time? Thank you.

17 DR. HENNEY: I think that to have a budget session
18 to understand how we got there would almost take a day-long
19 briefing. I think in short form, some of the shortfalls
20 that we have seen over time have been precipitated by a
21 couple of things.

22 There was a few years back passed the Balanced
23 Budget Act that you all know about. I think that that
24 certainly has put some squeeze on the agency's resources as
25 we sit before a committee that is given their allocations of

1 discretionary funds to spend and those discretionary funds
2 have been decreasing over time. And many of our allocations
3 that have been given to the agency over the last five to
4 seven years have been in very targeted areas rather than
5 just overall increases in the budget, which would provide
6 the agency a bit more flexibility.

7 I think it's fair to say, however, within the
8 context of the discretionary money provided to our committee
9 in Congress--which are the agriculture committees, because
10 we were first derived as an organization from the Department
11 of Agriculture and our committee jurisdiction has never
12 moved to health--that we fare reasonably well by percentage.
13 It's just that by that percentage, it's still a low dollar
14 amount and it's oftentimes targeted.

15 The other thing that has been very painful for the
16 agency, quite frankly, has been the fact that we have not
17 been given cost-of-living increases for five to six years.
18 So as we need to every year still give our staff their due
19 in terms of their increases in salary, those must come out
20 of the other parts of our operating budget or by not hiring
21 more staff. So you see those declines happening because of
22 the cost-of-living increase. That has been largely because
23 they have not been requested, and it's primarily because the
24 kind of generous allocation that gets made to the rest of
25 the health budget usually means that they can absorb their

1 cost-of-living increase.

2 So we've had a squeeze in two kinds of areas, the
3 very targeted increases so we don't have much flexibility
4 about where we can spend the money we do get, and not being
5 given cost-of-living increases, not requested and the not
6 provided, has really put a real damper on our ability to
7 keep some of these things going at the level that you might
8 expect or we would like. So there are pressure points two
9 ways there.

10 Larry, I just don't think it's going to be
11 productive for us to get into a back-and-forth on this.
12 Those are just sort of the underlying facts, I think.

13 I think that the second issue, with respect to the
14 Red Cross, I think it has been well enough known in the
15 paper in terms of we have had the Red Cross under a consent
16 decree for some six to seven years. We have found continued
17 problems during the course of inspection. I think Red Cross
18 acknowledges that and now it is really a difference of
19 opinion in terms of a sanction that might be imposed if we
20 see further problems, and that is the point of real debate
21 right now. But we do believe there needs to be full
22 compliance with the law and statutes, absolutely yes,
23 because that is the only way we are going to absolutely
24 assure a safe blood supply.

25 MR. SASSICK: Do you think you need additional

1 regulatory powers in a situation like this, or are they
2 adequate right now?

3 DR. HENNEY: They're adequate.

4 MR. BARNETT: Anyone else, questions? Yes, there
5 are two back here, one on this side and then one back here.

6 MS. FISHER: Barbara Loe Fisher with the National
7 Vaccine Information Center. To what extent does CBER need
8 or want increased resources to conduct basic science
9 research in-house to develop a scientific base of knowledge
10 in order to more effectively regulate the vaccine industry?

11 And secondly, because FDA operates theirs, which
12 was mandated under the National Childhood Vaccine Injury Act
13 of 1986, do you think it's within your purview to create a
14 penalty mechanism for physicians who do not report
15 hospitalizations, injuries, and deaths following
16 vaccination?

17 MR. BARNETT: You might explain what "theirs" is
18 just for the rest of the audience.

19 DR. ZOON: Yes. Thank you, Barbara, for those
20 questions. For the audience, "theirs" is the Vaccine
21 Adverse Event Reporting System, so everybody understands
22 what that is.

23 CBER believes regulatory research for biological
24 product safety is extremely important. There are issues
25 with respect to not only vaccines but other biological

1 products that are key to not only ensuring their safety but
2 making sure that they are continued safe even post-
3 marketing, and I think that's an important part of our
4 mission and clearly something we wish to do and support to
5 the best our funding allows us to do that.

6 You asked, would we like more. I would have to
7 say, sure, I think it would be helpful and appropriate. But
8 I think we also recognize, as Dr. Henney mentioned earlier,
9 that even with wanting more, that we also have to work with
10 others to make sure that even in the absence of more that we
11 try to get as much information and data to maintain the
12 public confidence in biological products, and I think
13 vaccines are right up there at the top. We're very eager
14 and anxious and are continuing to do work in this area and
15 will continue to foster that.

16 The second one, regarding a penalty mechanism
17 based on the Childhood Vaccine Act, I think we would need to
18 go back and take a look at that with our lawyers at FDA and
19 assess that, but it's something that I'd be happy to take
20 back and look at.

21 MR. BARNETT: With one eye on the clock, I'm going
22 to go and call up the next of the center directors, Dr.
23 David Feigal, who's Director of FDA's Center for Devices and
24 Radiological Health, and Dr. Lee Richardson, who will be the
25 lead respondent from the Consumer Federation of America.

1 Dr. Feigal?

2 **CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

3 DR. FEIGAL: Thank you, Mark. Let me just get
4 started right away with the slides.

5 As Kathy did, I'd like to begin with the mission
6 statement for the Center for Devices and Radiological
7 Health. We have set two mandates, and you can see that in
8 the mission. One is to promote and protect the health of
9 the public by ensuring safe and effective medical devices
10 and also safe radiological products.

11 It is worth pausing for a moment to mention what
12 those are. Those, in fact, are not just medical products.
13 It's actually all consumer products that emit radiation,
14 whether that radiation is microwaves, such as cell phones
15 and microwave ovens used, whether it's radios, televisions,
16 tanning lamps, a very, very large number of consumer
17 products. Approximately 20,000 of them per year come to the
18 market each year in the U.S.

19 The next slide. Now, a vision of how we do our
20 business is actually quite simple. We think that to ensure
21 the health of the public, we need to be active throughout
22 the total product life cycle and that it is not just our
23 business but it's everybody's business. It's the
24 manufacturer's responsibility, it's the health consumer, and
25 it's the lay consumer's responsibility to understand how the

1 product life cycle for devices and radiological health
2 products affect them.

3 Go to the next slide. The scope, it's very broad.
4 The medical device industry covers things ranging from
5 medical equipment, some of it is the kind of heavy hospital
6 equipment like CT scanners and MRI scanners, or small things
7 like scalpels and clamps and tubings. The implants are a
8 particularly important group of products that we regulate,
9 as well as diagnostic devices, including laboratory tests.

10 I mentioned we also have responsibility for the
11 radiological health products, and a special law which was
12 passed some years ago that I'll say a little bit more about
13 in a second is our responsibilities for the quality of
14 mammography. And then recently, we've had some increased
15 responsibilities in the regulation of tests for the clinical
16 laboratories.

17 The next slide. As Kathy showed you a little bit
18 about her resources, let me show you ours in terms of the
19 size of the staff. This is actually the entire history of
20 the agency. Although FDA is a 100-year-old consumer
21 protection agency, the Device Center is one of the newest
22 centers and it was founded in 1976 as the merger of two
23 programs.

24 The yellow part of the bar is the radiological
25 health program and the blue part of the bar is the device

1 program. And one of the things you can see over the 25 or
2 26 years of the history of the program is that there's been
3 a large shift in resources from the radiological health
4 program into the device program. It's gotten to a level
5 that concerns us because we think there are important
6 issues, particularly as there are a larger and larger
7 percentage of products which are being imported.

8 And just in the last couple of years on the
9 radiological health side, we've intercepted night vision
10 goggles that were going to be sold to consumers that emitted
11 radiation, x-rays to the face, that had been used in the
12 Russian army and would have caused cataracts in the users
13 over time. We also recently stopped importation and got the
14 manufacturer to correct microwave ovens that didn't properly
15 interlock so that the microwaves didn't turn off when the
16 oven door was open.

17 The little red bar up at the top is the size of
18 the staff at FDA that runs the mammography program, although
19 this is a program that's much larger than this. Ninety
20 percent of the workforce for this inspectional program is
21 actually done by the States and the red bar is our part of
22 the staff that runs the program. And then up at the very
23 top in the last column you see the very small Clinical
24 Laboratories Act staff.

25 The next slide. I want to just say a word a

1 little bit about how FDA protects the consumer and kind of
2 what are the methods that we use. Some of our
3 responsibilities relate to making sure that the first human
4 use of devices is safe, and we require for those types of
5 products an IDE, an investigational device exemption, to use
6 those products.

7 We're concerned about the safe experimental use
8 during product development, and that before products are
9 marketed for widespread use, that they be safe and effective
10 or substantially equivalent to previously marketed devices,
11 and that products have an adequate adverse experience
12 evaluation by the manufacturer with reporting to us.

13 Another fundamental method in how we protect the
14 consumer is by making science-based regulatory decisions. A
15 large emphasis on that has been, and many of the arguments
16 have been over what's the appropriate level of evidence for
17 making a decision, for example, for something to come on the
18 market or for a new biomaterial to be used.

19 Increasingly in the device world globally, there
20 is a move towards using standards and standard approaches.
21 I think we'll see the blend of these two approaches as we
22 use these mechanisms.

23 And then finally, a very important part of
24 consumer protection throughout the FDA is a category I would
25 call integrity assurance. These are the areas where we deal

1 with fraud, where we deal with products which are
2 manufactured badly, or where we deal with the kind of
3 unacceptable clinical practices that occur during the
4 evaluation of new products.

5 The next slide. This is another way of looking at
6 the FDA consumer protection tools. The oldest and the
7 earliest tools that we have, that actually go back to the
8 turn of the last century, were the insistence that there be
9 truth in labeling. In the 1930s, they actually gave drugs
10 and the very first controls for devices began looking at
11 pre-market safety controls and then pre-market effectiveness
12 controls. We also have consumer protection tools in the
13 Center for Devices for post-marketing studies. We actually
14 have more authorities to require post-marketing studies than
15 there are for drugs and biologics, and the requirements for
16 post-marketing event reporting and conformance to standards.
17 These are all methods that have been designed as consumer
18 protections and work in an interlinked way.

19 Well, what's the role of the consumers? We hope
20 it's going to be an expanding role. We value very much the
21 consumers on the advisory panel members. We have consumer
22 members on all of our advisory panels and have had that for
23 some time. We also appreciate the focus groups that have
24 worked with us on providing consumer and patient oriented
25 information about devices.

1 We also value the reporting of device adverse
2 experiences. There are some manufacturers who would not
3 know about some of the problems that they have if groups of
4 patients who have had problems with devices hadn't come
5 forward to talk to us about those problems, either directly
6 or through the MedWatch forms.

7 And consumers play an important role for us in
8 retrieving failed devices. When we have the opportunity to
9 look at a device, particularly an implant, that's been
10 removed because it's failed and determined the reason for
11 failure, we can improve those devices.

12 And we realize that we're dealing increasingly, in
13 a phrase that a colleague of mine used, with information
14 empowered consumers. The way that consumers use the net now
15 to talk about diseases, to find out about products, to find
16 out about studies is rapidly increasing.

17 The next slide. What I wanted to actually show
18 you at this point is some of the examples of our web pages
19 that are consumer oriented. The majority of our web pages
20 actually contain guidances and the laws and the regulations
21 that are more oriented to the manufacturers and to the
22 medical professional consumers, but this is a site that
23 illustrates some of the things we're trying to do in the
24 future.

25 This is a site that presents consumer-oriented

1 information on LASIK eye surgery, but there is also
2 information for the health practitioner. It's device
3 specific. It has links to FDA labeling. One of the
4 challenges for devices is that there is no compendium of
5 device labels. On the drug side, you know you can always go
6 to the Physician Drug Reference, the PDR, and look at recent
7 copies of the approved labels. But for devices, there's no
8 such resource. And you'll see, and actually, I'll show you
9 other pages. Go to the next slide.

10 If you drill down and you want to say you've heard
11 an advertisement and they're mentioning a specific type of
12 laser, or you're curious to see what's been approved for the
13 different lasers, you can actually drill down and see what
14 has been approved. What are the types of conditions? So if
15 you're considering a surgery and you want to have an
16 intelligent discussion with your ophthalmologist, you
17 actually can get a leg up by knowing exactly what the
18 approvals are and understanding a little bit about what your
19 visual challenges are.

20 You'll notice there are some hyperlinks about the
21 approval number and date. Now, on the next slide, you'll
22 see what happens if you click to that. These are pages that
23 are actually available for all of our PMA products and we
24 hope to make them available for the broader category of
25 approvals, the 510(k) products. These actually provide the

1 actual documents, the labels, the approval order to the
2 company, and the review, and if we could--I thought I needed
3 LASIK there for a second.

4 [Laughter.]

5 DR. FEIGAL: But if we could have the next slide,
6 please. I just drilled down and clicked on the page that
7 takes you to our reviewer's assessment of the product for
8 this indication. So if you're interested to say, well, how
9 much data was there for that indication for this product,
10 you can get down there and you can see that in this case,
11 and I just--down at the very bottom, it says that this was a
12 study that involved 24 surgeons, 21 centers, a cohort of
13 1,276 eyes. And then it'll go on in more detail. It'll
14 describe the side effects, it'll describe the kinds of
15 problems. This, we hope, will add to the phrase of
16 information empowered consumer.

17 And then the next slide is an example. From our
18 link, you can actually get to the manufacturer's site, and
19 although it says up there "eye care professionals only," you
20 can actually print out the patient information bulletin from
21 this site.

22 So we think this kind of page in an area where
23 there's many kinds of devices, and LASIK is one good
24 example, where the consumers often want to make up their
25 minds before they--or at least make a lot of the decision

1 making before they go and see an eye care professional and
2 their source, if they don't have an objective source, is
3 advertising and their friends and neighbors who have had the
4 procedure.

5 Go to the next slide. This is back on the rad
6 health side of the coin. This is our home page for our
7 mammography program, and I just wanted to again show you a
8 little bit of our outreach here. This is also a page that
9 has both information for lay consumers and for mammography
10 professionals.

11 Go to the next slide. This is what the
12 mammography program essentially does. There was a program
13 of voluntary inspection that was proposed when there was
14 first some consumer activism for improving the quality of
15 mammography, but only a fraction of the facilities actually
16 volunteered for voluntary accreditation.

17 And so when we go in yearly, we check the dose, we
18 check the equipment against a phantom that has--it's a
19 device that simulates looking at a breast for masses and
20 tests the ability of the device to find those. We look at
21 the equipment. We look at the qualifications of the
22 technologist or radiologist, the health physicist or the
23 facility. We look at the procedure for patient complaints
24 and we make sure that patients are getting their results on
25 time. And we assure, as best we can, that the hospitals and

1 that the facilities are abiding by requirements that
2 patients can self-refer for mammography. It's actually a
3 requirement that HCFA has that we agree with, and it's a
4 requirement, actually, for HCFA reimbursement that you
5 provide those services.

6 Go to the next slide. This is actually a slide
7 from the middle of a longer presentation on the history of
8 how this program came about. It's actually a user fee
9 program and not a very controversial one. It's a fully-
10 funded user fee program. But the part I highlighted was
11 that part of the reason we have this law is that there was
12 vigorous lobbying of Congress by consumer groups who found
13 the situation of self-policing by the mammography facilities
14 unacceptable. There was just too much variability in the
15 quality of the services.

16 The next slide. This is, again, a screen shot
17 from a mammography page. This is a newsletter that is
18 available in hard copy, but it's actually more convenient to
19 get it from the web. These are just three of the different
20 pages. Up in the corner with the beard leaning on his
21 shoulder, there's John McCrowen [ph.], who heads our program
22 here.

23 Can I have the next slide? This is a more
24 consumer-oriented bulletin. Again, it can be printed out.
25 It's available in hard copy, but it's on the web and it's up

1 to date on the web.

2 The next slide. So we encourage you to use our
3 web pages. Actually, I almost don't need to say that
4 because some of our web pages alone have 100,000 consumer
5 downloads of booklets per month for products that are used
6 only that often per year. And so we think there's a lot of
7 use of this, but we hope to see it expand. We would like
8 feedback on how to have a more effective consumer side to
9 our web page and how to make it more effective.

10 You can give direct feedback to the web if you get
11 to the website. You also can e-mail me just by saying
12 Director@cdrh.fda.gov, and we have a consumer hotline, as
13 well, that you can call and talk to a live body.

14 Let me just close a little bit on the theme of the
15 total product life cycle and how that relates to science and
16 how we do business. This is a diagram that encapsulates a
17 little bit the way that products are developed, that devices
18 are developed. They begin as prototypes. There are some
19 pre-clinical or non-clinical studies that are done. There's
20 clinical testing for some devices. And then manufacturing
21 and marketing for commercial use begins. Products become
22 eventually obsolete or removed from the market, either by
23 market forces or less gracefully if there's a recall, and
24 the cycle begins again as products are replaced.

25 And one thing that's different about devices and

1 drugs is that the average life expectancy of a given model
2 of a device is only about 18 months before it's replaced by
3 the next model of that device. So this is a rapidly
4 spinning process that's going all the time.

5 Go to the next slide. When we want to protect the
6 consumer throughout the life cycle, I think what this
7 implies to us is that we acknowledge our responsibility for
8 safe and effective devices from the concept to the
9 obsolescence of the product. This is a global process, that
10 stakeholders, consumers, the manufacturers, the public
11 health community, all are partners.

12 It's inherently a science process. We intend to
13 work to meet all of our statutory responsibilities and we
14 intend in the center to meet our own standards for quality.
15 We'd like to be able to pass an FDA inspection if we had to
16 do that.

17 Go to the next slide. So if you step back and you
18 look at what are some of the science that surrounds the
19 total product life cycle, you see the kinds of challenges
20 and the types of disciplines that we need to do our work.

21 At the earliest stage, at the concept stage, we
22 need to have people that are expert in design and
23 engineering. If we're designing an implant, for example, we
24 have to understand biomaterials, how are they
25 biocompatibility [sic], what are the toxicology issues for

1 implanted materials?

2 What's the mode of action? Can we develop hazards
3 in the early testing phase that will predict how the devices
4 have to be designed so that they won't fail?

5 We need the clinical sciences within the center
6 that represent the fields of clinical trials and statistics.
7 As manufacturing begins, we need the systems that understand
8 how to manufacture products sterilely. There are hot topic
9 issues in our quality systems. Reuse of single-use devices
10 is currently one.

11 As the product matures and is more widely
12 marketed, we get to rely on the sciences of analyzing events
13 as they're reported and forensic engineering as we evaluate
14 failed devices and problems, and risk analysis at the end of
15 the life of a product and to help in the decision making
16 about what to do about old products. There's actually that
17 done on a grand scale in the last year with Y2K, which seems
18 like a million years ago at the moment.

19 But when you step back and look at this, I think
20 you'll see fundamentally that the regulation of devices is
21 inherently a science-based activity, all throughout the life
22 cycle of the product. Our challenge is to make science-
23 based regulatory decisions; to have effective communications
24 with consumers, with medical consumers, and to ensure that
25 safe and effective medical devices are available.

1 That was my last slide, so let me stop.

2 MR. BARNETT: Thank you, Dr. Feigal.

3 Dr. Richardson, a little response?

4 MR. RICHARDSON: I think you got an excellent
5 presentation in the sense of seeing just how many pieces
6 there are to the puzzle, both from the point of view of the
7 FDA doing its work and also from the point of view of the
8 outside looking in as to what needs to be done and where
9 decision points are and everything from first contacts with
10 potential makers of products all the way through what could
11 be a life of many decades for a particular product. It is
12 an enormous undertaking.

13 One of the thing about devices that occurred to
14 me, and I haven't had any of my consumer friends disagree so
15 far, but here's tossing it to you, too, and that is there
16 isn't really anybody who's interested in devices as such, as
17 a generic category. What it is is a device that does this
18 and works to help out on a particular disease or a
19 particular infirmity, and that's why you're interested in
20 it. If you have a bad knee, you're interested in a device
21 for a bad knee. If you have bad ears, then you're
22 interested in a device for ears. And if you have certain
23 eye problems, you're interested in devices related to that.

24 So the normal organization of consumers is around
25 the problem as opposed to the device, so I think that adds

1 to the challenge, at least in the device areas, with what
2 limited knowledge I do have, to the center to try to deal
3 with really a huge area of constituents who have come in
4 many shapes, colors, and sizes in terms of their problems
5 and issues.

6 One of the things about the consumer definition
7 that we always have to keep in mind is that consumers are
8 coming in at least two forms. Much of the presentation
9 fairly and interestingly looked at the issues of generally
10 informing consumers, or also being able to help consumers
11 who have a specific question search through and find the
12 answers. But those are really two sides of the same coin,
13 consumer information.

14 The first is a whole lot easier. Here is general
15 information about a particular kind of device or a problem.
16 The second one is a search engine and contact people who can
17 deal with persons who have a specific need and would like to
18 get really authoritative information from FDA.

19 And approaches there would be very different. The
20 first can be done by highly informed single individuals,
21 even, in preparing pages on a particular issue. The rest
22 requires an organization that functions and can get you from
23 your first point of inquiry, whether it's through the
24 website or a telephone call or an e-mail, to the place where
25 the answers are. It's also much more resource-intensive,

1 obviously, to try to do a lot of that.

2 I picked up on the concept of product life cycle.
3 It might be interesting, since my real profession is as a
4 business professor, wearing a consumer hat--I'll leave that
5 to you to evaluate--but product life cycle from a business
6 point of view is getting past all this preliminary stuff,
7 such as regulations, that we have to go through in order to
8 get into the market. Then you get into the product life
9 cycle. The motive is to push the process fast, keep the
10 cost down, and then get to market, hopefully finding the
11 customer acceptance.

12 The consumer point of view, I think, is we want to
13 know that everything preliminary to the product life cycle
14 in the industry definition of it, before it's born and
15 becomes a reality offered by doctors or drug stores, that it
16 has been properly evaluated, and then once it enters into
17 the market, which, as we know, is where 275 million guinea
18 pigs sometimes have to really further use it and test it in
19 order to find out small problems but maybe very serious
20 problems that affect particular groups, and it's impossible
21 in an economic sense, perhaps, to do all of the testing in
22 advance. There are just things you find out once you turn a
23 particular idea that's been approved in a laboratory setting
24 or in small-scale testing into a product that's out there
25 being used by real people.

1 Part of what the problem is, of course, is real
2 people not only find occasionally, as with drugs, very
3 serious problems with those drugs or with devices, perhaps,
4 as well as other products that are approved by the agency,
5 but people don't use them as predicted, or they run into
6 issues that are unusual.

7 I want to talk a little bit today about a
8 participation I did with FDA. It happened to be driven by
9 the fact that I'm also a patient in that area with somewhat
10 impaired hearing. One of the issues, I have found, in
11 talking to audiologists is that a huge number of their older
12 patients simply have trouble operating hearing aids,
13 forgetting about how to operate them.

14 I have a family experience that occurred over
15 about 15 years where it became progressively more difficult.
16 Meanwhile, hearing declined and the ability to manage one's
17 two hearing aids, remembering to change the battery or
18 knowing what's the problem or even remembering to put it on
19 or what to do when it seems to be blocked in your ear and
20 all kinds of other issues, these kinds of management issues
21 need to be, or consumer management issues, I think, need to
22 be monitored.

23 Are all those people who are buying and not
24 complaining, are they really getting the use out of it,
25 whatever it is, product or device, in particular in this

1 case? Are they really getting the full use out of it as you
2 anticipated or were told by the company, or are they filing
3 their devices in the nearest desk drawer because they're
4 just so frustrated with it? That's when it's removable,
5 that is.

6 I wanted to kind of address the process of
7 consumer participation. I will go in and out of what groups
8 can do versus what an individual consumer can do in the form
9 of participating in an issue before this center. I don't
10 want to really focus on the particulars of one company and
11 one product. I may slip and tell you the name of the
12 company, but I'm not trying to remake my case. I'm trying
13 to illustrate some points. And, as you might expect, this
14 has to do with a product related to hearing, a device.

15 There are 30 million people in the United States
16 who have some kind of hearing impairment and the degree of
17 this is, of course, measured differently by different
18 people, but it's a large number of people and it ranges from
19 modest to extreme. So the solutions for all these people
20 are clearly going to be different.

21 What is astonishing from the trade associations,
22 the professional health groups, is the small percentage of
23 people who are seeking any help at all. Men, I guess, are
24 worst of all. They just can't admit that they can't hear.
25 And so I as in denial for, I don't know, I admit to five

1 years, but it might have been 15 before I really believed
2 anybody telling me they had said something that I didn't
3 hear.

4 But the point is, from a public health point of
5 view, that maybe the biggest issue in this particular area
6 is making people aware of solutions and dealing with it, and
7 that's not just an FDA charge to do something about that,
8 but it's a huge problem that doesn't seem to be particularly
9 well addressed, but yet people who are expert in the field,
10 like audiologists, will tell you that right off. I wish
11 more people would come in here. It's a serious part of this
12 problem.

13 But in any event, partially to try to find out how
14 the process works and partly because I was interested in
15 this particular kind of product, I found by accident a
16 company that existed so far totally to introduce one
17 product. It was an insertion that you'd have to have an
18 operation, and also you'd have to carry something on the
19 side of your head which really picked up the sound and
20 transmitted it to that device in your ear. But anyway,
21 complicated and it required an operation.

22 When I discovered the company's point of view,
23 they seemed to think it was a panacea for moderately
24 impaired consumers, and I thought, well, that's interesting.
25 Sure, it's trouble with hearing aids, but do you really want

1 to go through at least one operation and perhaps two and
2 have something inserted in your head when maybe another
3 alternative is better? So I didn't know the answer to that,
4 but I wanted to check into it.

5 I found, as I began to test the process on how to
6 do that, that I needed a lot of help and I had been on an
7 FDA advisory committee and I probably should be the one
8 telling other people how to use it. I found getting to
9 specifics about a particular procedure or process in the FDA
10 and where it is and who can I contact, whether it's for
11 consumer information or even technical information, wound up
12 consuming more of my time through the whole effort than did
13 thinking about it and trying to analyze the issues once I
14 discovered them.

15 That may be inevitable to some extent, but on the
16 other hand, maybe that's the way to focus on improving the
17 process, is to make the consumer process simpler. I wish we
18 had a Congress that would do that instead of saying, make
19 the industry's process so simple and fast, but let's maybe
20 focus on the consumer speed and simplicity.

21 If people get frustrated trying to use the
22 process, that means FDA gets less input from either
23 individuals or groups who might, if the process was faster
24 and more efficient, be able to make a better statement and
25 provide more consumer perspectives on a particular issue.

1 So that's kind of a general principle that I saw as I
2 struggled with e-mail addresses and phone numbers and so
3 forth trying to find the answer, and I was calling toll-
4 free. I can imagine someone in the West trying to make all
5 these phone calls and paying the bills as a consumer or a
6 volunteer organization.

7 Another thing I realized as I did this, I was only
8 getting in on the last short part of the cycle. This
9 product has been in development a long time, several years,
10 and it only surfaces for me to find out anything about it in
11 later stages, or at least that's the way it appeared. And
12 I'll come back to that when I tell you what the company told
13 me about another company.

14 MR. BARNETT: We're running close to 15 minutes
15 behind.

16 MR. RICHARDSON: So there's a need, then, for a
17 way to tell consumers and consumer interest groups that
18 issues are coming down the road.

19 I essentially got involved 30 days before product
20 approval for the general market. That was too late to
21 really be effective. I think many consumers and consumer
22 groups are going to be part-time participants in the process
23 and not follow the life of a product through that whole
24 cycle Dr. Feigal mentioned.

25 So early knowledge is needed. There's a need to

1 get the details on the process, who to contact, related to
2 particular issues not simply the general process followed by
3 the agency in dealing with issues in general.

4 Also, I think there should be more referrals and
5 connections to other agencies. For example, FDA and CDC and
6 other elements within HHS are often collaborating,
7 particularly in the life of the product, and more
8 connections to find out where the real action is and the
9 resources are would be helpful. Thank you very much.

10 MR. BARNETT: Thank you, Dr. Richardson.

11 Let me open the floor now to questions from the
12 audience. We'll start over here and go around.

13 **DISCUSSION**

14 MS. COHEN: I thought I was going to be quiet, but
15 I can't. My name--and some of you are already looking and
16 knowing who it is--my name is Susan Cohen and I've been a
17 consumer member of an advisory panel and have been
18 reappointed.

19 I sit in these rooms and I think, this is not
20 America. You talk about websites. We have 43 million
21 Americans without any health care at all, and I'm sure most
22 of those people don't have websites. Why doesn't the FDA do
23 public service announcements on the media? Questions to ask
24 your doctor when they provide medication. This idea of
25 being wedded to a website for me is appalling because we

1 have too many people that have to spend money on other
2 things. So let's be visible.

3 In terms of calling the FDA a consumer protection
4 agency, you know, I spent 15 years in consumer protection.
5 You're not a Federal Trade Commission. You have too much
6 voluntary compliance. When you have phase four, they must
7 comply within a year. If they promise to provide you
8 things, they must sign a written agreement that they must
9 provide that information within a specific period of time.

10 In terms of--and I think that cease and desist
11 agreements are very scary for manufacturers and if they know
12 they have to comply, then they might do something.

13 In terms of PDUFA, I need a little help. I
14 understood that in the budget, the users' fee comes in, but
15 the budget for the staff of the FDA had been reduced and,
16 therefore, you weren't as effective in moving as quickly as
17 you wanted to move, and I'm not always sure quick is that
18 effective, and that perhaps they don't have to supply as
19 much information as they did before.

20 I'd really like to have some clarification on the
21 budget and on this PDUFA fee, and users' fees come from
22 industry and industry has power and you have to have equal
23 power. So if I'm wrong, I'd like to be corrected on that,
24 please.

25 MR. BARNETT: We had a couple of interesting

1 questions here, dependence on the web as opposed to other
2 sources of information for the public, and the situation
3 with PDUFA. Does anyone want to--

4 DR. FEIGAL: Well, let me just comment a little.
5 We use all the media. I mean, in the last month--well,
6 yesterday, I was on Canadian public radio in an area that's
7 also heard in Detroit on the drive-by on a live interview
8 talking about LASIK and consumer considerations about that.
9 In the last quarter, I've been on the Larry King Live show,
10 which requires cable, which some people still may not have,
11 but talking about cell phones. I was in the November issue
12 of Glamour magazine, much to my surprise--

13 [Laughter.]

14 DR. FEIGAL: --talking about the safety of breast
15 implants. So it's not the only media that we use.

16 Your point about public service announcements is
17 well taken. We have not provided the kind of background
18 feeds and the kinds of things that local areas could use.
19 But it's an area--I think, historically, if you go back more
20 than a decade, I think you'll find that the assumption was
21 that FDA provided consumer protection by keeping the
22 manufacturers in line and would work through the
23 manufacturers, not directly with consumers. And I think
24 what you're seeing is the change in that approach as we move
25 forward, and with short presentations, it's not possible to

1 present all the things that we do.

2 But when 100,000 consumers download a consumer
3 booklet in a month, we don't have that kind of postage. We
4 don't have that kind of staff to even stick them in the
5 envelopes. So the web really is also something that I think
6 is very, very important.

7 Just quickly on the user fees. There are
8 different user fee programs. PDUFA is the program in drugs
9 and biologics that pays for approximately 50 percent of the
10 pre-market review for new drugs and biologics, and there is
11 nothing in the PDUFA program or FDAMA that changed the
12 standards, that lowered the standards of the kinds of
13 information that companies have to provide or changed the
14 penalties for providing us misinformation. We have
15 different authorities than the FTC, but we have some that
16 takes manufacturers out of business in a lot quicker form,
17 and the whole difference in rationale. The FTC's consumer
18 protection is based on the notion of business fairness,
19 where ours is based on public health protection. So the two
20 are complementary, and, in fact, we have shared
21 responsibilities between us and FTC.

22 The mammography program is an interesting one to
23 ponder when you think about user fees. It's 100 percent
24 user fee paid for, not 50 percent. It's paid for by the
25 mammography facilities, not industry. If we did not have

1 it, the programs that--the same facilities, before the
2 inspectional program, under the voluntary program, less than
3 a third of them signed up for voluntary certification. This
4 program is an example, I think, of where user fees work well
5 and where we're able to do something that was never done
6 before.

7 How many times do you find a service offered by a
8 physician or a hospital that's inspected on a yearly basis,
9 that meets standards and has a certificate that's required
10 in the lobby and that gives us the authority to take these
11 facilities offline? It's an unusual example. It's in a
12 focused area, but I think it's an interesting combination of
13 successes that would not have been possible to do if the
14 mammography facilities had not paid for their own
15 inspections, and they have an interest in providing quality,
16 as well.

17 MR. BARNETT: Thank you. I feel like a railroad
18 conductor, hoping the train's going to get in on time.

19 DR. FEIGAL: Too late for that.

20 MR. BARNETT: Yes, right.

21 [Laughter.]

22 MR. BARNETT: Let's just take two more and go on.
23 We have one back here.

24 MR. GOACH: Yes, hi. My name is Dave Goach [ph].
25 I'm with the American Society of Radiologic Technologists.

1 In 1981, Congress passed the Consumer Patient Radiation
2 Health and Safety Act. This law mandates that States
3 establish a safety net, a minimum level of education and
4 training for radiologic technologists. These are the hands-
5 on people performing health care radiological procedures--x-
6 ray, CT scan, mammography.

7 To date, 19 years later, 15 States and D.C. have
8 done nothing, passed no laws. We have seen at ASRT
9 documented cases where literally individuals are flipping
10 burgers at Wendy's one week and the next week they're
11 exposing the general public to ionizing radiation. Despite
12 FDA and CDRH's mandated position in protecting the public
13 from non-beneficial and/or unnecessary exposures, it has
14 been inactive, and, in fact, from our experience, unaware of
15 the problem or even the existence of the '81 Act.

16 The CARE Act, the Consumer Assurance of Radiologic
17 Excellence, was introduced this year and it ties a State's
18 compliance to the '81 Act and Federal funding of Medicaid.
19 We expect it to be reintroduced in the 107th Congress. This
20 is not an obscure bill that ASRT is pushing. It's supported
21 by 15 other health care organizations, including the
22 American College of Radiology. It's endorsed by the
23 National Coalition for Cancer Survivorship, the Cancer
24 Research Foundation of America, and the American Cancer
25 Society. It also has other supporters, other consumer

1 groups, veterans' groups.

2 The FDA has deemed it--

3 MR. BARNETT: Excuse me. I'm going to interrupt
4 you for a moment. The ground rules were that we were going
5 to give priority, and we have limited time, to consumers--

6 MR. GOACH: This is my question.

7 MR. BARNETT: --and so what I will ask you to do
8 is to discuss that later, perhaps, with some of the FDA
9 folks during the break or during the lunch hour. It's a
10 good question.

11 MR. GOACH: Well, my question is directly related
12 to the mammography point he made up, if I could just finish.
13 It's two sentences.

14 MR. BARNETT: Okay. Make it a quick one.

15 MR. GOACH: The FDA has deemed that the quality
16 mammography, as one of your slides points out, that
17 technologists are qualified and certified, and we support
18 that. I state for the record, ASRT supports MQSA. However,
19 mammography is only eight percent of all medical imaging.
20 My question is, can we expect FDA to take a proactive stance
21 to ensure the quality of imaging for the other 92 percent of
22 imaging?

23 DR. FEIGAL: Well, thank you for your question,
24 and actually, thank you for your activism on this issue
25 because it's one that actually has kind of slipped off of

1 many groups' radar screens. In fact, the Environmental
2 Protection Agency, which has some responsibilities in this
3 area, and the NRC, which also has responsibilities, have
4 also had steady reductions in the size of their programs and
5 staff.

6 One of the areas we've been proactive and are very
7 concerned about are the increased radiation burns we're
8 seeing associated with the use of more high-tech invasive
9 cardiovascular procedures, the use of the stent that Mr.
10 Cheney had a couple of weeks ago. The level of training and
11 the design of the equipment that delivers that are all parts
12 of things we take responsibility for.

13 But you are right to criticize the fact that the
14 programs have diminished in size rather strikingly and they
15 need repair. They need activism on our part. They need
16 activism on your part.

17 MR. BARNETT: Thank you. One more.

18 MS. HAIRE: Doris Haire, American Foundation for
19 Maternal and Child Health. Is there any FDA regulation that
20 requires the makers of ultrasound equipment to provide the
21 user with the amount of energy emitted within specific
22 ranges of times? As you know, ultrasound is used with wide
23 abandon in this country, even more so in other countries,
24 but we find that many women are exposed to ultrasound hours
25 at a time during labor.

1 DR. FEIGAL: One of the challenges is to give the
2 consumer back information that's usable for them, and I
3 think even many physicians wouldn't know what to make of the
4 amount of energy exposure unless we find some way to
5 quantify it. I say that just to point out how challenging
6 the issue is. It's an issue that we've grappled with.

7 We have taken the stand, for example, that--they
8 were described as boutique ultrasounds that were being set
9 up in shopping centers and other areas where pregnant women
10 could get a photo of their baby while they were out
11 shopping. We took a stand that this was not an acceptable
12 practice. It was not acceptable to have this excess
13 exposure, even though people would say, well, what's the big
14 deal? It's sound waves. And I think that's one of the
15 challenges of radiological health, is that there's issues
16 associated with each type of exposure.

17 MS. HAIRE: Do you agree that the long-term
18 effects of ultrasound on human development is unknown?

19 DR. FEIGAL: We would agree with that. There have
20 not been the kinds of studies that demonstrate what the
21 upper threshold would be at a safe level.

22 MR. BARNETT: Okay. I'm going to call a halt here
23 because we are running behind. We want to have enough time
24 at the end to get these folks back up here and to respond,
25 and so it's time now to take a break. Let's make it ten

1 minutes and we'll be back here at that time. Thanks.

2 [Recess.]

3 MR. BARNETT: Okay. If you'll have a seat again,
4 we'll get started.

5 Our next FDA center in the tank, so to speak, is
6 the Center for Food Safety and Applied Nutrition, Joe
7 Levitt, the Director, and his lead respondent will be Dr.
8 Michael Jacobson of the Center for Science in the Public
9 Interest. So Joe, I'll turn it over to you, and again, we
10 have a 15-minute guideline for presentations and responses.

11 **CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**

12 MR. LEVITT: Thank you, Mark. Of course, to me,
13 15 minutes is about one breath.

14 MR. BARNETT: I know you, Joe.

15 [Laughter.]

16 MR. LEVITT: So you should have told me ten.
17 Thank you. It's a pleasure to be here. Again, I'm Joe
18 Levitt. I'm Director of the Center for Food Safety and
19 Applied Nutrition of the FDA, and Mike, welcome.

20 MR. JACOBSON: Thank you.

21 MR. LEVITT: I've got my prepared presentation,
22 but I want to respond and pull in just some of the comments
23 and themes that came through this morning, and one is, I
24 think, the need that I heard, really, was the need for FDA
25 to open up as much as possible its decision making process

1 to provide the consumer input. And actually, that was one
2 of the strong views that were presented to me when I took
3 this job about three years ago, including from Michael
4 Jacobson, and we've tried to do a number of things to
5 respond to that.

6 We had a broad priority setting meeting where all,
7 if you'll allow the term stakeholders--I heard different
8 views on that--but people that are interested in FDA come in
9 and tell us what they thought our priorities should be, and
10 we utilized that and I'll talk about that and priority
11 setting, and Mike testified and presented there.

12 We had two open public meetings on the whole
13 subject of dietary supplements. You'll hear me talk more
14 about that, and I think actually Irene Heller [ph.] from
15 your staff was there. We had Dr. Henney and I and Sharon
16 Smith Holston chair three public food biotechnology meetings
17 around the country, and again, we had consumer
18 representations at each of those panels.

19 We had a public meeting on the subject of dietary
20 supplement claims dealing with the Pearson decision, and
21 Bruce Silverglade came and spoke at that. This summer, we
22 had, what we called a current thinking meeting on our egg
23 safety on-farm standards that Caroline Smith DeWaal and
24 Richard Wood, and I see Richard is on at the next panel, but
25 was very helpful in that process.

1 We recently held a roundtable discussion with
2 consumer groups and other groups separately on the subject
3 of methyl mercury, and we've continued our priority setting
4 process in a written fashion, and actually we went out and
5 reread your comments from this past August in terms of
6 priority setting for the future.

7 So we have tried to set a tone of open public
8 participation, recognizing from your point of view this may
9 sound like five things over the course of three years, and
10 from our point of view it feels like a lot. So we do have
11 to figure what the right balance is. But at least I want to
12 say we clearly have made an effort, and we've also gone out
13 to other conferences. We spoke at the annual National Food
14 Policy Conference that's here in town. I've been a couple
15 times to the National Consumers League on dietary
16 supplements, and there are more things, but if I do that, I
17 use up my 15 minutes.

18 So with that, I just want to use that as kind of
19 an opening. I'm clearly very engaged. When I took this
20 job, I will say quite bluntly I was told one of the real
21 needs in the foods program was a stronger focus on
22 consumers, a stronger open door policy, and I've tried to
23 take that to heart, though obviously welcome additional
24 input.

25 What I'd like to do today is a few things. Number

1 one, talk a little about the values we're bringing to the
2 organization, talk a fair amount about priority setting,
3 talk about resources--that has come up already today a
4 couple times, talk a little bit about long-term goals.

5 Values--when I came, although I have worked at FDA
6 my whole career, by now about 22 years, my previous job
7 being in medical devices, so I enjoyed the last panel in
8 particular, but nevertheless, when you move into a new job,
9 people want to know kind of, who is this guy? What does he
10 really stand for? What is he trying to bring to the job?
11 And one way I tried to do this was to present the following
12 values to our staff, if you could go to the next slide.

13 Number one is public health and safety, that we
14 are a public health and safety agency and that ought to
15 underline basically what we do. That's why we work here.
16 That's what we want to accomplish.

17 Number two is respect, something you don't often
18 see on one of these slides, but I think with having worked
19 in the Commissioner's office for a decade or so, I've always
20 been impressed with the need to hear respectfully views from
21 many different quarters. The FDA affects virtually all
22 aspects of citizens in this country and I've tried to bring
23 a very respectful tone. Of course, we hope we get that in
24 return, as well, but I put that very high on the list.

25 Number three is integrity. Having lived through

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1 myself, again, in a previous life, the generic drug episode
2 at FDA, if FDA loses its integrity and its credibility,
3 we've lost our essence of what we bring to the table. And
4 so we try to put integrity, again, very much front and
5 center and uphold those high standards. I know all my
6 colleagues at FDA share that.

7 Number four is dedication. If you say nothing
8 about FDA employees, you will say they are dedicated--we are
9 dedicated. People work long hours. People sacrifice
10 higher-paying jobs and we want to be sure that that same
11 dedication is there day in and day out.

12 But it's not just a dedication to working hard,
13 it's a dedication to excellence, to excellence in science,
14 to excellence in a regulatory policy setting, to excellence
15 in communication.

16 And you put all those together, you see the first
17 five letters down spell out PRIDE. We try to instill a
18 sense of pride within the organization, within the program,
19 and I have gotten since then, happily, a lot of feedback.
20 You walk in our building, you'll still see signs like this
21 three years later as part of our culture.

22 MR. BARNETT: Did the acronym communication first
23 and then the words, or the words and then the acronym?
24 That's on my time, not yours.

25 [Laughter.]

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1 MR. LEVITT: Well, it's a little of both. I have
2 found when you put together something like that, you need an
3 acronym or you will get one whether you wanted one or not,
4 and so as long as you're doing it, you can try to put things
5 in a little different order. But I was happy the way that
6 came out.

7 Priorities--when I came, it was very clear--at the
8 first priority setting, it was interesting. We had a lot of
9 people present. The headline of the trade press the next
10 week was, "Everything CFSAN Does Should be a High Priority,
11 Stakeholders Tell Levitt," and, of course, we kind of
12 expected that.

13 But nevertheless, as the meeting went on that day,
14 I pressed one of the speakers that I felt I knew well enough
15 to do this and said, look, give me a break. You know,
16 you're telling me we have to do everything. And he said,
17 look, it's my job as an advocate to tell you what I think
18 you need to do, and that's going to be what my folks want.
19 It's your job to set priorities and it's our job to live
20 with that, but to hold you to them. And I said, that's not
21 a bad deal. I can live with that deal.

22 And so that's what we did. We went and we set up
23 through each year, and I've got my hand-held props, what we
24 refer to as a yellow book, which in my building is known as
25 the bible, and this sets out what we are committing to do

1 each year. The first year, we had our process and we asked
2 the first fundamental question as we looked across the
3 program and asked, where do we do the most good for
4 consumers? That's what I asked not just for the consumers,
5 that's what I asked the industry, that's what I asked the
6 health professionals, that's what I asked our staff. That
7 is why we're here. Where do we do the most good for
8 consumers, and we've tried to lay that out.

9 Unfortunately, the needs are so vast that the
10 list's a little bit half-empty, half-full. Yes, I like
11 what's on the list, but I like all the other things, too.
12 And so what we do to accommodate that a little bit, we have
13 our so-called "A" list and the "A" list are the things that
14 we are dedicated to accomplishing and bringing to fruition
15 that year. And the "B" list are additional areas that we
16 think are important, but either they're ongoing or we know
17 they're early enough in development they're not going to be
18 finished, but we want to give prominence to and show that we
19 do see them as important and there will be time working on
20 it. So we have developed those.

21 And then at the end of the year, we come out with
22 our report card. Actually, that says 2000. Last year, we
23 came up with our first report card for 1999 where we showed
24 we accomplished nearly 90 percent of what we set out on our
25 "A" list. Also interestingly, virtually nothing on the "B"

1 list, but to me, that was okay. That was what we wanted to
2 do. We wanted to focus on what we thought was most
3 important.

4 For this year, we converted from a 12-month year
5 to a nine-month year in order to get on the fiscal calendar.
6 You know, I began in the winter and so I thought calendar
7 year was really neat. But as I got into it, I became
8 convinced that so much works on the Federal budget cycle, we
9 ought to be on the fiscal year. So we said, all right,
10 since this is a nine-month cycle here, three-quarters of the
11 year, our goal will be to accomplish three-quarters of what
12 we set out to do, and indeed, that's what we were able to
13 do.

14 I've got a chart here, which you can't read and I
15 know you can't read it, but each one of these lines adds up
16 to 84 of the "A" list goals here that we accomplished, and
17 an additional 24 of what we call substantial progress made
18 will be carried over into next year, and that was 78
19 percent, so we did meet the goal that we set out for
20 ourselves and the success is really across the board.

21 There are four main categories. Number one is
22 food safety. I think those involved in food safety know
23 that it is of paramount interest. In the back, I see "FDA
24 Reminds You to Fight Bac" as one of our slogans of the
25 program, but we have set out together with other Federal

1 agencies and with State and local counterparts a true farm-
2 to-table program to control all the way back to production
3 and all the way through to consumption.

4 We have through that program devised additional
5 preventive systems for the industry through what's called
6 HACCP, Hazard Analysis Critical Control Points, beginning in
7 seafood, trying to expand into juice, piloting in other
8 areas. We have our good agricultural practices. We've just
9 published a regulation just this past week on egg safety for
10 refrigeration and for safe handling instruction for
11 consumers, again thinking of the consumers.

12 I think what is most important here, because I
13 would spend more than 15 minutes just on this one topic, is
14 that if you think farm-to-table, or from production to
15 consumption, FDA has traditionally spent time at neither
16 end. FDA has spent most of the time at the middle at the
17 food processors. But as we're looking at bacterial
18 contamination, pathogens in the environment, they don't just
19 go to the manufacturing facilities. They're everywhere.
20 And what we've found is where the germs are, we need to be.
21 We need to have a presence.

22 That means we have to go back earlier to the farm,
23 to the production, where I have to say we're not all that
24 welcome sometimes, where we had to devise strategies to make
25 us welcome, and all the way through the consumer. If there

1 are things consumers can do to make food safe, keep food
2 safe, we want the emphasis there, too. That's not to shift
3 the weight. We want the weight to be applied everywhere, if
4 you will. Dave Feigal had a nice slide about it's
5 everybody's business. In food safety, we clearly feel that
6 it's everybody's business from farm to table and have a very
7 extensive program there.

8 Most recently, in this year's report, you'll see a
9 focus, both an increase in inspections, but even more
10 important than the increase is a focus on those facilities
11 that produce food we consider to be at high risk of
12 microbial contamination. And so we have increased those
13 number of inspections.

14 We have also increased vigilance in a number of
15 ways on imports--more work at the border, more inspections
16 overseas, more education overseas. We import a lot of fresh
17 fruits and vegetables from around the world and we have
18 taken, if you will, our food safety program on the road. We
19 have gone down to Mexico, down to South America, most
20 recently down to New Zealand and are moving next year over
21 to the other part of the globe, to Asia and to Europe, so
22 that that is brought to bear. We find importers are really
23 interested because they want to be able to import in this
24 country. We want to be sure there's the same level of
25 protection.

1 Food additives--we were able to receive some
2 additional funds on food additives and we have both a new
3 program underway for what we call the indirect additives,
4 something in a plastic that might migrate into the water or
5 from the packaging, but also for direct food additives. We
6 want to be very clear that this is, and somebody mentioned
7 this earlier, this is not an industry service program. We
8 have a job to do, which is an independent review of the
9 data, and we try to instill in all our reviewers that we
10 want your best advice on what the review ought to be, and we
11 give equal, if you will, kudos whether they say yes or
12 whether they say no. What we care about is, is it
13 scientific? Is it thorough? Is it thoughtful? Is it
14 according to the standards that we put out?

15 Dietary supplements--very important, very much an
16 emerging area, a very challenging area. We spent about a
17 year a year ago going through and developing what we call
18 our dietary supplement strategic plan, which lays out all
19 that has to be done under DSHEA, which was passed in 1994.
20 And what I say is, if there was, in hindsight, being given
21 this law, and I won't comment on the passage of the law--
22 Mike may want to do that--but since we have this law and
23 it's the law of the land, since it is not a pre-market law,
24 in other words, products don't come to us before marketing
25 like they do for drugs or many devices, things go to market

1 and we police the marketplace and it's a post-marketing law.
2 Because of that, Congress didn't think in terms of FDA
3 needing funds or people to do that, and yet most of our
4 center, just talking about food safety, almost all food
5 safety is a post-marketing program.

6 So what we've done is we've said, all right, a
7 post-marketing program is still a regulatory program. This
8 is what it takes. You need safety, you need labeling, you
9 need enforcement, you need to set your boundaries, you need
10 your science base, you need your outreach. We've laid it
11 all out in our dietary supplement plan and the Congressional
12 committee in this year's report asks us to say, all right,
13 you've got your plan. What will it take to fund it
14 properly? And so we're busily finishing that report so we
15 can get that to the Congress and say what our needs are
16 there.

17 Finally, biotechnology. It is amazing how this
18 issue really emerged over the last year. I reference the
19 public meetings the Commissioner and I and Sharon Holston
20 chaired and I think those meetings were not only helpful in
21 the general sense but somewhat sobering, because what we
22 heard at that meeting is consumers are really looking to FDA
23 to, what I call do the public's bidding and not have any
24 perception that we're somehow doing the industry's bidding.
25 That was, I think, a strong message. We wanted to be sure

1 that there is high confidence. We believe in it. We
2 believe the science is there. But we are strengthening our
3 programs in a number of ways to try and respond to that and
4 be sure that we are properly assuring consumer confidence
5 and having our programs both be strong and be viewed as
6 strong.

7 In terms of next year, we'll be coming out with
8 these in a few weeks, but I think primarily we will, number
9 one, try to finish unfinished business. Number two, project
10 the importance of continuity of major programs. Everything
11 I just said you'll see carrying through. There will be more
12 to do on food safety and more on food additives, much more
13 in dietary supplements, biotechnology, and so forth, and I
14 think even as we change administrations, having worked in
15 FDA through a number of changes of administration, a lot of
16 these base programs, I think, continuity is very important
17 to project, and that, indeed, will be the reality.

18 And finally, I would just note that our center is
19 getting ready to move locations. We have a new building
20 that is being built out in College Park right by the Metro
21 stop, a mile from the campus, which will help with our
22 collaboration with the University of Maryland, but just the
23 act of moving takes time and work. We've been in our
24 building for 40 years. Nobody has thrown out a scrap of
25 paper in that time. We are moving both offices and

1 laboratories, which has not been done, and so it is going to
2 be a big chunk of our time and we're trying to work that
3 into our planning.

4 I'm sure I'm behind, Mark. I'm going to try to--

5 MR. BARNETT: Yes. I was going to just remind
6 you, you're just about--

7 MR. LEVITT: I'm going to do this real fast,
8 faster than it deserves, but I can do it fast.

9 The first slide shows when I took this job in
10 1998, so there's going to be an update. What I saw from
11 1978 was basically a reduction of 20 percent, and that was a
12 reduction of 20 percent, this is the people that work in
13 CFSAN. Even with an increase for largely seafood, a little
14 bit for imports, a little bit for nutrition labeling, but
15 this was largely the seafood positions that came in there,
16 but nevertheless, even with that, we have a net decrease of
17 20 percent. That's why priority setting was so important.

18 The next slide, though, shows that if you take out
19 those targeted areas, it's not a 20 percent, it's a 33
20 percent reduction, and most people in the program were not
21 working in seafood and were not working in imports and
22 that's the world they saw. They also saw a program where
23 most people had worked there all those 20 years and so they
24 know Joe left, Mary left, Susan left, Jack left, and they're
25 left. And as you can see, there's a certain demoralization

1 that comes with that.

2 Now, in the last three years, I was lucky. I took
3 the job just after the first set of new resources came in
4 1998. It takes about a year before you see them really come
5 up, but you see they've gone up to 851 last year. I just
6 looked at the new numbers yesterday. For this year, we'll
7 be up around 900. So we will have made up half of that gap
8 in those three years, and that's good. Consumers and CSPI
9 in particular have been very vocal and persistent in meeting
10 with members of Congress and explaining why those food
11 safety funds are so critical.

12 But, there's this part two of the story, which is
13 the next slide. Again, if you take away the food safety
14 resources, and even all of these were pathogen food safety,
15 so that still doesn't include and would include here--
16 pesticides would be included in here and a lot of other
17 areas--it just keeps going down, because, as Dr. Henney
18 said, if we don't get our cost-of-living increase, which we
19 haven't for seven or eight years, and there's a five percent
20 increase, we'll say, that means if we could pay 20 people
21 last year, we can only pay 19 this year. And so even though
22 we need more people, we need people to leave to pay for the
23 people that are here.

24 If that doesn't sound--I'll let you put your own
25 characterization on it, but that's the world we live in. We

1 have had to live with a world that is going down, and when
2 you see that sharp decline there, that really is what other
3 centers in FDA also feel as a result of when we stopped
4 getting--that's when we stopped getting our cost-of-living.
5 So that's where we would have been if we hadn't gotten the
6 new funding. But it also means if there isn't something
7 done, you can see it goes up. It can go down again quicker
8 than you realize. So that is, if you will, a resource
9 update.

10 When you look at the long term--I can do this in
11 one second--we have, if you will, felt we've gotten through
12 a lot of short-term issues. We have things like food
13 safety, dietary supplements they're trying to get on a
14 longer-term track, but if you think globally, we have gotten
15 together the center and dedicated ourselves to a three-point
16 program, what we feel is building a truly world class
17 organization, and there's three parts to it.

18 Number one is we need a strong science base for
19 informed public health decision making, and I think
20 historically we've done pretty well at that, although if
21 there are gaps, we need to plug those and reinforce.

22 Number two, we need to have the capacity to
23 implement those decisions in a timely way, and if there's an
24 area we've fallen down, that's it, and you know that, and
25 there's a long list. As supportive as consumers have been,

1 they've also been quite critical of time it takes and so
2 forth, and I understand that. And so we have this in terms
3 of capacity building. That is really the most important
4 thing in terms of follow-through.

5 And number three, to have a culture shift, what we
6 call towards a culture of accountability, cooperation, and
7 respect. We want to be accountable, but we feel we can do
8 it in a cooperative way and a way that is mutually
9 respectful.

10 And you put that all together, we have declared
11 this a new day at CFSAN. We hope you are feeling some of
12 that out in the consumer community. Thank you.

13 MR. BARNETT: Thank you, Joe.

14 Dr. Jacobson?

15 MR. JACOBSON: Thank you, Mark. Good talk, Joe,
16 and very nice to see you, Commissioner Henney. Thank you
17 very much for holding this meeting and inviting CSPI to
18 participate.

19 I want to focus on two general areas. One is the
20 resources at CFSAN, following up on your slides, and then
21 discuss what we think is inadequate attentiveness to a
22 variety of specific consumer concerns.

23 Over the past quarter century, the complexity of
24 America's food system has increased greatly. Thousands more
25 foods are on the market. More and more foods are imported

1 from around the world. Dietary supplements and functional
2 foods have become the rage. And genetically engineered
3 products have entered the marketplace. Moreover, new laws
4 such as NLEA and DSHEA have given the FDA new
5 responsibilities.

6 Unfortunately, as you explained so clearly,
7 CFSAN's staffing has not increased along with the increased
8 challenges. Indeed, the staffing has actually declined by
9 that seven percent over the last 22 years.

10 According to Mr. Levitt, CFSAN's staffing--that
11 decline is incredible considering all the changes that have
12 happened, and I think it's scandalous. It endangers the
13 public's health and welfare. Plainly speaking, inadequate
14 funding means more contaminated food and dishonest labels,
15 fewer analyses and less research, slower product reviews and
16 more unsafe or untested products.

17 Without adequate resources, CFSAN simply cannot do
18 its job. The FDA's overriding priority regarding CFSAN
19 should be to have its overall budget and staff for both
20 headquarters and field operations, the inspectors, at least
21 doubled over the next four years--at least doubled over the
22 next four years. Let me add a few more details.

23 The FDA is responsible for inspecting over 57,000
24 domestic food establishments and millions of shipments of
25 imported foods. One indication of a problem is that the FDA

1 analyzed one-fourth fewer domestic food samples in fiscal
2 year 1999 than it did in fiscal year 1996, a 25 percent
3 reduction in those analyses.

4 When the President's food safety initiative was
5 first developed, FDA inspectors visited food plants on
6 average once every ten years. Unfortunately, it appears
7 that following nearly four years of funding increases under
8 the food safety initiative, things don't appear to be a
9 whole lot better today. In fiscal years 1998, 1999, and
10 2000, Congress appropriated approximately \$37 million in new
11 money to fund inspections. While that money should have
12 been enough to hire more than 350 new inspectors, FDA
13 staffers familiar with this issue have told us that the
14 inspection staff has not increased by nearly that much. One
15 wonders where all the money went, and from what you say
16 about COLAs, maybe a lot of the money went to COLAs.

17 Now let me turn to some of the specific issues
18 about which CSPI has been concerned. CFSAN is a great
19 believer in HACCP systems, but its seafood HACCP program has
20 serious problems. For instance, 30 percent of seafood
21 plants have poor HACCP systems and another 46 percent have
22 no plans at all. By FDA's own estimate, in 1999, only 54
23 percent of all seafood firms were in compliance with the
24 HACCP program, but that includes the 30 percent of firms
25 that have been exempted from the program entirely.

1 Unlike USDA's meat and poultry HACCP regulations,
2 there are no pathogen reduction standards and microbial
3 testing, which together provide a system check of the
4 quality of the HACCP plans. In addition, while seafood is
5 one of the most hazardous foods that the FDA regulates,
6 seafood plants are visited by FDA only once every one or two
7 years as compared to the continual inspection of meat and
8 poultry at USDA.

9 Although FDA published a proposal for HACCP in all
10 food plants, industry opposition thwarted the proposal. Now
11 the agency is using a piecemeal approach for HACCP
12 implementation, an approach that will take many years, if
13 not decades, to implement and will never really work without
14 pathogen reduction standards, microbial testing, and
15 frequent unannounced inspections.

16 FDA needs to rethink its approach to food safety
17 regulation. In addition, we urge the agency to seriously
18 consider the need for comprehensive statutory reforms to its
19 food safety mandate.

20 Switching subjects now, a recent NAS report
21 concluded that mercury-contaminated fish potentially harms
22 as many as 60,000 infants and children every year. Yet, the
23 FDA has downgraded to its "B" priority list of "we won't do
24 it this year" the development of a better mercury in fish
25 standard. That, unfortunately, is standard operating

1 procedure for CFSAN, which long has failed to provide
2 adequate protection to at-risk consumers, in this case,
3 women and children. We urge CFSAN to act now to set and
4 enforce an action level for methyl mercury in fish that is
5 consistent with the NAS's findings.

6 Another food safety issue is shellfish. Every
7 year, shellfish contaminated with vibrio vulnificus bacteria
8 kill one to two dozen people. Another shellfish hazard,
9 vibrio parahaemolyticus, has caused outbreaks sickening
10 nearly 700 people since 1997. For years, CFSAN has tacitly
11 accepted those deaths and illnesses by not requiring
12 pasteurization or other processes to ensure that shellfish
13 harvested from warm waters in summer months, which carry a
14 near certainty of contamination, to ensure that they're
15 safe.

16 In 1999, the FDA solicited comments on our
17 petition for a zero tolerance for vibrio vulnificus in
18 shellfish but has not taken any further action. Meanwhile,
19 more people are dying.

20 You mentioned genetically modified foods, and
21 those obviously pose new challenges. CFSAN may institute a
22 mandatory pre-market review, but we fear that that will be
23 an opaque, not transparent, process and will not provide for
24 formal approvals. That plan will provide more fuel for
25 biotech critics and will not maximize consumer confidence.

1 The FDA either should establish a mandatory
2 transparent approval process, or if it believes it doesn't
3 have the statutory authority to do so, call on Congress to
4 provide that authority. Senator Durbin and Congressman
5 Kucinich have introduced sensible bills that would give the
6 agency that authority.

7 Food additives, too, raise health concerns. CSPI
8 has filed petitions concerning the approval or labeling of
9 the carcinogen potassium bromate, the stimulant drug
10 caffeine, the allergenic coloring called carmine, diarrhea-
11 inducing sorbitol, and other additives, but CFSAN has not
12 acted on any of those and many other petitions.

13 In addition, in the last few years, unapproved
14 ingredients, including herbs, have been added to so-called
15 functional foods. CFSAN has failed to really go after that
16 problem and nip it in the bud, although it's taken some
17 actions.

18 While foodborne illnesses, GMOs, and food
19 additives are controversial, the biggest cause of disease
20 and premature death related to our food supply is the food
21 itself, all too often loaded with fat, sodium, and refined
22 sugars. The nutrition label may be the FDA's best and only
23 means of helping consumers choose more healthful foods.

24 We applaud the FDA for moving, though slowly, to
25 add trans-fat to the nutrition fats label, a change that

1 could save thousands of lives a year, and we hope that that
2 will come out in this fiscal year, if not the next month or
3 two.

4 Over the past 17 years, per capita consumption of
5 refined sugars has increased by 30 percent. That's probably
6 the single biggest adverse change in our diet and has
7 probably contributed to soaring increases in obesity and
8 also increases in diabetes. Clear labeling, including the
9 listing of percentages of a daily value, could inform people
10 about the added sugars content of foods and help people eat
11 less, as the dietary guidelines for Americans recommends.

12 Health groups like the American Public Health
13 Association, many nutrition experts, and even the U.S.
14 Department of Agriculture have endorsed the labeling of
15 added sugars. However, makers of junk foods have mobilized
16 massive opposition. We hope that the FDA will not succumb
17 to industry pressure and instead will help beleaguered
18 consumers.

19 We're also concerned about other parts of the
20 label. The FDA has long failed to vigorously enforce the
21 misbranding section of the law. Exceptions abound. You see
22 them every time you go to the supermarket. Companies lead
23 people to think that certain products are made of whole
24 wheat when they're not. Other foods are labeled to
25 exaggerate their fruit content. Such tricks cheat people

1 and make it difficult to choose a healthy diet, and they
2 also hurt honest companies. It's high time that CFSAN
3 devoted adequate resources to preventing those kinds of
4 unhealthful, costly deceptions.

5 To summarize, CFSAN, notwithstanding the many
6 things it does well, is not a sufficiently aggressive
7 protector of consumers. It should be CFSAN, not a small
8 nonprofit group, that discovers Cry9C from the BT StarLink
9 corn contamination in foods and solves the problem. It
10 should be CFSAN, not a consumer group, that identifies
11 dishonest labels and unsafe ingredients and gets the
12 products off the shelves.

13 I urge CFSAN to do everything it can to promote
14 the public health, despite sometimes fierce opposition from
15 industry and Congress. The FDA must fight for a doubling of
16 its food budget over the next four years and CSPI and other
17 consumer groups will do everything we can to help you from
18 the outside.

19 Thank you again for inviting me to participate.

20 MR. BARNETT: Thank you, Dr. Jacobson.

21 Let's open the floor for some questions. Go
22 ahead.

23 DISCUSSION

24 MR. SAPONE: My name is Sean Sapone with
25 Childbirth and Family Development. I have a question for

1 Dr. Levitt, although I'd appreciate Dr. Jacobson's response,
2 perhaps, as well. The use of antibiotics in agriculture for
3 livestock is becoming a growing concern. What do you
4 anticipate the future response of CFSAN to be?

5 MR. LEVITT: Can I just pause and say, if you can
6 hold that for the next panel, I think they will be more
7 appropriately able to answer that.

8 MR. BARNETT: Okay. Yes, right here. Right up
9 front here.

10 MR. DRUKER: Steven Druker with the Alliance for
11 Bio-Integrity. I find it hard to believe that FDA continues
12 to claim that genetically engineered foods can all be
13 presumed generally recognized as safe in light of the fact
14 that it knows full well that there is serious scientific
15 dispute today, that the District Court has acknowledged that
16 in the Alliance for Bio-Integrity, Center for Food Safety
17 lawsuit we have shown significant disagreement among
18 scientific experts and the fact is that you were informed,
19 Mr. Levitt, by myself and many of our scientists' plaintiffs
20 during those public hearings that you're boasting about
21 about the extent of scientific concern, independent
22 scientists who are not funded by the biotech industry, and
23 yet the sole legal basis for these foods remaining on the
24 market is the claim of the FDA that there is an overwhelming
25 consensus among science that they are safe.

1 That is a false claim, and although the court
2 upheld you on the narrowest of technical grounds, the court,
3 because it said it would not in this lawsuit consider
4 evidence beyond May of 1992--and by the way, that is
5 probably going to be reversed on appeal--but you have these
6 foods on the market because of what you call a rebuttable
7 presumption they are GRAS, that they are generally
8 recognized as safe.

9 If you will not look at evidence beyond May of
10 1992, it's not a rebuttable presumption. If you want to be
11 responsible, if you want to earn respect for having
12 integrity, then you're going to have to earn it, and the
13 food supply is now being exposed to foods that many experts
14 say could be very dangerous and you know that. If you
15 continue to make this claim and do not regulate them as
16 containing new food additives, then there is something
17 grievously wrong with your approach and history will judge
18 you very harshly because of it.

19 MR. LEVITT: I think the way I want to respond to
20 that is, as was pointed out, this is an issue that has been
21 subject to litigation. The District Court did rule in FDA's
22 favor on virtually every point before it. If that is
23 appealed, then we'll deal with it, obviously, at the next
24 level. We'll see what comes out there. But that position
25 that we've held, as I said, has been upheld in court.

1 I think it is important from our scientists' point
2 of view, we do very much, as I've said, stand behind the
3 safety of these products. We do have a new proposed
4 regulation coming out to strengthen the review program. I
5 would expect you to be commenting on that when it comes out.
6 But it is designed to both strengthen the program and
7 provide increased transparency to the process, and so I
8 guess I would urge us to let that process continue and to
9 try and make advances where we can.

10 MR. BARNETT: Dr. Jacobson, did you want to
11 comment?

12 MR. JACOBSON: I wanted to ask you, Joe, the FDA
13 has said that it's going to come out with a proposal this
14 fall. Fall ends in a week. When do you expect it to come
15 out and might this regulation be delayed by a change in
16 administration?

17 MR. LEVITT: I am still hopeful that it will be
18 coming out this administration. I'm not in charge of this
19 administration, but that's my anticipation.

20 MR. BARNETT: Okay. Another question back here?

21 MR. MENDELSON: This is a similar follow-up. My
22 name is Joe Mendelson. I'm with the Center for Food Safety,
23 a nonprofit organization. I was curious on your priorities
24 to still continue, you mentioned two citizens' petitions.
25 Dr. Jacobson just mentioned one, as well.

1 Back in March of this year, our organization,
2 along with 54 other organizations, many of whom testified at
3 the public hearing, submitted a petition outlining proposals
4 what we think would be inclusive of a good regulatory system
5 for genetically engineered foods and I was wondering if you
6 could comment on whether that's a priority to respond to
7 that, as well, or whether you think that this new proposal
8 is going to be a response to the petition and what type of
9 priority you are giving this citizens' petition. Thanks.

10 MR. BARNETT: Thank you.

11 MR. LEVITT: We do have the citizen petition. We
12 have reviewed it. We do think that our proposal is, in
13 part, responsive to what you're getting at and we would be
14 looking for your comments during the comment period to it.

15 MR. BARNETT: Okay. Let's go one more. Back
16 here?

17 MS. HOCHANADEL: Thank you. My name's Deborah
18 Hochanadel. I'm with the Massachusetts Breast Cancer
19 Coalition, and today I'm also speaking with the voices of
20 several other organizations that are also consumer health
21 groups--Boston Women's Health Book Collective, Breast Cancer
22 Action of California, Breast Cancer Action of Montreal,
23 Center for Medical Consumer, DES Action, National Women's
24 Health Network, Women's Community Cancer Project, Working
25 Group on Women and Health Protection. We just are speaking

1 with one voice. That's why I had to mention all of our
2 groups.

3 We believe strongly that the FDA has a role to
4 play in the genetically modified food debate. Because we
5 represent women who do most of the food buying and who are
6 most likely to be responsible for what children eat, we have
7 a strong interest in the safety of food supply. We urge the
8 FDA to exercise its authority to assure that genetically
9 modified foods reach the marketplace only when they are
10 proven to be safe for all over an appropriately extended
11 period of time.

12 It's tragic, but true, that too much of the recent
13 history of public health is the story of uncontrolled
14 experiments on human health. First, we began widespread
15 civilian use of chemicals developed for wartime without
16 first testing their effects on human health. Next, we
17 experienced and continue to experience increased reliance on
18 pesticides, many of which are known or suspected to cause
19 cancer, among other diseases.

20 Now, in addition to these existing exposures,
21 we're being inundated with genetically engineered foods,
22 even though the long-term human health effects are unknown.
23 The burden of proving that genetically engineered foods are
24 safe should fall squarely on the companies that are
25 marketing these foods. It should not be up to consumers to

1 prove they're harmful. Genetically engineered foods have
2 not been thoroughly tested for their effects on human
3 health.

4 To allow these foods to be marketed makes us once
5 again guinea pigs in vast uncontrolled experiments. We will
6 be guinea pigs no longer. Please be aware of this. The
7 interest of the public's health must be put before private
8 profit. Thank you.

9 MR. BARNETT: Thank you. Do you want to respond,
10 Joe?

11 MR. LEVITT: Well, again, really, all three
12 speakers, all three questions have spoken to the same issue
13 of biotechnology. I think this reflects the broad public
14 interest there is in this issue. In my time at the FDA, I
15 can't remember having public meetings around the country
16 with so many people. The one here filled a room at least
17 twice this size, maybe three times this size.

18 There was a lot of public interest in it and we
19 are both trying to listen, trying to exercise our best
20 scientific judgment and experience in being sure that
21 whatever we're doing as next steps provides for a round of
22 public participation, both in our proposed regulation, which
23 I said we hope will be coming out on the review process, as
24 well as a guidance document we're putting out with respect
25 to labeling. And I think, again, by providing a period for

1 public participation is, as I said, an important part of the
2 process.

3 MR. BARNETT: Again, I'm trying to balance the
4 need to get as many questions as I can from you with the
5 need to have enough time at the end of the day for these
6 center directors to come back and respond to their
7 respondents, and so with that in mind, I think we'll go with
8 one more short one and then go on to the next. Here, okay.
9 Identify yourself and please try to make it brief.

10 MS. SMITH: Thank you. I'm Fran Smith with
11 Consumer Alert, and I've been interested in this discussion,
12 but also earlier Commissioner Henney had mentioned that
13 everything is to be science-based from the FDA's standpoint,
14 and also, I think she referred to the fact that there is a
15 problem in being too risk averse. I think in the
16 biotechnology area, I think there is a danger of a retreat
17 from science and danger of being too risk averse, and we
18 usually, from a consumer standpoint, we always look at the
19 risk of innovation. There always is a risk of new
20 technology. But there always is a risk of stagnation.

21 I'm very concerned when I see the FDA perhaps
22 listening too much to people who would look for zero risk in
23 every aspect of our lives. For instance, biotechnology can
24 reduce the risks of micotoxins in agricultural crops, the
25 most carcinogenic substances probably that can occur

1 naturally, and yet we have no one talking about some of the
2 risks that biotechnology can alleviate.

3 So as a consumer group, I would urge the FDA not
4 to look at only one side of the risk equation but to--I know
5 you phrase it risk versus benefit, but I think you really
6 have to look at risk versus risk and the risk of unintended
7 consequences from a zero-risk approach to regulation.

8 MR. BARNETT: Thank you. Response?

9 MR. JACOBSON: Well, I just wanted to interject,
10 the questioner identified herself as Consumer Alert, a
11 consumer group. Could you tell the audience how much
12 support you get from industry?

13 MS. SMITH: Right now, we get very little support
14 from industry. We have most of our money from individual
15 donors and foundation grants, and I think any food-related
16 industry right now is probably about \$10,000 or less. I
17 resent the ad hominem attack, Mr. Jacobson. You have worked
18 with me in the past and you know that we take consistent,
19 credible, principled, pro-market, not pro-business,
20 positions, and I think--

21 MR. JACOBSON: I wasn't casting any aspersions.

22 MS. SMITH: I'm sorry, Mr. Jacobson--

23 MR. JACOBSON: In the interest of transparency,
24 it's useful to know.

25 MS. SMITH: That is transparency. That is

1 transparency.

2 MR. BARNETT: We asked the question and it was
3 answered. Okay. Joe, any response to that?

4 MR. LEVITT: Again, I think the only way I would
5 respond to that in a way is the same as to the prior
6 response, which is we try to take, I'll say a balanced
7 approach in terms of looking at both what's ahead but also
8 what's on both sides. We need to look at what we know. We
9 need to know that we're not always going to know everything.
10 When do we know enough to go forward? When is it not
11 enough? These are judgment issues. These are scientific
12 judgment issues which we do all the time. Often, they are
13 subject to public criticism or different views from that and
14 that, I think, is simply part of the process.

15 What's important, I think, is that from an FDA
16 point of view, that we strive, too, as Dr. Henney said, as
17 I've tried to reinforce, be science based, think first and
18 foremost in terms of public health and safety, recognize
19 there will be people out there with different points of
20 view, have a public participation loop to be sure we're
21 listening to everybody, and then finally, adopt a position
22 that we feel we can defend, that we believe in, and stand
23 behind that, and that's how I think we provide assurance to
24 the public at large that the FDA is doing the right thing.

25 MR. BARNETT: Thank you, Joe, and that will

1 complete this aspect.

2 I will now call up the next center, which is the
3 Center for Veterinary Medicine. Dr. Stephen Sundlof is
4 Director and his responder will be Dr. Richard Wood of the
5 Food Animal Concerns Trust. By the way, Dr. Henney will be
6 back. She had another meeting, but she will return shortly.

7 If everybody will regain a seat, we'll begin. Dr.
8 Sundlof?

9 **CENTER FOR VETERINARY MEDICINE**

10 DR. SUNDLOF: Thank you. Thank you, Mark, and I'd
11 like to thank my counterpart, Richard Wood.

12 DR. WOOD: Thank you.

13 DR. SUNDLOF: I appreciate the effort to get here
14 and to talk with us today about some of the issues that CVM
15 is dealing with, and Richard has been one of our consumer
16 representatives on our advisory committee and has done an
17 outstanding job and it's really nice to be able to work with
18 somebody like Richard.

19 We're the Center for Veterinary Medicine, maybe
20 the least recognized center of the other four that you'll
21 hear about today, and it's kind of interesting to talk about
22 what CVM's mission is, and that is we have really a dual
23 mission. It's to protect public health, and also we feel a
24 strong commitment for providing for the animal health, as
25 well.

1 We're much like several of the different centers.
2 We have combined responsibilities, even though we're one of
3 the smallest centers in the agency. Like drugs, we have to
4 review and make judgments on the safety and efficacy of
5 drugs, just as the Center for Drug Evaluation and Research
6 does. In addition, we're very much like the Center for Food
7 Safety and Applied Nutrition in that we make food safety
8 decisions, and we even do a little bit of device work,
9 although we don't do any pre-market device work. So we are
10 like at least three other centers and we're unlike CBER,
11 biologics, in that the U.S. Department of Agriculture deals
12 with the vaccine issues.

13 But again, our mission is twofold. Healthy
14 animals will provide for wholesome food. We're concerned
15 about such things as drug residues, and the subject that
16 I'll talk about most extensively today will be in the area
17 of antimicrobial resistance, which a question was just asked
18 of the last panel.

19 We're also responsible for making sure that the
20 products that we approve for animals are safe and effective
21 and for protecting animal health. We have a number of
22 veterinarians that work at CVM, as you might guess, and they
23 all have a very strong commitment to maintaining animal
24 health, but we always put public health above animal health.

25 We had a law that was actually enacted a year

1 before FDAMA, the Food and Drug Administration Modernization
2 Act, and it's called the Drug Availability Act, and it was
3 our reform act. It did many of the same things for the
4 Center for Veterinary Medicine that FDAMA did for drugs. It
5 gave us some additional flexibility to speed up the process.
6 But one area that it did not touch was the public
7 protection, the food safety issues. That Act specifically
8 preserved the existing food safety provisions that we had
9 been dealing with over the past.

10 The process that we use is still very deliberate.
11 The drug must be safe, and when we talk about safety for
12 veterinary drugs, we're talking about safety to the animal,
13 just like a human drug must be safe to patients; safe for
14 the public who consumes food derived from those animals; and
15 they must also be safe for the environment. They also must
16 be effective, just as human drugs must be effective.

17 The applications are reviewed on the basis and
18 such things such as economic requirements are not factored
19 into any of our decisions, even though we require many, and,
20 in fact, most of the same stringent factors that FDA does
21 for human drugs. The economics of the animal drug industry
22 are much, much different. There's no third-party payers.
23 They are generally fair low-profit margin compared to their
24 human counterparts. So there's a different economic dynamic
25 in the animal drug sector. Nevertheless, we do not take

1 those issues into account when we make decisions on whether
2 or not to approve an animal drug.

3 The area I'd like to spend a lot of time talking
4 about, because it is our top priority area, and that is
5 antimicrobial resistance. About six years ago, we decided
6 that we really had to take this issue more seriously in
7 terms of how we regulate these products to ensure that the
8 use of the drugs in animals does not put the public at any
9 undue risk. So we've taken that very seriously. It
10 demanded a tremendous amount of resources in order to put
11 together the kind of program that we thought would be
12 adequately protective of the public health.

13 Fortunately, at the time that we were struggling
14 to put our programs into place, the President's food safety
15 initiative came along and we were able to benefit
16 substantially from that in building the program that I'm
17 going to be talking about today.

18 One of the first things that we recognized is that
19 we needed a new regulatory process by which to evaluate
20 these drugs before they were approved for use in animals,
21 and that document was published in 1999. It's called the
22 framework document. It has a much longer name, but most
23 people refer to it as the framework document. It is
24 available on our website for anybody that wants us to take a
25 look at it. And since that time, we've been working on

1 various pieces of that to try and implement them so that we
2 can build the proper regulatory structure to be able to
3 evaluate drugs on the basis of their ability to cause
4 antimicrobial resistance.

5 We think that having open discussions on this has
6 been very beneficial. We've had, in addition to open public
7 advisory committee meetings, we've had three open public
8 meetings since October of 1999. We had a general meeting on
9 antimicrobial resistance, followed in December by a draft
10 risk assessment that we published on campylobacter and the
11 use of flouoroquinolones in poultry. In February 2000, of
12 this year, we held another public meeting to look at such
13 things as the amount of pathogens that the animals carry
14 with them and how this would impact our ability to approve a
15 drug.

16 We will have our next meeting next month. It will
17 be probably one of the most important meetings that we're
18 going to hold. It's on regulatory thresholds. Where do we
19 draw the bright line from a regulatory standpoint when a
20 drug has produced resistance in animals that are now a
21 public health threat to the public? And so we're going to
22 have a public discussion on that. We expect that--we
23 actually expanded that from two days to three days because
24 we think we're going to need a lot of input from the public
25 on that.

1 One of the areas--we've been dealing with this
2 issue actually for about 25 years and it's a very--the
3 reason that we probably have not made as much progress in
4 that time as we would have liked to is because it's a very
5 scientifically complex problem to try and regulate. It's a
6 natural process that antibiotics do select for bacteria that
7 are resistant to them.

8 There were actually three National Academy of
9 Science studies that were conducted prior to 1996 in which
10 the conclusion was, we don't know. We can't really
11 determine what the public health impact of antimicrobial
12 drugs are on the public health. We have concerns, but there
13 simply is not the kind of data that are necessary to be able
14 to concretely identify what the public health risk is. And
15 they recommended that a lot more studies be conducted and
16 that it would be a substantial cost to conducting those
17 studies.

18 That's when we created a National Antimicrobial
19 Resistance Monitoring System. It is an ongoing, day-to-day
20 surveillance system to look at antimicrobial resistance as
21 it comes from animals, food animals. We take samples at the
22 slaughter facilities through the USDA's HACCP program. We
23 send those to a central laboratory in Georgia, have those
24 analyzed to determine whether or not they're resistant to 17
25 different classes of antimicrobials.

1 We also have the same system going on in the human
2 side through the CDC FoodNet system, so that samples are
3 coming in from the human population. We understand, we can
4 identify what the resistance patterns are in humans, look at
5 it in animals, try to make the determination whether or not
6 there is a correlation between the use of the drug in
7 animals and the resistance developing in people, and if we
8 see that there is a problem, we can intervene early.

9 Some of the uses of the data from this system,
10 which is absolutely critical--I would just say that it is
11 absolutely critical to have this kind of surveillance system
12 before you can have any kind of regulatory program because
13 you have no idea if you take regulatory actions if they're
14 actually having any benefit unless you have a system that
15 gives you feedback.

16 But we use this data to initiate field
17 investigations of outbreaks and there have been some
18 outbreaks that would not have been identified quickly had it
19 not been for this system. It provides background data for
20 risk assessments, which we are relying more and more on to
21 make sound regulatory systems. It has stimulated research,
22 because as we find things, we ask more and more questions
23 about how did we get to this point. It improves the
24 knowledge of our risk factors. Once we identify the risks,
25 then we can look and find out where along the chain the

1 greatest risk may have occurred. It triggers broader
2 research in additional programs that I'll talk about, such
3 as judicious use programs. And the program is expanding
4 through the President's food safety initiative.

5 But the program is--the number one function of the
6 program is to allow us to make good regulatory decisions,
7 and based on this program and based on ours, we have
8 proposed to withdraw one antimicrobial drug from use in
9 animals at this time because we have evidence that
10 resistance is occurring at levels that we consider to be
11 unacceptable. And so in October, we did issue a notice that
12 we intend to withdraw the approval, and that's it.

13 Judicious drug use--we're also cooperating with
14 other organizations, such as the American Veterinary Medical
15 Association, to educate and develop educational materials
16 for veterinarians so that they maximize the therapeutic
17 effect of antimicrobials when they're treating animals, but
18 also minimize the development of resistance, and we are
19 funding some of those educational programs and will probably
20 do more of this in the future.

21 We're also looking at alternatives. Through the
22 approval process, we're looking at alternatives to
23 antimicrobial drugs and such products as competitive
24 exclusion products. These are cultures of bacteria that are
25 administered to animals that colonize the animals'

1 intestinal tract and compete with the bad germs, the
2 salmonellas and the campylobacters and other pathogens such
3 that animals, by the time they become food, should have
4 fewer of these pathogens that might infect the public.

5 And this year in our appropriations bill, there
6 was additional language inserted that said, give these kinds
7 of products expedited review status because they are purely
8 for public health purposes, and we intend to do that.

9 In addition to animal drugs, we also do something
10 in food additives. We generally call those feed additives.
11 We regulate all animal feeds, whether it's dog food, cat
12 food, or feeds that are fed to chickens, pigs, horses,
13 cattle, et cetera. CVM is in charge of the safety of all
14 that food, and again, we are not only concerned about the
15 safety to the animals themselves, although that is a primary
16 concern. We are certainly interested in making sure that
17 anything that goes into animal feeds will be safe to the
18 consuming public.

19 BSE, "mad cow" disease, is one of the areas that
20 we have dealt with. We've done this through regulations
21 prohibiting certain animal proteins from being fed back to
22 cattle in order to make sure that this disease does not
23 occur in the United States.

24 We have other issues, such as dioxin and other
25 substances that can potentially contaminate feed and present

1 a public health risk. This is a huge area. There's--when
2 you think about how much animal feed there is produced in
3 the United States compared to human food, it's staggering.
4 Just the number of animals in the United States far
5 surpasses the number of people in the United States. So
6 it's a fairly broad responsibility.

7 So some of the challenges that we're going to be
8 facing in the future, the whole issue of antimicrobial
9 resistance will occupy our time for the foreseeable future.
10 We hope to make a lot of progress this year. We certainly
11 think that the meeting we'll have next month will give us a
12 lot of guidance to what our next steps should be. In the
13 meantime, we are not sitting on our hands and not taking
14 action where we think that there are problems. Our goal is
15 to protect the public health. We hope we can do this and
16 still meet the needs of our animals who actually rely on us
17 for making sure that they have the products that they need.

18 Finally, I'd just close by saying that the role of
19 the consumer is to continue to participate. This is really
20 important to FDA. This is not something that we just talk
21 about. This is deeply ingrained in the culture of CVM and I
22 think the rest of FDA, is that we want to make sure that we
23 treat the public, all of our stakeholders or our clients or
24 however you want to call it, that we don't favor one sector
25 over another, that we are constantly in touch. When we

1 announce something, we want to make sure that it gets
2 announced to everybody at the same time. We want
3 participation. This is core culture in the organization.
4 We want consumers to be better informed and better
5 protected.

6 I think that I can close there with our following
7 slide, basically repeating what I said. We do have a home
8 page that talks about most of the things that I talked about
9 today. We keep that updated and we encourage people to
10 check in with the website frequently. Thank you.

11 MR. BARNETT: Thank you.

12 Dr. Wood?

13 DR. WOOD: Thank you for this opportunity to
14 respond to Dr. Sundlof and the work of CVM. I also thank
15 you for this meeting. Consumers, as we define ourselves,
16 often participate in larger stakeholder meetings, as Dr.
17 Sundlof expressed, and find ourselves very few in number in
18 comparison to the other stakeholders in the room. Perhaps
19 our voice is heard--I'm sure it is--but we often have the
20 feeling of being overwhelmed and it's good to have this kind
21 of singular and specific focus and opportunity for this kind
22 of discussion.

23 FACT advocates for farm management systems that
24 promote the safety of meat, milk, and eggs, organizations
25 predicated on the assumption that healthy animals means

1 wholesome food for consumers. I'm delighted to see that CVM
2 has adopted our mission statement for themselves.

3 We currently have about 30,000 individual
4 supporters nationwide and we also sponsor a demonstration
5 farming system on 12 farms in Pennsylvania with a salmonella
6 enteritidis control program on these farms for layers, egg
7 layers. We also now are working with hog farmers in the
8 Midwest.

9 FACT has been involved and has responded to many
10 of the CVM activities over the years and I'll comment on two
11 areas at the center. It's work related to antibiotic
12 resistance and to BSE.

13 MR. BARNETT: By the way, both of you said BSE,
14 and there may be people who don't--you're talking now about
15 what people commonly refer to as "mad cow" disease.

16 DR. WOOD: That's right.

17 MR. BARNETT: Okay, for those of you that are not
18 veterinarians.

19 DR. WOOD: And I'm not a veterinarian, either.

20 We applaud the Center for Veterinary Medicine for
21 making antimicrobial resistance a top priority. In our
22 view, a benchmark for giving this concern greater priority
23 for CVM came in a guidance document that really hasn't
24 received much attention in and of itself, but it signaled a
25 significant turning point in terms of CVM's relationship to

1 public health. It's Guidance Document 78, which was
2 finalized, I believe, one year ago today, and it
3 acknowledges that the use of microbial drugs in food animals
4 selects for resistant bacteria that if transferred to humans
5 can have an adverse effect on human health. The guidance
6 document requires that applications for new antibiotics
7 intended for food animals must now assess the potential
8 human health impacts of the drugs, and that's new. This
9 requirement, when implemented, in itself is a consumer
10 protection act, as we see it.

11 The most recent and best example of CVM action on
12 behalf of public health is illustrated in the proposal that
13 Director Sundlof identified in the proposed ban on
14 fluoroquinolones from use in poultry in light of recent
15 sharp increases in resistance to fluoroquinolones in
16 campylobacter bacteria. For those of you in the room who
17 may not be familiar with this, campylobacter is the most
18 common cause of gastrointestinal illness acquired through
19 food in the United States.

20 Physicians have used fluoroquinolones as an
21 essential treatment for foodborne disease since 1986, but
22 fluoroquinolone resistance to bacteria were rare until after
23 1995, when FDA approved the use of these drugs in drinking
24 water for poultry. I think you see the connection. By
25 1998, the CDC found that over 13 percent of the foodborne

1 campylobacter bacteria infecting people were resistant to
2 fluoroquinolones, and last year, the resistance rose to
3 nearly 18 percent, an increase linked to fluoroquinolone use
4 in poultry and which is part of the basis of the new
5 evidence that forms the basis for CVM's notice.

6 On behalf of a consortium of consumer and public
7 health groups, I do thank Dr. Sundlof and the Center for
8 Veterinary Medicine and the FDA for initiating this notice.
9 We now call on the FDA for speedy action in implementing its
10 ban, and the proof of this pudding lies in FDA's timely
11 summary judgment on this question. As fellow consumer
12 advocates, contact Commissioner Henney and ask for speedy
13 movement on a ban.

14 Other CVM examples of implementing the Guidance
15 Document 78 are more difficult for us to identify from a
16 consumer and public health perspective. The framework
17 document was introduced soon after the guidance document was
18 drafted. The framework, if adopted by the agency, can be a
19 useful tool for future approvals. It would provide the
20 context around which consumers and other stakeholders could
21 review and respond to FDA antimicrobial decisions using the
22 same set of assumptions and criteria employed by the agency.
23 Unfortunately, the framework is still not in place.
24 Hopefully, the January meeting that Dr. Sundlof referred to
25 on thresholds will bring us closer to its implementation in

1 some form.

2 Now moving to the other end of the spectrum, in
3 our view, the most glaring failure of the Center for
4 Veterinary Medicine to protect human health is in allowing
5 the continued use of non-therapeutic antibiotics in food
6 animals. We trust that the Virginia Miocene Risk Assessment
7 that is now underway is a first step in addressing this
8 issue, and yet we are still waiting for a response to a
9 petition filed by consumer, public health, and leading
10 physicians on March 3, 1999, requesting that the
11 Commissioner rescind approvals for sub-therapeutic
12 antibiotic uses in livestock that impact human health
13 therapies. The sponsors on that petition were consumer
14 groups that included the Center for Science and the Public
15 Interest, Environmental Defense, Public Citizens Health
16 Research Group, Union of Concerned Scientists, and FACT.

17 Many of these same groups, among others, supported
18 the \$3 million appropriated to CVM for its fiscal year 2001
19 antibiotic resistance work, and FACT was pleased to learn
20 that the center apparently intends to use these funds to
21 target several approved animal drugs for safety review,
22 followed perhaps by possible withdrawal from the market.

23 There is no question about FDA's authority to
24 withdraw a drug from the market, but if CVM needs a
25 framework for action on its prior approvals of non-

1 therapeutic antibiotics, we encourage FDA's support of
2 legislation similar to that introduced in the last session
3 of Congress by Sherrod Brown. This legislation directs that
4 essential antibiotic drugs are not to be used in livestock
5 unless there is a reasonable certainty of no harm to human
6 health, Guidance Document 78. The legislation clearly
7 provides FDA with the statutory authority to act and gives
8 both FDA and the industry a time line for such a review.

9 Finally, we call for the public disclosure of
10 antibiotic sales information. Health officials have
11 indicated that a major obstacle in assessing the link
12 between animal drug use and rising resistance is the lack of
13 data on how extensively antibiotics are used in food
14 production. One only has to look at the debate that's going
15 on right now around fluoroquinolones in poultry, where on
16 the one hand, health officials are finding resistant
17 campylobacter in broilers at the supermarkets, and yet the
18 poultry industry is saying that they aren't using the drug
19 all that much. How much is Baytril being used on poultry
20 farms? What is the volume of doses used per hen? Regarding
21 sub-therapeutic drugs, licensed feed mills report the pounds
22 of feed sold, but how much active ingredient is in the feed?

23 It is time for the industry to stop playing shell
24 games when it comes to their food animal use of antibiotics
25 impacting human health. CVM must require the reporting of

1 specific sales data that could also be available to the
2 health community and to the public.

3 The public has at least two important functions
4 when it comes to defining how antibiotics are to be used
5 with animals. First, consumer representatives should be at
6 the table along with scientists and other stakeholders to
7 define the criteria by which an antibiotic for food animals
8 is approved. For example, should resistance testing be a
9 part of the approval process? What kind of provisions are
10 in place if resistance were to occur?

11 Second, consumer representatives should be at the
12 table to help identify the threshold for antibiotic
13 resistance. At what point of resistance is an antibiotic to
14 be considered a threat to public health? These and other
15 roles are critical for consumer involvement.

16 FACT is also concerned about any steps taken to
17 expedite the animal drug approval process. Once a drug is
18 approved, it is rarely removed from the marketplace and the
19 process of removing that drug can often take years. The
20 approval process must not be truncated for expediency's
21 sake. Both the public and animal health may suffer in the
22 long run and may ultimately lead to unhealthy animals
23 producing unwholesome food.

24 I've been at FACT since 1995 and in these few
25 years, I've heard CVM officials on two occasions lift up a

1 concern of great importance to consumers as CVM's top
2 priority. Today, we heard that antibiotic resistance is
3 CVM's top priority, and as I've stated, FACT welcomes that
4 priority and that emphasis.

5 The other recent occasion for CVM setting up a top
6 priority recently followed the adoption of the rule to
7 prevent the occurrence of BSE, which is bovine spongiform
8 encephalopathy, or "mad cow" disease, in U.S. cattle. At
9 that time, the center vowed to implement an intensive
10 inspection process of feed mills and rendering plants and
11 many steps have been taken by CVM in that regard. Most
12 notably, I understand that 9,000 inspections of feed mills,
13 cattle producers, and renderers have been completed over the
14 last couple of years.

15 I remember taking part in a teleconference
16 designed to train feed mill operators in this regulation.
17 But a recent GAO study found that more needs to be done.
18 The GAO reported that in these inspections, the FDA found
19 over 18 percent of the firms surveyed were not aware of the
20 regulation that was adopted in 1997, including 11 percent of
21 the renderers. So much for the teleconference. Twenty-
22 eight percent of all those surveyed did not label their
23 products with the required cautionary statements that the
24 feed should be not fed to ruminants. Twenty percent of the
25 firms did not have a system in place to prevent commingling

1 of ruminant feed materials with non-ruminant feed materials.

2 Further enforcement steps must be taken by CVM as
3 soon as possible. It is time to move beyond education and
4 warning labels to enforcement and to the penalty stage. I
5 understand that a rule addressing animal feed is being
6 drafted, but there's no time line for it being published or
7 even discussions with stakeholders, as far as I know.

8 At the same time, the science around the "mad cow"
9 disease, BSE, continues to emerge. Careful attention needs
10 to be paid to the eight new BSE cases in Britain or the
11 spread of the disease may possibly be linked to cow blood in
12 cattle feed, a protein source that is allowed in feed for
13 U.S. ruminants.

14 In conclusion, we will soon see a change in the
15 administration, I think. Some significant building blocks--
16 significant building blocks--to protect public health have
17 been put into place over the last few years by CVM. The
18 next administration must cement those blocks together so
19 that CVM can fully respond to both animal and human health.
20 As these steps take place, it is our hope that consumers are
21 involved in the building process all along the way. In our
22 view, the greater the involvement, the better the final
23 structure. Thank you.

24 MR. BARNETT: Thank you, Dr. Wood.

25 Before we go to lunch, I want to open the floor to

1 questions and comments again. Do we see a hand? Yes, sir,
2 right up on the aisle. Identify yourself, please.

3 **DISCUSSION**

4 MR. GOLDBERG: Adam Goldberg, Consumers Union. We
5 do believe that FDA should act to phase out medically
6 important antibiotics that are used in animal agriculture to
7 promote growth and compensate for unsanitary growing
8 conditions. To that end, the fluoroquinolones. We do think
9 that FDA should act promptly to finalize its proposed ban
10 and I was just wondering what the time line looks like.

11 DR. SUNDLOF: Well, the next time line is January
12 2, and that's when the one company that has the approval has
13 to provide us with the basis for their position that the
14 drug is safe. At that time, we review the information that
15 they provide us and that time frame will largely depend on
16 how much information they provide, but we will be reviewing
17 that as quickly as possible.

18 Then following that, we will publish a notice of
19 hearing and that notice of hearing will state the time and
20 the place and the date of the hearing, at which time there
21 will be a hearing before an administrative judge and that
22 process--how fast that process occurs is largely a matter of
23 the courts at that point, so that I don't have much control
24 over the legal process at that point. But it is our
25 intention to move as quickly as possible.

1 MR. BARNETT: Another one? We have no takers? If
2 that's the case--oh, we do have one more. Okay.

3 MR. KAY: My name is Brett Kay. I'm with the
4 National Consumers League, and the question I had, Dr. Wood,
5 you had mentioned that a large portion of renderers and
6 others in the animal feed business had not been aware of a
7 lot of the regulations concerning ruminant feed and other
8 issues related to BSE and I just wanted to ask Dr. Sundlof
9 what the FDA is doing to follow up to ensure that all of the
10 animal feed manufacturers, particularly those renderers, are
11 aware of the regulations, particularly ruminant-to-ruminant
12 feed and other issues that might affect BSE.

13 DR. SUNDLOF: The idea is to--let me just tell you
14 what the whole plan is. The whole plan is to inspect 100
15 percent of all firms that handle these prohibited materials
16 except at the farm level, where there will be just too many
17 farmers mixing feeds. But we do a lot of spot checking on
18 those. But everybody that's a renderer has been inspected,
19 is my understanding. Those that were found not to be in
20 compliance are being reinspected to make sure that this time
21 they are in compliance.

22 It's most important for the renderers to be in
23 compliance, because if they don't label their product,
24 everything downstream from there, people can't comply with
25 the rules. So we take this issue fairly seriously, and

1 having 100 percent inspection is pretty unusual for FDA, but
2 you only have to look to Europe to see what kinds of
3 problems it can get into.

4 And the issue in Europe is it wasn't that they
5 didn't have strict laws. The problem seemed to be--the
6 reason that we're still continuing to see the disease appear
7 in Europe is because they didn't have good enforcement. So
8 it was an enforcement issue. At least, that seems to be the
9 thinking. I think we've learned a lesson from that and we
10 intend to make sure that that same problem doesn't occur
11 here in the U.S.

12 MR. BARNETT: Did I see another hand up here? If
13 not, let's go to lunch and let's be back and begin again at
14 1:30.

15 [Luncheon recess.]