AFTERNOON SESSION

MR. BARNETT: If you'll find your seats, we'll get started again.

Our next center in the FDA is the Center for Drug Evaluation and Research and its Director, Dr. Janet Woodcock. Our lead respondent will be Cynthia Pearson of the National Women's Health Network. Dr. Woodcock, I'll leave it to you to start and we have a 15-minute guideline for time.

CENTER FOR DRUG EVALUATION AND RESEARCH

DR. WOODCOCK: Thank you. Good afternoon, everyone. It's a pleasure to be here. I was asked to speak, as were the other speakers, about FDA's priority, and for me it's in the area of drugs.

What I want to say to you is the following. We think our priorities are the public priorities, or we try to make our priorities the public's priorities. We feel that's what we're here for, is to serve people who take medicines and what their priorities are. And what they tell us, what they have told us, because we have tried to listen very carefully, people want safe, effective, cheap, fast, and available drugs, and they want them to be accompanied by extremely clear and unbiased information about the drugs.

The public definitely wants safe drugs, and the emphasis that people put on the safety of drugs really

relates to how urgently they feel they need the medicines. People who have severe illnesses or feel seriously compromised by their illness tell us, in general, that they are willing to assume greater risks than people who are going to take a medicine for a headache or for a toothache or something, and that balance is something that's very difficult for us to manage because people want the risk of medicines to be managed.

That's really the definition of safety, that adequately safe drugs are put on the market, and for those drugs that are on the market, all of which have risks, that those risks be managed. In other words, people are informed of the risks, they understand what measures can be taken to avoid the risks, they feel their doctors are fully informed about the risks, and so there is a complete understanding of what risks are taken in order to get the benefit.

Another thing the public wants, another part of safety is that the quality of medicines be assured, and the issues around quality most recently have arisen with regard to imported drugs. There is a concern of counterfeiting drugs and those counterfeit drugs being imported from outside the country. There is concern about the quality of drugs that are perhaps manufactured around the world and imported into this country, and FDA and the Center for Drugs and the field organization are in charge of making sure that

that quality is assured. That's definitely a big part of safety of medicines.

Another part of safety is that people are safe because health fraud is being pursued. Over the recent years, FDA's ability to deal with health fraud has lessened because of our resource constraints. We've also shifted a lot in the drugs area of our health fraud resources into pursuing drug sales on the Internet, which was identified as an emerging threat to people's safety, particularly the sale of prescription drugs directly to consumers over the Internet. And so while one part of safety is the issue of dealing with health fraud, I think that's something we haven't been able to address as stringently as we would like in the recent years.

And also, appropriate advertising. Part of safety is that people are not misled through advertising about the benefits or the safety of the drugs that they use, and, therefore, a regulation of advertising to ensure that it's appropriate, truthful, and balanced is an important part of safety.

Now, there's been some concerns about one aspect of safety which relates to newly-approved drugs and consumers have raised this point repeatedly, that they're concerned that the increased speed of review of new drugs is leading to increased drug withdrawal rate. And we've

published this information before, but I thought I'd put it up here.

You can see on the far right-hand column, there is a percent of drugs that have been withdrawn from the market based on the year they were approved in five-year brackets, and you can see that the rate of drug withdrawals has not increased over the years. Nevertheless, the number of drugs that have been approved has increased, and, therefore, the absolute number of drugs withdrawn is going up.

In addition, FDA and the Center for Drugs, I think, is taking a more aggressive attitude toward drug safety over the last four or five years. This has resulted in older drugs being withdrawn from the market as well as newly-approved drugs being withdrawn from the market, and partly ironically, I think, this increased posture toward drug safety has led to increased concern, because more drugs actually have been withdrawn overall. But these drugs have not been weighted toward recently-approved drugs.

Now, lately, over the past few years in the context still of safety, the FDA has been talking about risk management, and we mean a number of things by risk management. We think it's no longer acceptable for anyone to just say that drugs are safe and effective because that is misleading. It's not possible for any drug to be 100 percent safe.

We have been aiming toward a broader recognition throughout people who take medicine and the treating community, the clinical community, of the risks of drugs that are out there. These risks are detailed in long lists within the package insert, which many of you may have seen if you look in the PDR, but we don't feel that the recognition of these risks has really penetrated into people's consciousness the way it needs to be to be dealt with.

Another aspect of overall risk management of drugs is the fact that for many drug classes and for patients with many different diseases, there are a lot of alternatives available. And once that happens, once there are many alternatives available for a given condition, you start thinking more about looking for the most safe alternatives, the best alternatives, rather than concentrating on getting some drugs out there to treat the condition. And this is somewhat of a different ballgame than just looking at overall effectiveness and safety. This is looking at which drugs stand out as far as having an inferior risk profile, and what should be done about that.

And the consequence of that, and that's my third bullet, is that what you're going to begin to see is that some older drugs will become obsolete as safer drugs are approved and appear on the horizon, and our attitude in risk

management is that we can't just sit by and hope that the clinical community won't use these drugs. We need to move aggressively and perhaps get these drugs off the market.

If I can go over just a couple, Mark, if I'm keeping in my time here--

MR. BARNETT: No, we're okay. I'm watching.

DR. WOODCOCK: He's looking at his watch already--at recent safety-related actions that we've taken with respect to drugs, the drug Rezulin was removed from the market. It had been the first in its class of a novel class of anti-diabetic drugs, but it came with a cost, a price of a rare but often fatal liver toxicity and that drug was removed from the market when safer drugs in the class became available that offered the same benefit but did not carry that risk.

Phenylpropanolamine, or PPA, you all may have read about. That was an over-the-counter ingredient. It was in--many of you have taken it. It was in many, many cough and cold type of remedies and some weight loss, over-the-counter weight loss drugs. It had long been under a cloud, though, because of possible association with a risk of hemorrhagic stroke, and when additional epidemiologic data became available that strengthened that connection, we put out a public health announcement urging people not to take this medicine and many firms have withdrawn it from the market.

We will have to go to rulemaking to actually remove it from the market and we intend to do that.

The drug Accutane, again, another safety-related issue. The drug Accutane has been on the market for several decades. Accutane is a major human teratogen, which means it reliably causes birth defects, serious birth defects when taken in a certain stage of pregnancy, specifically in early pregnancy. The FDA over all this time, despite fairly significant efforts, was still getting reports of babies being born with birth defects as a result of Accutane, an event that is entirely preventable. In addition, the drug has recently, over the past six or seven years, felt to be associated with some severe psychiatric side effects.

As a result of all this, we had an advisory committee this summer and we're implementing with the company a really unprecedented series of restrictions on Accutane distribution that will be designed to try and overtly prevent birth defects from happening at all, and also will make sure that anyone who takes Accutane is completely aware of the risk of the psychiatric effects as well as other major side effects that Accutane may carry.

Finally, the drug Lotronex was recently withdrawn from the market. That was not our preferred option with Lotronex but it had developed some serious side effects that were found to be more serious after the drug was marketed

and we could not agree with the firm on an adequate risk management program for this drug. But again, as an example, we rapidly responded when safety information became available.

I could go on and on about drug safety. There are so many facets to drug safety. Another aspect that we're working on in drug safety and many other people are is the whole issue of medical errors. This was highlighted by the Institute of Medicine report that came out a year ago. The AARP just put out a booklet on this where they said that about 50 percent of the adverse events in hospitalized patients that were preventable in the elderly were due to adverse drug effects. That's 50 percent of the bad errors that occurred to elderly in the hospital.

And most of them were not what you read about, where the pharmacist gives the wrong dose to the patient. These were errors where the elderly were given inappropriate drugs, drugs that are known to have a bad effect in the elderly, or where the elderly were not monitored appropriately to make sure that bad side effects did not develop in them.

So one of the problems FDA's facing in wrestling with in the area of medication safety is how medicines are actually used out there. How are they used? How can they be used safely? This is, as the Institute of Medicine has

identified, this is a very serious problem for a health care system.

Now, we all agree that this problem is not going to be amenable to blaming different people--blaming doctors, blaming health care systems, blaming the FDA for the way medicines are used. There is a consensus, I think, of people who are working on this that we have to get beyond blame and go ahead and try to make serious modifications in the way health care is delivered that focus on safety, and that would help us tremendously at the FDA in medication safety, if this can occur.

Unfortunately, one of the things that probably for medicines, greater safety of medicines, is going to partly be coupled with decreased prescribing autonomy for the clinical community, and this is a very difficult subject that we are trying to deal with and we expect that--we already have gotten a great deal of push-back on this issue where we're trying to do restricted distribution for certain drugs.

Now, the public doesn't just want safe drugs, and I hope I've given you some understanding of the different fronts that we have to labor on to make sure that drugs are safe. They want effective drugs, drugs that work, and that is a long fight that we've been engaged in for 40 years, ever since the drug amendments were put into effect

requiring that drugs be studied to see if they work. We still are working to make sure that drugs get studied adequately and they have proper end points and standards when they're approved to make sure that drugs are effective and we know enough about their effect.

Right now, I think the clinical pharmacologists tell us they don't believe the Center for Drugs approves drugs that aren't effective. So in some ways, that battle has been won, but there are new battles. Effective for who? We know when we approve a drug, it's studying a population. It's not going to work for everybody, and there might be ways to identify who that drug will work in and that's probably one of the next frontiers in effectiveness.

The next bullet we have, the similar issues as we do for safety and effectiveness in that some drugs are becoming obsolete in their effectiveness. The public definitely wants the drugs of today. They don't want 100-year-old drugs unless they're still really good, like maybe aspirin.

Quality that I talked about earlier is also important for maintaining effectiveness of drugs, and we still have problems, different quality problems, and the FDA labors to oversure [sic] the manufacturing of drugs, proper manufacturing, and make sure that quality is maintained and that effectiveness is maintained for people.

But overall for the public that takes medicines, it's most important that we focus on improving the armamentarium, in other words, improving the quality, the effectiveness, safety, quality of drugs that are available to the public.

MR. BARNETT: We're getting close.

DR. WOODCOCK: Close? Okay. I'll go really fast on the next few slides.

The public also has told us they want drugs to be available to them and accessible, and I know some of the consumer groups in this room may have different opinions on this and I'll be very interested to have a discussion about this. Everybody agrees in general that generic drugs, if they're adequately equal and switchable to the innovator versions, provide economic access and lower the overall costs. That's been proven of drugs. And so our generic drug program is very important to us in lowering the cost of drugs and providing access to drugs.

OTC drugs, for a large segment of the public, including me sometimes when I want some drug, it's very nice and convenient to be able to get that drug over the counter and not have that huge barrier to some people to having to get it through the health care system. If self-care can be delivered by the person to keep that drug safe and effective, that is very important to access.

Many people feel that availability of drugs shouldn't be impeded by delays in the review process, and that's the other side of reviewing drugs "too fast," is that prolonged delays in the review process that occurred in the past delay the availability of drugs to people in the United States.

And finally, a lot of people want investigational drug access. That's what the public tells us, people who are sick and don't have alternatives. We are continuing to work on this to make this work safely for people but also to give them access to investigational drugs.

As far as low-cost drugs, we struggle in our program because we have ongoing efforts by the innovator companies to thwart generic competition and we are spending a tremendous amount of effort that we didn't have to spend in the past, the legal effort and our staff's scientific effort, in order to deal with these disputes. It takes a tremendous amount of time. We are under pressure from the pharmaceutical industry because they actually have a need to decrease their research and development costs because they are under price and cost pressure.

And finally, there are many people who believe that direct consumer advertising is driving up costs, and I want to talk a little bit in the next slide about direct consumer advertising. I want to point out, because people

may not realize this, it's always been legally permissible in the United States to do direct consumer advertising. This isn't new, it's just the volume of it that is new and it's in your face now--I saw some on the Metro when I was riding down here--and people are disturbed about this.

We are trying to study the effects of this increased direct-to-consumer advertising. We find that it's a double-edged sword. We find that untreated populations, of which there are many in the United States--probably half the people in this country have cardiovascular disease are inadequately treated, and we're talking about life-saving therapies that aren't reaching them. On the other hand, there's a concern that direct-to-consumer advertising will lead to inappropriate prescribing of drugs and, thus, increased side effects and so forth.

Unfortunately, CDER doesn't have the resources to do the scientific evaluation of the impact of direct-to-consumer advertising that we would like to do, and so much of the debate on this is left at just debate and different people's opinions and we don't have a lot of data on the scientific impact. We have data on the cost impact, but that's only part of the equation.

I'm almost done, Mark.

We also have heard the public wants good drug information and they would like to hear from FDA about

medicines because we are an unbiased source, at least presumably unbiased source, of information about medicines. We have been trying more in the recent years, in the recent six years, sa, to provide more information, but we aren't doing anywhere near what we would like to do.

We had a public meeting, I think three years ago in this very room where a representative of the pharmaceutical industry stood up and said CDER has no business informing consumers about drugs. So there are different groups who have different opinions about what we should be doing, but what we've heard from the public is that they would like to hear our assessment of medicines. And, of course, we do much of that assessment with the taxpayers' money.

This just goes through--we're really trying in many ways. The over-the-counter label is being implemented on over-the-counter products now. It's going to look like the food label. It'll really give that information on over-the-counter products in a way that people can understand.

We hope to propose very soon a revision to the drug package insert, the part that you read in the PDR or is stuffed in the box of your drug, the long, skinny thing, that would make it readable. I see some smiles in the audience. It isn't readable now, we agree, we understand, but we hope to propose that. We have to do that under

rulemaking.

The med guides, which we finalized the rule last year, which allows us for a handful of drugs every year to mandate consumer information that has to be given out to the patient by the pharmacy, we think that's a good start, and we're going to try to strategically use different regulations and guidances to figure out ways to get more information out. We understand there's a great hunger there for balanced, credible information on drugs.

The last one. Finally, I'm supposed to talk about our goals and priorities for 2001. I'm not going to bore you with our very specific initiatives, but internally, we need to support our people and we're working on that as part of the Commissioner's science-based initiative. We are improving our processes. In particular, we're doing more things electronically, many more things, including our processing of all the 250,000 reports of adverse events from drugs that we get every year. You can see that you definitely need a computer system to process and manage all those. And we're doing investments in our future as an organization.

But externally, I have told the center that one of my highest priorities this year is to have better outreach and build those external ties, really listen to all our different constituencies, medical community, nursing,

pharmacy, consumers, patient groups, and so on, build those ties so that we really are making sure that our priorities are your priorities. Thank you.

MR. BARNETT: Thank you.

Ms. Pearson?

MS. PEARSON: I'm not using any audiovisual aids, so if you want to bring the lights back up, it might help people stay awake after lunch. Thanks.

I'm Cindy Pearson. I'm the Executive Director of the National Women's Health Network. Many people in the room know the Network, but for those who don't, we are a national organization advocating for policies that protect and promote the health of all women and which also provides evidence-based independent information to empower women to make fully informed health decisions. We're supported by a membership of nearly 10,000 people nationwide and we accept no money from companies that sell pharmaceuticals, medical devices, dietary supplements, health insurance, alcohol, or tobacco.

I'm very pleased to be able to lead off the consumer response. I appreciate also very much having a chance to see Dr. Woodcock's planned remarks in advance, which I know everyone did. They're up on the website. I appreciate that. We're trying in these remarks to sort of span a response to the issues you've brought up and bring up

some other issues that are of concern to us specifically, also other consumer groups that we network with, many of whom are here in the audience, and I hope we'll get a chance to have a dialogue going after our opening response.

Since the Network was founded in 1975, and there are people who were involved in that era right here in the audience, we've closely monitored CDER. At times, we've been among the sharper critics, but we also feel that we are strong advocates for making expanded resources available to the center to pursue a goal that we believe we share with the FDA of ensuring that the drugs that are available to U.S. consumers are safe and effective. And so the comments I'm giving today reflect that tension, that at times we are critical, but we also believe that CDER is underfunded and they're not able to do the job that it wants to do.

So to lead off with drug safety, Dr. Woodcock has already mentioned and already put some data up about consumers' expression to the FDA that some consumers believe drugs have become less safe under the current era of pressure to approve them quickly, and we can read statistics. We acknowledge what your statistics show us. But I think we need you to hear also that we believe we see other ways in which the safety process has been overridden, at least at times.

We believe we can see examples and can discuss at

length examples in which drugs have been approved, even after FDA review staff have recommended against approval. Drugs have been approved when FDA staff was not given sufficient time for approval due to foot dragging in submitting data on behalf of the sponsor. And drugs have been approved after being recommended for approval by the advisory committee, but the advisory committee was not given access to all the important information that the agency and the sponsor had.

And so even, I think, underneath the summary statistics, consumers who watch the FDA can believe, as we do, that there are some problems that are still there that could potentially be changed and not be there.

We would also like, in terms of drug safety, for the center to work more closely with consumers and consumer advocates during the approval process. We believe that the consumer representatives that are currently on the drug advisory committee should have a vote. We believe that there should be more open public forums for discussions of drug approvals. We have a perception, at least, and this may be in the area of women's health, that the percent of open public meetings to the percent of approved drugs has dropped recently.

And we'd also like, in this age of the Internet and instant and easy availability, we would like for

consumers to begin to have more timely access to information that's provided to the advisory committee for their approval. It's not all proprietary. Some of it's going to be discussed in public and there's no real scientific reason why it needs to only be revealed to the consumers and the world at large on the day of the meeting.

And with respect to risk management, we agree. We know there was no golden era of all safe drugs. Every drug that's ever been approved, no matter how slowly, brings some risk with it. But we believe that with respect to risk management, it's very important to expand and make it appear to the consumer that risk management efforts are being applied consistently.

We have a recent example of mifepristone, which was recently approved for use as an early abortive agent. That's a very high profile example of a risk management strategy applied right up front at the time of approval, and the National Women's Health Network supports several methods that you used in that risk management strategy, such as the written patient agreement, the med guide requirement.

However, it's unfortunate that it came at a time when there had been little widespread experience with that high profile kind of risk management strategy because it makes it appear that mifepristone has been singled out, either because it's such a political hot potato or, and I

hope this isn't true, because the FDA believes that women seeking abortions and clinicians providing abortions require closer supervision than consumers and other sorts of health care providers do in general.

So just the message there is we like this. We'd like to see more of it. We'd like to see it more consistently throughout drugs, and if I can just take advantage of sitting here, saying also in devices and the other areas where the consumer is involved in making the decision.

On drug efficacy, I think historically we've had fewer quarrels with the agency, consumers in general. But I will say now, as the United States pharmaceutical industry sees the demographic bulge of this country move into middle age and has an interest in providing drugs for prevention in addition to providing drugs for treatment and cure, consumer advocates are beginning to raise concerns about what is the definition of efficacy and how often should we take our interest and the pharmaceutical companies' interest in getting drugs out quickly, which means that the definition of efficacy is an intermediate endpoint. It's cholesterol lowering or mammographic density or bone density, but how often should we push and say, we want to see that the condition is affected. If we are going to begin taking this drug as healthy and it has risks, because every drug does,

shouldn't we have a proven benefit of an actual health condition, since that's what affects our life as a healthy consumer.

And I want to comment in here some of the tension about being supportive and agreeing you need more resources and agreeing with your mission and then the tension of same sometimes. We just have to disagree. That cute slogan of consumers want drugs of today, not of a century ago, we do want drugs that work and there are conditions for which drugs don't work, so we would love some new drugs there. But we don't want new drugs just because they're new.

And the fact that that idea is getting out there is, in our opinion, and we get the freedom to say this, just a drug company marketing tactic. It benefits the pharmaceutical industry hugely to be able to come out with new drugs because that's the era when they have patent protection, when they can advertise heavily, make very large sales, and make quite a huge profit.

On the other hand, consumers, as long as there are some drugs available for the condition, benefit from using older drugs. They're better known. We know what the adverse reactions are. We know who shouldn't be using them.

So you're right. We are all for your consumer surveys that have given you information that leads you to say consumers want the drugs of today. You're right that we

want innovation with new products that offer a genuine improvement. But we don't agree with the claim that new is always better.

We also want to give some feedback here on encouraging development of products for the public health, and this is something that doesn't bubble up as a priority in your very overstretched center because there's not much push for it. There's certainly public health products that could be developed that would do enormous good for the world, like a microbicide, for example, that women and men could use to protect against HIV infection when condoms aren't an option. Some of those products are perceived to be not having a large market or a large affluent market and we believe that those of us in the public health arena that have to do our advocacy work to push for this kind of product development could benefit if the FDA would proactively release approval guidelines.

Obviously, you're not developing the drugs. You can't make it happen all on your own. But if you put out there a clear statement of what kind of trials would be required, what kind of steps need to be taken, and we have had some successes working with the center on some issues.

On the issue of low-cost drugs, how can we disagree? Everyone would rather their drugs were cheaper and we love those drugs that we can get cheaply, but we

believe it is not appropriate for the FDA to posture itself in a way that implies that it is responsible for the high cost of pharmaceutical products. The FDA can take action to lower costs by approving--they're whispering, but they do. They do. They keep saying we are. Well, you can approve more generics and we very much thank you for devoting full-time legal staff to fighting off the attempts to thwart you from approving generics.

But we do not believe that the FDA should consider compromising its standards for approval and balancing that against cost. It's critical for consumers that the FDA maintain the high standard that it has for demonstrating safety and efficacy, and industry complaints that the cost of doing research necessary to obtain this approval drives prices up are a little bit specious in light of the fact that this industry has higher profits than any other sector of American industry. Those profits are also calculated after research and development costs are taken into account. So we could say, perhaps, prohibiting direct-to-consumer advertising could lower costs, since companies would no longer have the billion-dollar-plus expense of running those ad campaigns, but we understand that might be somewhat controversial, too.

On direct-to-consumer advertising, the National Women's Health Network shares concerns with other consumer

groups that are here in the audience about direct-to-consumer advertising. You talk about it as a double-edged sword. We're seeing mostly the other side of that sword. We're seeing mostly inappropriate ads that overclaim benefits, that minimize risk, that misrepresent the intended audience or indication, and we understand that you have requirements for accuracy and balance and those requirements are necessary, but they're not sufficient. They're not doing the job. Advertising is designed to sell products. It's not designed to meet that other side of the sword of giving all comprehensive information.

In 1999, industry spent $1.8 billion in direct-to-consumer ads. It's on track to spend $2.5 billion this year. There's no kind of public health education campaign that can balance that out, that kind of sophisticated, effective advertising at that level.

You mentioned that CDER doesn't have sufficient resources to conduct the scientific evaluation of the impact of this. We're concerned--we think the resource problem is even more serious, that you don't have the resources back here to monitor the ads that are out there or to enforce those standards that you do have. Once a bad ad has aired, the genie is out of the bottle. That image that's been so cleverly crafted by brilliant advertisers is in people's brains and there's no way to ensure that any after-the-fact

action by the agency will correct the misleading or incomplete information that's already been received.

Under this current scenario, companies have little incentive to produce advertisements that are fully accurate, and we recommend that CDER improve enforcement of existing standards and institute a requirement for preapproval. That's controversial. You may feel you don't even have the authority, but we want to put it out there that we think that this would be an improvement and would protect consumers.

You can also consider a policy that I know other consumer groups would like to speak to in the question section of three strikes, you're out, you know, for the companies that keep making mistakes--mistakes, keep giving mistaken information out. Just cut them off.

We recognize that what we're asking for requires more--she's just laughing. We're in the consumer world. You're asking us what would help protect us. We're going to tell you what we think and get it into the discussion.

And we're also going to say something that's painful to say, because we want CDER to keep doing everything it is already doing on drug safety and effectiveness, but we think this issue of resources for direct-to-consumer ads is you may have to rob Peter to pay Paul and you may have to move existing resources around in

the agency while we go out and fight to get you more resources.

And the last specific issue I wanted to address is the drug information and the things that you were talking about at the end. We're really delighted that the OTC label is coming. The United States public is used to seeing the food label now and will be delighted to see something like that on over-the-counter drugs.

We've been advocating for med guides along with some of our colleagues in the audience for decades. We're happy to see you trying to get a rule through on those again. We're happy to see that you're starting to implement a handful a year. We'd love more. We believe that patients and healthy consumers can be important influential partners with their clinicians in managing risk if they get information in a usable format. So good luck moving that forward. We're with you all the way.

Just to summarize, I mentioned five goals that I think consumers have for CDER in 2001, five areas: Increased consumer input into the drug approval process; development of guidelines for approval requirements for classes of drugs that industry is not breaking down your door to look at but would have an important public health benefit; post-approval risk management of drugs, strengthening that, continuing your work on that;

prohibition of direct-to-consumer advertising or improved enforcement of direct-to-consumer advertising standards; and faster progress towards implementing the planned requirements for better consumer information. You should be able to do that, right?

DR. WOODCOCK: No problem.

MS. PEARSON: So, I didn't get yelled at for going overtime.

MR. BARNETT: No, you did really well. You weren't overtime. Thank you very much, Ms. Pearson.

Now, let's open it up for questions. Wow, okay. We're not going to be able to take them all. Let's start on this side--

MS. PEARSON: Do your best.

MR. BARNETT: Well, it's somebody who hasn't asked a question before. Okay, right there.

DISCUSSION

MS. ZUCKERMAN: I'm Diana Zuckerman from the National Center for Policy Research for Women and Families. In addition to agreeing with everything that Cindy Pearson has said, I wanted to focus a little bit more on direct-to-consumer advertising and the information available to consumers, and this is an issue for drugs as well as devices, but I didn't have a chance to say anything this morning.

I agree with Cindy that the ads that are being promoted for consumers are not providing information. They're the best persuasion that money can buy. That's what they're for. Let's not kid ourselves. And if you have a print ad in, for example, a women's magazine telling you how great a particular product is in the most persuasive way and then you turn it over and in microscopic writing you have a whole lot of words that you can--I speak for my aging self here--can barely read, but that even 20-year-olds can't necessarily read, either because it's too technical or they're too smooshed together and there's so much of it and they're so small and it's clearly not intended to be read and understood.

So somehow, these ads have to be done in a way that actually provides warning information for consumers, and I believe that one model we should use are the boxes that have warnings for cigarettes, where you have a clear warning of something important on the front page and then you might still have a back page, but it wouldn't be so crowded and the writing wouldn't be so small.

And also that the FDA really needs to do more in terms of its providing information directly to consumers. I think the RU-486 example is an excellent one. As far as I know, the LASIK surgery also look very good to me. I don't know nearly as much about that issue, but it seems really

clearly written, something that consumers could understand and give them a good sense of what's good about this product and what isn't so good.

And so we need more of that clear language, perhaps coming from the FDA, clearly stating what the risks are of a product as well--and let the advertisers talk about the benefits--and reaching out to consumers in a variety of ways, and not just the Internet, although that's an excellent way, I think, but reaching out to the press and to others that you don't necessarily reach out to. I'll give one quick example.

I was asked to be a luncheon speaker at a press luncheon for women's magazine health editors a few months ago on breast implants and I suggested that the people putting this together also invite someone from the FDA, a scientist who had just published new research showing a very high rupture rate of breast implants, and that scientist was invited and the official word was that she could not present at this luncheon because it was not a scientific forum.

Well, okay, but let's face it, if you want to reach out to consumers, you have to reach them where they are and a lot of women read women's magazines and these magazines promote many drugs and breast implants and some other devices very, very heavily. They advertise them and they write about them and they're getting a lot of hyped

information and they aren't necessarily hearing the other side. So here was a perfect opportunity for someone from the FDA to be there and talk about her new peer-reviewed research and it didn't happen.

Just as a footnote, a writer from Glamour magazine was at that luncheon, asked me who she should speak to at FDA, ended up interviewing Dr. Feigal, hence he was in Glamour magazine, but wouldn't it have been better to have her hear directly from the scientist who had done the research and get clear examples of what was going on?

So I ask you to reach out to the women's magazines and other magazines and other reporters that you wouldn't normally reach out to. Thank you.

MR. BARNETT: Thank you. Okay, another one, someone who hasn't participated before. Back there.

MS. CLANCY: Thank you. I would like to speak on behalf of those who are not represented and that being the general public. I worked in community health for 25 years and--

MS. PEARSON: Could you introduce yourself, please?

MS. CLANCY: I'm sorry. I'm Joan Clancy. I was a former representative on a consumer committee. I worked for 25 years in community health and 40 years in nursing, and I think one of the biggest open wide links is the fact that we

cannot get the message across to people. To the mothers in maternity patients, we would sit there and talk to them about the most basic things of how to take simply vitamins, prenatal vitamins, how to take birth control pills, and they just don't get it.

There is a plane there that we have not gotten on effectively, and you can talk about magazines, but there's a big portion of the population who will not buy a magazine, cannot buy a magazine, does not read the newspaper. Maybe television is their really only communication. It at least gives them some possible information.

Now, I'm not saying that all drug companies present in the very most uncovert way, but it still brings a presentation to probably most of our people now and I think that if we can heighten that to where they can bring information on an easily understood level--I mean, I think we all know the frustration just with AIDS, of how difficult it is to get to that. How difficult has it been for us to immunize our children? When you talk about adverse side effects, it's the same thing. We just aren't educating in that level enough.

We can sit here in meetings like this because we all come from somewhat of an equal background. But when you're in a general population, you don't have that, and we need to somehow be able to infiltrate and get into that

area. I don't know whether you have to start with children or where, but that's an area that we definitely need to invade.

MR. BARNETT: Thank you. Someone else who hasn't participated before? This gentleman back here, maybe?

MR. CLEMENTE: Hi. Frank Clemente at Public Citizen. On direct-to-consumer advertising, my understanding is that the FDA has had in process some regulations guiding what industry can say to the public. The guidelines that you have now, my understanding is those simply apply to what the industry can say to medical professionals, and I believe that's inadequate for the public at large.

My second question has to do with FDA, I think it was from 1982 to 1991, you used to keep track of new drug approvals and record whether a new drug had an important therapeutic gain or a modest therapeutic gain or no gain at all, and what you found back then was that 50-plus percent of the drugs were "me too" drugs. They had virtually no therapeutic gain. And as you know, in this world, with increased drug advertising and the changes in the drug industry and the marketplace, they want to produce a lot more blockbuster "me too" drugs. They're cheaper to produce. They don't have to do as much research, but they can make a lot more money off of it.

And so what I'm wondering about, why did the FDA stop its recording of new drug approvals? In my understanding, that was a discretion on your part and is there a reason it wouldn't implement that again?

DR. WOODCOCK: Well, the answer to the second question is, we do put a list of priority drugs. We just have two categories. Priority drugs are the drugs that are reviewed more rapidly and are thought to provide a benefit, a public health benefit or therapeutic gain over existing drugs. You're right. That's not a very large number of the new molecular entities each year. It's a fairly stable fraction of the new molecular entities, but that information is still available. So that's the answer to the first question.

The second question, on direct-to-consumer advertising, I'm not exactly sure what you're referring to. It is true that, and what Diana Zuckerman was talking about, I totally agree with her. The regs governing in print ads what has to be there, called a brief summary, and that's from the law, it says it has to be accompanied by a brief summary. So all that gibberish beside the ad is the "brief summary." It's probably true, we haven't adequately come to grips with what should be in there.

Where we have med guides, we're going to be able to have very good information in a standardized way along

with it, but often, those products that have med guides are going to be such risky products that probably will not be advertised direct to consumer. So we really, we need a better format that would accompany--at the very least, we need a better format to accompany direct-to-consumer print ads that provide this information, the risk information in a way that's comprehensible to consumers.

This has long been a source of frustration to me. I totally agree with you, but these things are not easy to get changed. This is how it's been done for a long time.

MR. BARNETT: Another one?

DR. WOODCOCK: That doesn't mean we shouldn't do it. Is there something in the works?

MR. CLEMENTE: --direct-to-consumer advertising--

DR. WOODCOCK: As I said, we've been thinking about--

MR. CLEMENTE: For 15 years.

DR. WOODCOCK: We know, okay, we know that these are not satisfactory. The brief summary is not a satisfactory vehicle for transmitting the information about that drug in a comprehensible way. We absolutely know that and I would love to get something out.

MR. BARNETT: Okay. Someone else who hasn't participated before? Anyone back there who has not? Right back there in the center.

MS. ROULEAU: I'm Mary Rouleau from the Auto Workers, and I wasn't here this morning, so if I missed something, I apologize, but--and I realize this forum may not be designed for the information I'm looking for, but here's what it is.

It would be very helpful to me as an advocate to know what kind of new safety programs you'd like to put in place for post-market surveillance--what you're doing, what you'd like to do, and what kind of dough you need to do it. I mean, we want to be your advocate on the Hill. So that's what I need to know, and if this is not the appropriate forum, I certainly accept that, but that's my two cents' worth.

MR. BARNETT: Do you want to respond?

DR. WOODCOCK: I can't give you the scoop on the dough, but let's put it this way. We had a hearing before Mr. Jeffords and Mr. Kennedy last year and it's a substantial chunk of change that we think would really be needed. Mr. Kennedy, I think, mentioned $50 million, but I didn't mention that.

We think that we could really enhance the safety net for people in this country for drugs and biological products if we had a much more active surveillance system. Right now, all we have is a passive surveillance system. It works very well to get the rare serious adverse events. In

other words, we learn very quickly about something unexpected. Not everyone in the audience will agree with this, but actually, it is true. We learn very quickly about the rare serious adverse event that's occurring, you know, the liver failure, the agranulous cytosis, the whatever that's occurring, but because physicians, pharmacists, nurses, and everybody report these to us spontaneously, in other words, voluntarily through MedWatch and they report them to the manufacturer very quickly.

But we don't have an active system out there looking at how drugs are used, how they're misused, which is, as I pointed out in my presentation, which is one of the major problems with drugs, is the way they're prescribed, monitored, and that's causing a lot of the side effects from drugs in this country. We have a lot of ideas about how that could be done, and we are implementing a few things this year, but a lot more could and should be done to manage the risks of drugs.

And we would, of course, as part of that, we would have the resources to get much better consumer information out there. We could have public information campaigns. We could really try to reach down to the level that was alluded to earlier of the average consumer out there who really maybe just watches TV, but we could reach out to that level if we were funded adequately.

We are working on this, and Dr. Henney wanted me to mention a couple of things. The Center for Devices is working on a sentinel system. They found that if they just went and educated the people in hospitals and taught them how to report and encouraged them to report and everything, they got, like, ten times more reports than what they're getting now about mishaps and the problems with the use of medical devices in hospitals. So it's clear there's a tremendous untapped knowledge and understanding out there about what's going wrong with medical devices that we could tap if we could fully implement this system. It's going to be implemented in a very small pilot way this year.

We're also working with a number of the other PHS agencies in a consortium, with HCFA, with ARC, and with the CDC, all of who get a piece of this information in their various realms. We're going to try and put our data systems together, share information, and, therefore, provide the best safety net we can with pooling our resources.

MR. BARNETT: Okay. I think we've got to move on now. Thank you two very much.

We've talked about the five centers in the FDA, but we have one more segment to go and that is a discussion of openness and transparency and that is the FDA's desire to be as forthcoming as possible in its dealings with outside organizations, and likewise to make its decision making

process as visible as possible. And so in this section, we're going to review some of the agency's history in this area. We're going to talk about the current initiatives in increasing transparency and we're also going to touch upon some of the constraints that we face as a regulatory agency in the transparency issue.

And speaking of constraints, we realize that we have made some individual disclosure decisions that may not be agreed upon by everyone. We don't want to focus on those during the discussion session. What we do want to focus on is three things: Number one, giving you a chance to comment on the transparency initiatives that you think are going to be helpful; number two, to share with us any general concerns you have about this issue; and number three, to let us know about additional steps you think we ought to be taking in this area.

And so to discuss that, let me call up Margaret Jane Porter, who is FDA's Chief Counsel, and the lead respondent will be Allison Zieve of Public Citizen's Health Research Group, and accompanying Ms. Porter will be Sharon Smith Holston, who is FDA's Deputy Commissioner for International and Constituent Relations.

OPENNESS AND TRANSPARENCY

MS. PORTER: Good afternoon. It's a pleasure to be here. As Chief Counsel, I have legal responsibility for

the agency's programs and cross-cutting initiatives and endeavors, including openness and transparency and the legal issues involved in those. I've asked Sharon Smith Holston, who's the Deputy Commissioner for International and Constituent Relations, to join me because we want to be sure to be as fully responsive as possible to issues that you might raise about specific initiatives on consumer outreach, about which I might not necessarily have the details.

It's a pleasure to be here and I hope that this final session will be sufficiently lively so that you're able to stay awake. You've seen my prepared remarks on the website, but I just want to review them again to perhaps refresh your recollection and give a chance to have a basis for comment, as I'm sure Allison will do so.

As the country's premier consumer protection agency, FDA has long recognized the value of providing consumers and other members of the public with useful information about the products the agency regulates and other FDA activities. FDA openness and transparency empowers consumers to make informed choices about their health. It helps assure consumer confidence in the credibility of FDA's processes. FDA is also a regulatory agency that must ensure the integrity of those processes and protect the sensitive information regulated entities are required to submit to it.

Even before the Freedom of Information Act was enacted, FDA promulgated regulations that attempted to balance these concerns. These FDA regulations have been for years a model for other government agencies. FDA continues to lead the world in its emphasis on openness and transparency.

It has been apparent for some time, however, that making more of the information FDA receives and generates available to the public will directly further FDA's mission to protect and promote the public health and improve our credibility with the public we serve. One of FDA's principal strengths is its science-based and risk-based approach to decision making. Open processes and objective standards and data are integral to this approach.

Moreover, consumers expect and need better and more timely information about the products FDA regulates. Regulated entities expect and need clear and transparent standards for compliance with FDA requirements. All FDA stakeholders need efficient methods of communication with the agency and FDA needs to modernize its processes so that effective and appropriate dissemination of information becomes an integral part of the agency's processes rather than an afterthought.

FDA will always want and need to protect certain of its deliberations from disclosure and it will always have

a legal obligation to prevent unauthorized disclosure of protected commercial and privacy information. Yet there is much we can do.

I don't need to emphasize the enormity of this undertaking. The amount of information FDA has to share with its stakeholders is staggering. Consider, for example, the FDA website with its more than 100,000 documents and 40-plus web-enabled databases, offering everything from patient information on new drug approvals to reports of adverse events with dietary supplements. Finding your particular needle in that electronic haystack can sometimes be a real challenge, and processing the tens of thousands of Freedom of Information requests the agency receives every year is equally daunting. Yet important progress has been made.

FDA has aggressively implemented the Electronic Freedom of Information Act, moving quickly to make available in electronic form frequently requested and other publicly available documents so that requesters have this information without needing to file separate FOIA requests and waiting for responses for them. This implementation has already led to a significant decrease in the number of FOIA requests and we hope you find it useful.

After an extensive evaluation, FDA has just launched its redesigned website, www.fda.gov, to give users quicker, easier access to the information they need. Based

on feedback from consumers, health professionals, and industry representatives, FDA's primary audiences, the agency designed a new site to place more of the most important and popular information front and center on the home page.

One of the biggest changes is the display on the home page of FDA's current news items. Reports of safety alerts and product approvals are included and updated regularly. Also featured on the new website, information on hot topics, such as cell phones and breast implants, that will be updated regularly, automated e-mail lists to which the public can subscribe, a reference room with links to FDA's Federal Register notices and backgrounds on laws and regulations enforced by the FDA, links to pages maintained by the various FDA centers, and you saw a number of those illustrated this morning, information about FDA activities, such as FOIA and clinical trials, special information for consumers, patients, women, and other audiences, an improved search engine. The site also enables users to report problems with products regulated by the FDA and to comment on proposed regulations.

All of the centers have undertaken important initiatives to maximize the availability and clarity of information about the process for review of applications and submissions to the agency in order to maximize the

availability and clarity of information for consumers and patients concerning FDA-regulated products.

For example, as Dr. Feigal illustrated in detail this morning, the Center for Devices' goal is to permit consumers to click on the name of a device and find the labeling and the basis for the approval and all of the other relevant information about a device.

A number of additional steps are outlined in the agency's report on statutory compliance under Section 406(b). There are copies of this report as you came in, and I think if you review it, you can see a number of additional steps that I won't take the time to go into now.

What are the challenges the agency faces in its efforts at improved transparency? As the agency makes more information available, the challenges of ensuring that the information is accurate and complete increase, I would say increase exponentially. In addition, the potential for inadvertently disclosing legally protected information increases.

Finally, there is the significant issue of presenting information in ways that can be useful rather than simply overwhelming the public with more data, and you heard Dr. Levin talk this morning about the challenge of providing individual consumers sufficiently specific information that they're seeking to make it really useful.

Ultimately, the solutions to these challenges lie in systematically redesigning the agency's processes using the technology that is now becoming available. An example is placing more responsibility on the submittative information to redact it appropriately, as the agency has proposed to do with the device 510(k) redaction rule. Finding the resources required to make the investments necessary in infrastructure, processes, and training to improve transparency is, of course, a major challenge.

We want to provide information that consumers want in a way that is timely and useful to you, and we welcome your suggestions on ways in which we can be more transparent, consistent with our obligations. Since there's no way the agency could or would make available all information some member of the public might want, we also need to be sure we don't create unrealistic expectations. We therefore look forward to continuing dialogue such as the one that we're having today so that you understand both what we're trying to do and the constraints under which we're operating and you have an opportunity to shape the agency's efforts.

MR. BARNETT: Thank you. Before I ask for Ms. Zieve's response, I want to clarify something. You mentioned that on the website you had information about cell phones and breast implants. There's no relationship between

the two. They're two separate topics, unless we start a new rumor here this afternoon.

[Laughter.]

MS. PORTER: Thank you very much, Mark. I was just trying to give some idea of the range. But you're right. There's no causal association.

MR. BARNETT: Ms. Zieve?

MS. ZIEVE: Thank you. I'm Allison Zieve from Public Citizen Litigation Group, speaking on behalf of Public Citizen as a whole and Public Citizen Health Research Group, as well. I'm sure that I speak not only for myself and Public Citizen, but for many consumers and consumer groups when I say that I appreciate Margaret Porter's assurances of the importance FDA places on openness and transparency. FDA documents are consumers best and sole source of objective information about new drugs and devices.

Speaking for my office, we have found that FDA's website, the information the FDA now routinely posts on its website, to be very valuable. It has saved us a lot of time in terms of making requests and the speed with which we therefore get the information. For example, the FDA now posts on its own initiative the approval packages for many new drugs, and that has been very helpful, if not always timely.

Nonetheless, without minimizing the logistical

considerations to which Margaret referred that are involved in improving transparency, I think the agency could be doing more and I'd like to offer a few examples of areas for improvement that I think should happen promptly, if not yesterday. I'll discuss a couple issues relating to the Freedom of Information Act and then I'll discuss a couple issues relating to the Federal Advisory Committee Act.

First of all, for several years, we have been asking the FDA through FOIA requests for copies of the protocols for phase four post-marketing studies required by the FDA as a condition of approval for some new drugs. Not once has the FDA responded by releasing the protocol.

In 1996, we sued the agency for the post-marketing study for the drug Metformin, and after about a year of litigation and the use of two experts appointed by the court, we got the protocol in full and $20,000 in fees. We would have rather had the protocol in 1996 and skipped the $20,000 in fees.

Since then, we have requested several more protocols, and each time the FDA has initially denied the request. When we have followed up by filing a lawsuit, the agency has then released the document without litigating. Forcing us to file a lawsuit to get information that the agency seems to agree is not exempt under FOIA is a waste of our time and resources and a waste of the government's time

and money, as well.

We were pleased when earlier this year the FDA proposed to make the post-marketing study protocols available as a matter of course in a proposed rule that would have implemented Section 212 of FDAMA. That section requires disclosure of information to identify post-marketing studies and it does not strictly address disclosure of the protocols. So we were disappointed, but we couldn't complain when the agency's final rule didn't include that automatic disclosure.

Nonetheless, even if FDAMA doesn't require disclosure, FOIA does, and I think the FDA's repeated capitulation on this issue demonstrates that. Rather than wasting the time and resources of requesters and the agency, I'd suggest that these protocols be released, certainly in response to FOIA request without the need for administrative appeals and litigation, but an even better policy would be to post the phase four protocols on the website as a matter of course, as is done with some of the approval packages.

And speaking of approval packages, I said some packages, because the FDA posts some on the website and not others. We haven't been able to figure out how the decision is made of which drugs' approval packages get posted and which ones aren't. It might be helpful to us to have some explanation of that.

But for the ones FDA doesn't publish, it's still taking us quite a bit of time when we're interested in that material and request it through FOIA to get the approval package released. Seven months has been about standard lately for getting the approval packages. We're still waiting for one that we requested in March of this year.

Second, getting back to my FOIA points, the agency continues to withhold safety and efficacy information. For instance, the agency frequently redacts safety and effectiveness information from the medical officers' reviews that ar released as part of approval packages.

For example, at present, we're still waiting to hear from the FDA in response to a November 11, 1999, request for 69 redacted pages from a medical officer review and several fully withheld pages from the attachment to that review that relate to efficacy data. Also, the FDA posted on its website that medical officers' review of the new use for a drug, Fosamax, with ten pages of safety information redacted.

In regard to two other requests, although we recently received the information, one release came only after we filed a lawsuit and both sides had filed rather lengthy summary judgment papers, and in the other case, we got it only after months and months of letters and back and forth and telephone calls to the FDA and eventually to HHS,

as well.

The repeated withholding of safety information cannot be justified under FOIA as the agency itself has recognized in numerous statements in the Federal Register, in litigation, through the MedWatch program, and in its regulation on the release of adverse event data. In addition, in informal comments with the FOIA office at HHS, these in relation to the release we were working on that I just mentioned, HHS told us that they agreed that the FDA repeatedly and incorrectly withholds adverse event data. Whether this is a training problem or a policy problem, obviously, I'm not in a position to say, but certainly these examples are illustrative of a larger problem.

Turning to the Federal Advisory Committee act, or FACA, in early 1999, my office sued the FDA over the agency's failure to make the materials sent to advisory committee members available to the public before or at the advisory committee meeting relative to those materials. The FDA settled with us by agreeing to make the advisory committee materials related to CDER's meetings available at or before the meetings, and if any of you aren't aware that that's happening, it is and you can get them on the website 24 hours or more in advance.

We agreed to settle that case without dealing with devices and biologics, but we were assured off the record

that those centers were working on the issue, and for some reason it wasn't going to happen now but it would happen, and so we put that aside. But more than one year after we settled the issue of release of advisory committee materials as to CDER, the FDA has yet to comply with this clear statutory requirement as to the other centers. Whatever the reason, the requirement well preceded our lawsuit and the FDA should make sure that the other centers, not just CDER, make the advisory committee materials available to the public before or at the relevant meetings.

Again on the topic of advisory committees, Section 120 of FDAMA states, "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel." This provision plainly requires public disclosure of the substance of the conflict, not just the fact of a conflict. In our experience, however, the agency has disclosed only that a member of the committee has a conflict without providing any indication of what the conflict is. This interpretation of that statutory provision seems flatly at odds with the requirement.

Let me repeat the provision, now that I've told you the problem. "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel." The FDA has not

only consistently failed to make the information available on its own, it has also failed to respond to a FOIA request for such information. To my knowledge, we only tried it once last August in regard to two members of one specific committee, to no avail, at least so far.

It seems to me that the agency's consistent violation of this provision could be remedied without any significant logistical hassles at all, and I'd suggest it should be corrected immediately.

While I'm on the topic of advisory committees, I want to mention one other matter because, although it's not strictly on the topic of openness, you're all listening to me.

[Laughter.]

MS. ZIEVE: The Food, Drug, and Cosmetic Act requires that advisory committees have "a representative of consumer interests." From our perspective, we see the FDA using this category as sort of a catch-all. For example, nurses are not by definition or even intuitively representatives of consumer interests, although any given nurse may be, but as a general matter, not. The FDA treats them as such. Pharmacists may or may not be representatives of consumer interests, but the FDA treats them as such.

In one instance, the FDA chose as a representative of consumer interests an academic pharmacist whose work was

as a researcher for pharmaceutical companies. That person seemed to be a representative of industry interests.

So I would urge the FDA to take a narrower view of that phrase, representative of consumer interests, what I would call a truer view of that phrase.

I began by applauding Margaret's comments and then I proceeded to criticize the agency on openness, and if that doesn't sound too inconsistent, I'm actually sincere on both points. The FDA has made good use of its website. It's been very helpful to us. I agree with Margaret that the FDA has been ahead of most other agencies in terms of FOIA regulations and often, in our experience, response time to FOIA requests. But at the same time, it has been recalcitrant in several areas as to which the law seems clear which causes a great deal of wasted resources, both ours and the agency's.

So I hope that in the remaining time, Margaret or somebody can respond to some of my comments, and I thank you all for letting me speak to you today.

MR. BARNETT: Thank you.

Would you like to add anything?

MS. HOLSTON: No.

MR. BARNETT: Okay, good.

[Laughter.]

MS. HOLSTON: In the interest of time.

MR. BARNETT: In the interest of time. Okay. Let's open up the floor for questions and comments. Yes, back here on the left, whoever had their hand up there. I saw a hand.

DISCUSSION

MS. SMITH: Thank you. Fran Smith, Consumer Alert. And as a representative of a consumer group, I'd also like to ask one of the respondents a question. Consumer groups are special interest groups in many cases. Some are allied with unions. Some are allied with trial lawyers. Some receive government grants in a significant way.

Do you think that those sorts of relationships should be disclosed when people are asked to serve on advisory committees with the FDA and other agencies? I think that's an important question, because consumer groups are special interest groups, just as any other civil society group. By excluding yourselves from requirements that everyone else must follow, it seems to be a bit unfair. Thank you.

MS. ZIEVE: I'm not sure what the questioner meant by requirements that everyone else must follow.

MS. SMITH: Conflict of interest, disclosure.

MS. ZIEVE: I think the statute requires disclosure of conflicts of interest from all members of the

advisory committee.

MS. HOLSTON: But I think the statute is specifically referring to financial conflicts of interest and that's what people are obliged to disclose. I'm not sure if you're saying that there are other kinds of conflicts that are not necessarily limited to financial conflicts, and that may, in fact, be the case, but that is not what the statute requires. And so to disclose that one is a member of a particular group that may have a particular perspective, while it might be interesting, it's certainly not a requirement that FDA could enforce in terms of its advisory committee meetings.

MR. BARNETT: Over here? Yes, sir?

MR. DRUKER: Steven Druker with the Alliance for Bio-Integrity. I have a follow-up question to an earlier statement I made on genetically engineered food, but it deals directly with the openness and transparency issue.

According to the FDA, genetically engineered foods are all on the market because each one can be presumed generally recognized as safe. According to the agency's own regulations, that means that each one of them has to have been demonstrated safe through the same quantity and quality of evidence that would have been required to establish it safe as a new food additive.

So I'm asking, especially because three of the

experts in our lawsuit have submitted declarations to the court saying they are not aware of any information, any evidence demonstrating that even one genetically engineered food is safe, let alone the whole lot of them, where is such evidence and make it available so that the independent experts who are supposed to be reaching consensus on it can do so.

And secondly, related to this, Commissioner Henney, on May 3 of this year, you declared FDA's scientific review continues to show that all bioengineered foods sold here in the United States today are as safe as their non-bioengineered counterparts, unquote. But The Lancet shortly before then had reported that in January of 1999, FDA issued an official statement saying FDA has not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants consistent with its 1992 policy, unquote.

My question, therefore, Commissioner Henney, is between January of 1999 and May 3 of 2000, what kind of comprehensive scientific review did the FDA, in fact, conduct?

DR. HENNEY: The kind of review that the FDA has conducted with all genetically modified foods that are now on the market and that are available for food consumption were the type that were contemplated in our original policy,

where we have what has been a voluntary consultation with industry where data may be shared with us in terms of what they intend to market, and as we see issues that may give us either safety concerns or the need to label products in a specific way, that has been done, and that has been done ever since that policy was enacted. So we didn't have a window of just six months that we were looking at.

I think what The Lancet refers to is that--and our policy never contemplated it--is that the genetically modified foods were to be reviewed in the same way as a food additive was.

MR. BARNETT: Thank you. Let's have one from the lady here. Yes?

MS. HOCHANADEL: Again, my name is Deborah Hochanadel and I'm with the Massachusetts Breast Cancer Coalition and I'm going to name the other members of a coalition that we are with because I'm speaking for all of them as one voice and you need to know all of those members: Boston Women's Health Book Collective, Breast Cancer Action from California, Breast Cancer Action Montreal, Center for Medical Consumers, DES Action, Massachusetts Breast Cancer Coalition, National Women's Health Network, Women's Community Cancer Project, and Working Group on Women and Health Protection. I just tell you who we all are because I'm speaking for more than one voice. That's why I raised

my hand to speak again.

What I want to speak to right now is conflicts of interest in the FDA advisory committees. A great deal of attention has been paid in the media lately to the fact that so many of the scientists and researchers on FDA advisory committees have real or apparent conflicts of interest. The public's faith in the decisions made by the agency are undermined by these conflicts, and you can see that here, and we believe they need to be addressed openly by the agency and corrected.

One aspect of this issue that is of particular concern to us relates to the possibility of conflicts of interest among consumer representatives to the advisory committees and among those who present testimony to the committees. Increasingly, groups that purport to represent a consumer viewpoint are financed in whole or part by pharmaceutical companies or manufacturers of devices that come before the FDA for approval.

The FDA should strengthen its requirement that all those who purport to represent a consumer point of view to the agency disclose whether they receive funding or other assistance from entities with economic interests at stake before they testify before the FDA. These conflicts of interest, like those involving the scientific and research community, need to be addressed and resolved by the FDA. We

look forward to working with the agency to develop strategies for doing so. The interests of consumers are very different from and frequently opposed to those of industry.

No group receiving 100 percent of its funds from industry can reasonably be expected to represent consumer interests at a policy forum. We question whether any organization that receives more than, say, ten percent of its funding from industry could do so.

In order to strengthen the FDA's conflict of interest policies, we urge that as a condition of participation in FDA public forums or the submission of written comments to FDA committees, all consumer representatives be required to disclose the percentage of annual funding that their organization receives from industry. We also suggest that the FDA separate its public comment time during advisory committee meetings into industry-free and industry-support segments, requiring all representatives of groups that receive ten percent or more of their annual funding from industry or any funding from a company with a matter before the committee, for that matter, to reserve their comments for the industry-supported segment of the meeting.

And I'm closing now, don't worry. When the FDA appoints consumer representatives to serve on agency

committees, those representatives should never have a financial relationship with the industry being discussed by the committee. That seems like a no-brainer to me. If a financial conflict of interest arises for a consumer representative during the course of that representative's term, the FDA should appoint a temporary consumer replacement for that meeting.

Again, we would love to work with you on this concept. Thank you.

MR. BARNETT: Thank you.

It's time now to go to our last segment in which we're going to call back the center directors and have them talk about what they've heard today.

But before I do that, let me see a show of hands. How many people here are from a consumer organization that want to speak and that have not been called on yet? Raise your hand if you're in that category. How many?

[Show of hands.]

MR. BARNETT: All right, one, two. Other than that, if you are from a consumer organization and you are here today, you have already spoken? Fine. So for those two people, let's reserve a little time when we do that.

I'll have the office directors come on back up. In the meantime, the rest of us can take no more than five minutes to just stretch while we change sets here.

[Break.]

MR. BARNETT: Let's start out, then, with a brief comment or question from the two people who raised their hands who had not yet had a chance to speak, and where are they? Yes, ma'am?

MS. DUNCAN: I'm Janel Duncan and I'm from Consumers Union, and actually, this question was prompted by the last session having to do with transparency.

I know that a lot of the information received by the FDA and analyzed by the people in the FDA, the scientists and others, is submitted by industry, and the information that is allowed to be released to the public is information that is not privileged. Often, the information that--the determination or the designation of the information as privileged, a trade secret or confidential commercial information, is done by the sponsor or the person submitting the information. I think it's become apparent that a lot of the information submitted as such doesn't necessarily qualify, and so that information, it's very difficult to have relief.

I wonder, what can be done to better ensure that there's not an abuse of that designation to make it easier to get information that is legally entitled to be released to the public?

MR. BARNETT: Who wants to respond?

MS. PORTER: The questioner raises an important question. As I referenced in my prepared remarks, in order for the agency to meet its desires to make the reams of material it receives more readily available, we're going to need to rely, in part, on the sponsors' designation. But we have the ultimate responsibility for assuring that material that is withheld as confidential commercial is, in fact, protected by law.

MR. BARNETT: Okay.

FLOOR QUESTION: I'm a consumer member of an advisory panel. I was with CDER. I still am with CDER. And I have to say a few things positive about FDA, and those people who know me best know that I speak my mind.

First of all, you have a wonderful new label for OTC. I hope you use it for prescription drugs.

I am impressed by the staff and the work that the staff does. I think they are underpaid and overworked. I'm impressed by the sincerity of FDA, but I do have a lot of problems, and here I begin. But I should tell you, so you know, I have an annuity from my husband, who was at NIH for 41 years. I have my retirement from Montgomery County Office of Consumer Affairs, and nobody, nobody can tell me what to do if I think it's against the thing I'm supposed to do, and it is an honor and a privilege to serve on an advisory panel.

I saw my husband through the age of the golden years of science. It is no more. It's rough out there. And as far as I'm concerned, politics and science give me a stomachache.

I think the thing that I'm very concerned about is, first of all, if I could do the advisory committees, I think there should be two consumer members. One consumer member is not enough. Maybe in my case, one is enough, but in some--

[Laughter.]

FLOOR QUESTION: And you have to have humor about this. Sharon, don't you dare laugh. If you don't have humor, then you don't belong dealing with anything because you lose your sense of perspective.

I think there has to be better training for some exec secs and some of the chairmen. I served on a committee recently on PPA and I'd like to talk about what I saw there. When I asked to see a consumer insert, I was told by the chairman, "Why don't you go to the gift shop and buy one?" Now, that's disrespectful to a consumer member who is there to serve.

PPA, to me, phenylpropanolamine, was very interesting, that all kinds of scientists appeared to represent industry. Research grants are very hard to get now. They might even be harder if they don't come through

with an NIH budget. So everybody is competing for money from industry.

I am concerned about that pressure that's brought to bear when these consultants come in in front of the FDA. PPA, there was a man--and I'd like to tell you a few stories, because this is a reality--who runs a diet clinic for one of the universities. He doesn't need PPA to get people to lose weight. All you have to do is close your mouth. But he came to represent industry that he needed PPA.

And then all these so-called scientists came to defend the use of phenylpropanolamine, and I'm thinking, this isn't an antibiotic. This isn't going to make any difference in anybody's life if you don't have it. And I'm really worried about getting research grants and it affects consumers directly. My dream is to have a pool of money given by industry, not directly by any name, and people who applied to get that money, because once money is attached to a research grant, I'm very concerned.

I'm worried about post-marketing. I think it should be stringent. I think they should be monitored for one year, absolutely, to see what's going on, and they must report. And I'm also concerned about off-label use. That's another thing that worries me.

I think there should be more clinical trials in

communities where they have health clinics, in poor communities, where you get diverse cultural, you get gender. I think that the trials are done maybe among people who don't need the trials as much, but let's go into the inner city and let's bring some health care to the inner cities along with doing clinical trials.

So I think that there's a lot to do and not enough money, but I think I want full disclosure and that truly worries me now, is the grabbing from money to do research. I think something else has to change.

And I think that the other thing is, industry wants to extend their patents now so they come to extend their patents. I mean, there are more important things for them to do than worry about extending their patents and, therefore, making generics less expensive for people.

So I think that there are so many issues, and this nice lady back here, she really struck me. She really was talking about consumers. I'm a consumer member, but this isn't my world. The world is out in the inner cities. The world is among the poor. The world is among people who don't have websites. The world is about those who really need help, and I hope that we can reach through these clinical trials more needy people, and thank you for allowing me to make my speech.

MR. BARNETT: Thank you.

I think--was there one more person who raised their hand earlier that had not had a chance?

[No response.]

NEXT STEPS

MR. BARNETT: Good. Okay. That being the case, let's go back to what we heard earlier today and ask the center directors that are up here to respond--I'm not going to call on anybody in order, you can just do it voluntarily--as to what you heard today from your responder and also what you heard from the audience. And, by the way, Dr. Feigal changed his appearance to Dr. Lee Joseph. Dr. Feigal had to go back. Dr. Li Joseph, who is Director of the Office of Health and Industry Programs in Dr. Feigal's center is here in his stead. So, anyway, who wants to begin? Yes?

DR. ZOON: Thank you, Mark. I appreciate it. Since I was first on the agenda this morning, I'll take the opportunity to be first in making comments. And those nanobots really do wonders.

What I'm going to try and do, Art mentioned a number of different issues related to CBER and what I'll try to do is cluster them so my remarks aren't too lengthy because I want to leave plenty of time for my colleagues to comment, as well, and I'll try to touch on a number of issues as they relate to earlier comments from the audience.

One, there were a number of issues, Art, that you raised on budget and staffing needs of CBER, both in general to meet the scientific challenges as well as dealing with some very specific items, including gene therapy, and I think we would be very happy to discuss with interested parties at a separate meeting maybe workload issues, what it would take for different models, because some of these things have different needs. And I think in fairness, not to not give you a direct answer but to really discuss it in greater depth, I think that might be a more appropriate environment in which to do it and we'll be happy to discuss that.

The other issue that you raised dealt with ethical issues. What perhaps I'd like to do is say that this is a new emerging area and we're very much in tune with the increasing scrutiny from an ethical perspective. We, as I mentioned, try very hard to get that representation on our advisory committee, depending on subject matter that might be appropriate for that. We're also often asked to participate in the National Bioethics Advisory Committee, which we participate in.

We think that's a very important piece for a broader public scrutiny, and that would include everything from specialized new medicines through general issues on clinical trials and human subject protection, which covers

the gambit. I think those are very important. We look for opportunities to get both specific and broader public health input.

There are also other advisory committees, not just FDA advisory committees but now Department advisory committees dealing with blood and one that's being formed on xenotransplantation, which for those who may have come late is the use of animal organs or tissues and cells in humans as an alternative to a short supply of human organs and tissues.

Again, so there's a great deal of participation. There's ethicists involved. So we hope that in this way we'll get broad input into those matters. But there may be still more to do in this area and we will be vigilant in looking into that.

Human subject protection is a big area, one I know that Dr. Henney feels very strongly on and FDA has some very specific initiatives underway looking at a variety of different areas, including issues related to institutional review boards, as well as working with the Department of Health and Human Services on issues of informed consent, working with the new office headed by Greg Koskie dealing with human subject protection. So we take this very seriously, both as what we can do as an agency, and it doesn't affect just CBER but all the agency centers. We are

a player in that and feel very strongly that we have an important role there.

Blood, a very important area. As you mentioned, we established a blood action plan in 1997. I can say that blood is safer today in the United States than any other time in the past. Can we do better and there's more to do? Yes, and we are constantly vigilant. We are looking at new technologies, such as nucleic amplification testing to improve the detection of adventitious agents in the blood. We're also looking at better ways of improving donor qualifications and questions so that they're more understandable to folks who are donating blood. There are many areas.

The blood action plan actually touches on all of these areas with respect to actually ensuring a blood supply, an adequate blood supply, but making sure that blood supply is safe. If there are compliance issues, we are not shy on taking action. Those of the blood industry that know us know that we expect standards to be met and that is clear. But we also recognize our role in working not only as the FDA but with the rest of the Public Health Service, which Dr. Satcher is head of the Blood Safety Committee, working with CDC and NIH in making our blood supply in this country as safe and available as possible.

With respect to PDUFA III, as you mentioned, we're

starting negotiations on that. PDUFA has provided the agency additive resources above the base resources for new drug and biologic review. My sense, and the question you asked, you know, are there good points and bad points, in my opinion, there have been many good parts to PDUFA about helping the agency get resources that weren't available to us to do some of the enhanced review processes that we have needed. But as cost-of-living increases were not realized in other areas, our ability to do activities not covered by PDUFA were challenged, and I think that dichotomy still remains a challenge to not only our center but to the agency as a whole and it's something that we are trying to open up in a broader process to get the input to reflect a broader constituency on how to proceed with PDUFA III.

With respect to--

MR. BARNETT: We're pushing close to closing time and I want to get enough time for other folks.

MS. PORTER: Just one last comment on vaccines--

MR. BARNETT: Okay.

MS. PORTER: --because I know that was--if I can. Is that okay?

MR. BARNETT: You may. You may.

MS. PORTER: Thank you. One last comment on vaccines. Vaccines are clearly a very important product area for CBER. We want to engage the community in

understanding their ability to report adverse events, clearly because vaccines are preventative medicines. In many cases, we give them to our babies and we want to make sure that our babies are safe and protected. The more input we can get from physicians, from parents themselves to provide data into the agency is extremely important to us.

And so I would encourage all the consumer groups, if we could work with you to encourage that kind of input into the agency, we would value that. And we're also working with the Center for Drugs on looking at better adverse reporting systems, as well as working with the Center for Disease Control to enhance the information coming into the agency, particularly with blood and vaccines, but working with the Center for Drugs on other therapeutics. And I'll stop there.

MR. BARNETT: Okay. Let me ask, as we go down the line, to pick out a couple of items to zero in on that you heard about today rather than being comprehensive. Li? Or you don't have to comment at all, if you don't want to.

[Laughter.]

DR. JOSEPH: I will make it very general and brief. Specifically, I heard a request for a very specific kind of information for consumers that is easily accessible, easily found, and that contains the details and/or contact people so that if there are questions, there's a means of

following up. We've been working on that very item because we've been as equally frustrated within the center itself. So that is obviously one area that we are addressing and we will continue to address.

Although I realize not everyone uses the web as frequently, but we're trying to make that very user friendly and very plain terminology so that it's easily understood. But we're also doing a lot of work with multiplier groups, developing materials in very simple, plain, direct language and asking them to provide them to the constituents because we can't get to everyone.

And I think my last point was in terms of the radiation issues that were addressed. Dr. Feigal did not mention that because of--he did mention that because of the decreased resources in this area, we have taken a step back and we've begun to revitalize the radiation program and are thinking of devising an algorithm that helps us prioritize those very issues that some individuals brought up here that we need to address. And so we'll direct what resources we have to addressing those high-priority issues based on certain criteria. Thank you.

MR. BARNETT: Joe?

MR. LEVITT: I have five points that I thought I would mention in way of summary. Number one is Michael Jacobson clearly recognized the need for increased FDA

funding and on a scale different, meaning larger, than we've been experiencing even recently. He called for a doubling of the foods program over four years, including both headquarters and the field. And he expressed some frustration at, notwithstanding recent funding, and he, having just heard my presentation about the cost of living, realized that's what had happened.

But within foods, we have had the benefit of increases over the last four years averaging about $24 million a year between CFSAN and the field, but our cost-of-living increases are about $12 million. So, you see, we're only netting about 50 percent and people expect to see the full benefit of 100 percent and the 50 percent leaves you with a dissatisfied feeling externally. I can tell you, internally, it does, too. But nevertheless, I think the funding issue was the first thing he said.

Second, Mike had a long list of "to do"s and really covered all the areas that I had mentioned in terms of food safety, food additives, dietary supplements, biotechnology. A lot of the items that he had listed, we have on our "A" lists or our "B" lists. A lot of it has to do with time, attention, and priority.

What I didn't say this morning, but the analogy I usually give, is I think it's better for FDA to pick a few boulders and move them up the mountain and over the

mountaintop rather than putting 100 pebbles up the mountainside at one mile an hour. I like to kind of see results and I think the public wants to see results. As somebody referenced the food label as an FDA success, that was a massive effort but over a small number of years which got that done and over the mountaintop. I'd rather what we do, do well and some things not at all rather than do everything poorly, and I think too often sometimes we try to do everything, but it means we do everything poorly, and so we're doing our best on that.

Third, from the public comments only reinforce what we've been feeling over the last year, that every question was on food biotechnology, that that is a dominant public interest issue. We are devoting a lot of time and energy to it. You heard me respond to what we are doing.

Fourth, there was one comment earlier on in one of the earlier sessions that I've been thinking about all day since I heard it, which was a--it was during the device session and it was a woman who just spoke a moment or two ago who made reference to the fact that the web, while we all feel, hey, we're putting all our stuff on the web, the web doesn't reach everybody, and as I sat here it struck me that so much of our food information, especially food safety information, is designed to reach everybody. How do we do that?

I'm looking back to the "Fight Bac" program. It's a major public/private partnership involved in, if you will, marketing that message. But are we really reaching consumers, and if not, what are the ways that we could reach consumers? I don't mean consumer advocates, I mean consumers, you know, the 200-plus million that need information about food.

We recently did a study of food safety practices in the kitchen where somebody who was given a grant from us went and videotaped--you may have seen this on TV--videotaped people in their kitchen. Now, they knew that they were being videotaped. They didn't know that they were being videotaped for food safety. They thought they were being videotaped, I guess, for cooking technique. But nevertheless, they knew they were being videotaped, and yet they on videotape show every mistake in the book in terms of good hygiene in the kitchen, even with all the awareness we've tried to have. And so how we really reach everyday consumers is to me an important take-away that I didn't expect to get coming in today, but I'm glad and I'm thinking about it.

And finally, there was a reference near the end of the day in another context, I think it was direct-to-consumer advertising, about that FDA should rob Peter to pay Paul because this is so urgent. And just one, if you will,

one of Margaret's terms is push back a little bit on that, because, to be honest, we are the world's masters at robbing Peter to pay Paul. There is nobody in the world better off than the FDA at that.

And what we're finding is that is short-term gratification for long-term cost, that it is not worth it over the long run and we're realizing it, that the public really needs, if you will, both hands, and what happens when you rob Peter to pay Paul, it's like doing your job with one hand behind your back. It's good for a while, but then you lose the benefit and we are really feeling that.

And so, I think, as we plan our budgets, plan our programs, plan our priorities, it should be what we do, do it well, give your whole all to it, and not think that we can just pull a little from here, pull a little from there. We ought to do it right, because I think that's what the public wants and deserves.

MR. BARNETT: Thank you, Joe.

Dr. Sundlof?

DR. SUNDLOF: Yes, I'll respond to some of the questions, primarily the ones that Richard Wood proposed, and in, I think, in just about every case, I agree with the comments made. I thought they were very insightful.

Basically, I think I heard that there was general acceptance and people were pleased that we had taken a very

proactive approach to dealing with the issue of antimicrobial resistance by issuing guidances and moving to withdraw those drugs that we think are of greatest concern, but that we need to move faster on it, and I certainly can understand the feeling of frustration with that because I experience it every single day. We would like to move as fast as possible, but having this input certainly helps us in making that happen back at the office.

More responsiveness to citizens' petitions, I think I heard that from not just CVM people but for some of the other centers that were not responding in enough time to citizens' petitions that are considered very important by the consumer community, and again, take that to heart.

We need to have--one of the issues that I really wanted to respond to is the need to have more data on sales of antimicrobial drugs so that we can get a better idea of what the use of these drugs in animals is doing in the human population. We are in the process of writing a regulation to do just that and we are fairly far along on that. So within a relatively short period of time, you should see a proposed regulation and proposed rule coming out that would specify exactly the kind of sales information that we are going to be requiring on antimicrobial drugs that are used, especially in food-producing animals. I heard that consumers need to be involved in all of the discussions on

antimicrobial resistance and we certainly welcome that.

One other issue, and I thought this was good and I hadn't really ever thought of it in these terms, but we mentioned that we had implemented processes to expedite some of the review of the drugs, and the concern that was raised by Richard was that you're trying to get them through faster, but if you have problems, you have a hard time getting them off the market. And are you doing anything on the post-approval side to expedite that process? That's where we may really need some strong support from the consumer community in trying to make that process a little bit easier. But that would be a tremendous help for us.

The last area was on the BSE, the bovine spongiform encephalopathy, and the needs to start taking stronger enforcement actions against those companies that are found in violation, and I think that has been our thought, too, that we've gone through this education period where we've gotten out and we have done the inspections. We've had an impact in people when we reinspected, that the majority of those people have come into compliance, but there are still some people out there, some firms out there, that despite our efforts have elected not to comply and we need to take stronger enforcement action against those and I feel that that's certainly justified.

We'll be having many meetings with the people on

this issue because of the increased concerns that have been raised over in Europe and the concerns that I have about problems that have been created in Europe moving across the Atlantic into this country. It's an issue that we consider to be extremely important, and I think I'll close there.

MR. BARNETT: Okay. Janet?

DR. WOODCOCK: All right. For the sake of brevity, I'll respond to Cindy's five goals that she put forward for the following year and also a little bit about some of the Freedom of Information issues for CDER.

The first goal was that consumer groups should have more input, and actually, we've been seeking consumer input this year, CDER had, and we went about a process. We weren't necessarily seeking consumer advocacy group input. We went around the country and had meetings and sought consumer input, and that sort of reflected some of the things that I said about what we find that people actually want.

But it isn't effective for us--because there are so many people in this country, we can't reach out to everyone of them all the time and we need to work through the consumer groups. It sounds like--we certainly respond when people approach us, but it sounds like we need to institute some more formalized process with the consumer groups. Since we're probably not going to go on a United

States tour again this year, I think we can do that and try to improve access to the center for the consumer groups.

The issue of the advisory committee reps is a different and complicated one and I will leave that to Sharon to talk about. But we can put together a better process, I think, for drugs.

The second one was, can we put more guidelines, particularly in areas--it's easy to get guidelines out when there's a lot of activity in an area and people are clamoring, but I think we have had success in the past of putting out a guidance in an area that we felt was underserved and stimulating research by sort of showing people what the goalpost is and what you have to do to get the ball over the goalpost. I have been personally urging our staff to publish these guidances, with signal lack of success in some instance.

There is a topical microbicide working group, for example, and what they tell me is they feel there isn't enough data. It's sort of the chicken and the egg problem. You don't have enough data and you haven't tried it very much in humans and you don't have enough data to design the standards by which then you could judge other folks. But I will go back and talk to them, and also, I think we will have emphasis on this.

The related issue of the surrogates for approval,

we actually haven't adopted very many surrogates for efficacy lately. Most of those were in the far past and most of them have been validated. Both cholesterol lowering and fracture rate, say, for osteoporosis have been validated by trials, by mortality trials that have been done or bone fracture rate trials that have been done and shown for some products that they do have an effect. Also, of course, the HIV model, the surrogate endpoints have been validated.

So I'm not sure. I think, in general, and I was having a discussion with--we didn't mention pediatrics today, but that's a huge area. We're having a tremendous sort of blossoming of trials in children. We've already learned crucial information about the use of drugs in children that we wouldn't have known if these trials hadn't been done. In a number of cases, that information has gotten on the label. So that is another area in which we're going to need many more guidelines. We need a lot more information. It's a very important area.

But what I was going to mention is that, just like in the adults, one of the issues is we don't have long-term information. We don't have information on the long-term effects of the use of drugs in children, nor in what Cindy was talking about, do we get information often on long-term use, either effectiveness or safety, of drugs in adults, and that's another area that I see in the next decade or so

really is going to require some work, and the pediatricians are certainly thinking about this.

Post-approval risk management, you urged an increased profile there, and certainly we agree with that. I think we at FDA agree with that and have said that in order to confidently approve drugs, we have to have confidence that the system is going to be able to manage the risks of those drugs and that's an issue we have. As I said, the people in the health care system are already pushing back on us about this, so this is going to really be a back and forth. This is going to be a real challenge to go forward on. But certainly everyone in CDER, we're realigning ourselves and our organizations around management of risk and that's something that we can all understand and understand how we need to go forward on that. So that's been very positive for the center.

Prohibit direct-to-consumer advertising--that reminds me, one of my staff once told me--we were having a lot of problems with visas and they said, "Dr. Woodcock, you just have to change the immigration laws," and they really felt that I had the authority and the power to do that because I was a center director. Obviously, I would know how to do that.

[Laughter.]

DR. WOODCOCK: I mean, I'm not saying that this

couldn't be done, but I think that there are many other players and legal issues involved in advertising other than what the FDA has authority over. We certainly hear you about DTC and we're willing to meet additionally with people who are interested in that. And as I said earlier, of course, I think that the current brief summary isn't satisfactory and I need to check on how we're doing on that.

And finally, the last one was improve our consumer information. Yes, we agree. I mean, everybody else has said that, too. We agree we need to do that. Our scientists are not real good at this. Their idea of consumer information would just leave you falling down laughing. It's like the post-graduate level, and what do you mean, hyperwhipademia [ph.]? And they have to put all these long words in. So we really have had to hire new people and everything to actually translate this information into things that would be comprehensible to anyone because we can't get our scientists to just write this down. It doesn't make any sense.

So we have some challenges in consumer information, but I think we're on the right path and we appreciate the feedback that you think it's valuable, but it is another resource effort for us. We're trying hard. We aren't doing as well as we should. We're kind of wimpy at this, but we can get better, and if it's valuable, we will

do it. We will make it better.

And we know we need to make it available in ways other than on the website and via the Internet. We know that, and actually, we can partner with people to make that happen. We have done some consumer campaigns ourselves, such as on GHB and on drugs on the Internet that have really penetrated, with pamphlets and leaflets in different ways into our society.

And finally, on the FOI issue, yes, we do have some problems. For CDER, at least, the information, the redaction is a problem. We're behind. Our FOI people are in a hallway. They're crammed into a hallway. Their conditions are terrible and they're behind on getting this stuff redacted. But we have a legal obligation to do it correctly. We can't release information that is illegal for us to release, and so each of those pieces of paper have to be read by our FOI people to make sure they're correct, and so we have a tremendous burden and we haven't been able to keep up with it. That's the bottom line. And we're going to try some additional efforts, and I think you'll see an improvement in our services here, but it remains a problem for us. I freely admit that.

MR. BARNETT: Thanks. Let me ask sharon and Margaret, although they're sitting at opposite ends of the table, let me ask them collectively if they want to respond

to what they heard today.

MS. HOLSTON: I did want to respond specifically to the whole issue about conflict of interest for-- particularly for consumer representatives on advisory committees, and this is a topic that really has generated a great deal of discussion within the agency. It is something that we're actively working on now with the members of our consumer consortium.

And the more I listened to what people were saying, the more I was beginning to think maybe we should go back to square one and think about, what is the purpose of having a consumer representative on the advisory committee? What is the role that we expect that individual to play, and then try to decide who is the best person to fill that role.

Sometimes, it may be that the best person to appropriately represent the perspectives of consumers may not be, in somebody's definition, "a consumer." They could even be, God forbid, an academic whose institution may have some ties to the regulated industry, and I'm not suggesting that that's the way we should always go, but I think it's a question that we have to ponder very carefully and decide, who do we want?

And if it's someone who has absolutely no financial ties of any kind to the regulated industry, then so be it. We just have to figure out how to find that

person and get that kind of person on our advisory committees. So maybe the answer is, we just need a bigger pool of people to pick from. But it is something we're grappling with and we're going to be doing a lot of work on it.

DR. WOODCOCK: Can I say one thing about that? With regard to the people who spoke up about the conflict of interest on some of CDER's advisory committees, we looked back at this because it was in the press and this all goes to that people think there's a bias towards approving drugs and everything. Sixty-four percent of those were connections that got waivers, were connections with a competitor to the drug being under discussion. So it cuts both ways. Competitors have to be--people with ties to competitors, those have to be scrutinized as well as the ties to the sponsor company under evaluation.

MS. PORTER: Let me respond, too. Allison had to leave, but I do want to certainly agree with the overall goals that she articulated of consistency and predictability and responsiveness in the agency's FOIA process. I think, as Janet has alluded to, there are significant challenges in becoming more responsive and still meeting our legal obligations, but I think everybody agrees with the seriousness of the problem.

I would also agree that we should not spend

resources on litigation that can be avoided. It's time consuming and very intensive for everyone.

I would emphasize, as Dr. Woodcock did, that there are legitimate protected interests here and sometimes it takes a lot of time and effort and careful negotiation between the requesters and the submitters to be sure we get the right resolution.

MR. BARNETT: Thank you. And finally, let me ask Dr. Henney if she has any final comments to make.

DR. HENNEY: This has been a good day, and as I said at the beginning, I think that it is just a start of what I think that we need to keep doing in terms of both listening, being open as an agency to not only how you view us but how you see our own priority setting.

I think that we didn't assume that the day would be comfortable. We thought that you would come in with ideas anywhere from the prodding to the provocative, and you've done that. I think that you've been very candid and I hope that what we have done is listen with both open ears and open minds. I think many of your ideas clearly, just in terms of the comments of the center directors, have been heard.

I think probably the biggest frustration that I have sensed in the room, that we didn't have more time to hear from more of you about more issues that you wanted to

weigh in on. I think you know who we are. I think that, as you have follow-up to this particular meeting, I hope that you'll channel that either to the right person or at least through Sharon's office so that we can hear the additional kind of comments that you might have made had we had more time in this day.

I think one thing that I heard was not only our desire to keep doing this kind of thing on a periodic basis, but perhaps even a format suggested that came out fairly early by Art, who suggested that we see this more as a plenary and that at some point we arrange conversations that have more of a break-out or a dialogue or freely roving around from room to room so that you can register the things you want where you want, or something like that.

I don't think that we are inhibited by how we choose to construct the next session. I hope they'll continue to be constructive. I would probably have us leave on probably one of the greatest philosophers of the 20th century, the words of, I think it was Will Rogers who said, we're on the right track, but it's not enough to be on the right track. We need to get moving.

So we all agree, I think, that this has been a reasonably good day. We've heard each other, I believe. We just need to keep moving towards the goal that we all have, and that's the best of public health for this country and

really the world. So thank you very much.

MR. BARNETT: Thank you, Dr. Henney. Thank you to everybody on the FDA panel, and thank you all for coming and for your good questions.

[Whereupon, at 3:50 p.m., the proceedings were adjourned.]

- - -

CERTIFICATE

I, **THOMAS C. BITSKO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

THOMAS C. BITSKO