critical issue that is not getting enough attention. We propose that the FDA take a more active control and oversight for post-marketing surveillance of adverse reactions for AIDS drugs and make it public, make the public aware of the results of this surveillance.

And I know as consumers for the Committee of Ten Thousand, we are going to do our part in helping the FDA try to secure that funding because we believe it is very important to the community who is suffering from HIV and AIDS. Thank you for the opportunity.

DR. FRIEDMAN: Thank you.

MR. BYRD: Thank you very much.

MS. DUCCA: Good afternoon. My name is Anita Ducca. I'm the director for Regulatory Relations for the American Red Cross. I'm pleased to be here today to provide the views of the Coalition for Regulatory Reform, CFRR or the Coalition, on the Food and Drug Administration's meeting to talk with stakeholders about FDA modernization.

CFRR was formed in 1994 at the request of FDA to bring the blood and plasma industries together to jointly explore ideas for a more efficient regulatory system for blood and plasma products. The coalition consists of the American Association of Blood Banks which includes the American Red Cross and the Armed Services Blood Program Office, America's Blood Centers and the American Blood Resources Association.

CFRR represents virtually the entire spectrum of blood and plasma collection and transfusion interests. Today I will highlight the key points we wish to make based on the collective view of the whole blood, transfusion and plasma industries. CFRR supports FDA's desire to utilize state of the art science in its risk-based decision-making processes. Product review and approval times can have a direct impact on the availability of life saving products.

In the blood and blood products industry, FDA has a host of new tools for modifications or changes to approved applications that ostensibly

are the result of the agency's risk-based decision making. The annual report, the changes being affected and the comparability protocol are intended to reduce the regulatory burden associated with minor changes to approved applications. Similarly, full implementation of the biologics license application would free up scientific resources.

To increase its scientific resources, FDA could enhance collaboration with domestic and international health organizations. Collaborative efforts between CBER and the United Kingdom are one example. We also recommend expanding interactions with domestic health organizations such as NIH and CDC. We also encourage further collaboration with us, the regulated community.

There is much to be learned from each other. Interaction with the North American Technical Advisory Group to address the issues surrounding bar code labeling of blood products and the NAT inter-agency task force has permitted active exchange of information with other

scientists on the cutting edge.

We invite further FDA participation on such groups. CFRR also urges the agency to consider the need for exchange of information within the FDA particularly across centers and with the Office of Regulatory Affairs. For example, the Center for Drug Evaluation and Review recently approved a new drug for the treatment of psoriasis which included as part of its package labeling the warning that individuals taking the drug should not donate blood for three years after the date of last administration.

However, CBER, and consequently the blood and blood products industry, were not informed about this package label warning as quickly as they might have been. We urge ongoing and continued consultation between the centers and with the regulated community to review the scientific information necessary to make such policy determinations.

FDA has also asked about focusing its resources on areas of greatest risk. Some of this

work has already begun. In 1998, FDA announced a blood action plan aimed at reinventing some regulatory aspects of the agency's approach to blood. Recently CBER has also developed a device action plan and a tissue action plan. These action plans represent important steps to begin focusing on areas of greatest risk.

However, more could be done. As part of its risk-based resource assessment, FDA could reinvent its inspection program towards a systems based approach. A systems based approach will help provide greater focus on important safety and quality steps within the manufacturing sites.

Self-certification licensure programs such as the proposed red blood cell immunization and whole blood irradiation self-certification programs could hold promise for appropriate allocation of agency resources. CFRR is ready to work with FDA to expand the scope of these self-certification programs to other areas.

We suggest that FDA perform a comprehensive cross-cutting review of

responsibilities of the centers along with the Office of Regulatory Affairs to help identify areas where the FDA resources could be emphasized and where they could be deemphasized. Currently, the manufacturer of a new piece of equipment used in the processing of a blood product must undergo a 510(k) review by the Center for Devices and Radiological Health. CBER then reviews the blood facility's license application for that device often including quality assurance data before the equipment can be used at the facility.

Sometimes there is a prelicensure inspection prior to license supplement approval and during a facilities annual inspection, FDA local district investigators will often review the same information pertaining to the device and its validation. CFRR urges FDA to reconcile these processes with an eye towards eliminating the existing overlap.

FDA should be acknowledged for its efforts to communicate with stakeholders. The internet home page is a superior resource for all interested

stakeholders. In addition, stakeholder meetings and solicitations of public comment offer an opportunity to provide feedback to FDA on FDAMA's implementation. CFRR urges FDA to continue its current trend of announcing proposed policies via the internet and Federal Register notices and to hold public and stakeholder meetings.

However, it is essential that such meetings be announced sufficiently in advance to permit adequate time to prepare. It is also essential for FDA to make publicly available all non-proprietary information provided to its advisory committees. We understand the need to be consistent with applicable regulations and to apply appropriate controls for confidential commercial information. However, this information, such as scientific data and algorithms discussed at the Blood Products Advisory Committee meetings will considerably aid our ability to participate.

In conclusion, the coalition applauds the actions FDA has taken towards implementation of FDAMA and we look forward to future interactions.

Thank you.

MR. BYRD: Thank you.

DR. CHODOSH: I'm Sanford Chodosh. I am the president and one of the founders of a group called Public Responsibility in Medicine and Research, commonly called PRIMR. This is our 25th anniversary year and I'm very pleased that we were invited to address this as a stakeholder. I have to also mention that I'm a government employee. I work for the Veterans Administration and what I say does not in any way represent what the Veterans Administration believes.

I've also been a clinical researcher for well over 30 years, mostly in the area of pharmacology, and I have been an institutional review board or IRBD chairperson in the past for, oh, ten, 15 years. So that I come with a lot of credentials about what I want to speak about and that has to do mostly with number one and number two questions about the state of the art of science in what the FDA does and how to exchange and integrate scientific information. I really welcome

this opportunity to present my ideas concerning how the FDA could influence the scientific aspects of the research carried out for regulatory purposes.

I believe that a significant change should be made to serve the goals of the drug and device approval process while still gathering useful scientific knowledge. What is the current state of affairs, and this is mostly in bullets because I wanted to be sure I covered it in five minutes. Right now, by and large, industry plans and carries out studies sometimes by the scientific groups in the industry and sometimes by the marketing groups in industry. They do require often approval of the FDA. However, the onus is on industry to develop these plans.

The protocols by and large reflect FDA's minimum standards to obtain approval and as far as the company is concerned for market acceptance purposes also. Legally--I didn't realize this until recently--industry only has to submit study results to the FDA. They do not have to under law legally supply this information to investigators,

the institution or the human subjects.

Indeed, industry rarely provides reports to investigators and often needs to be even coaxed to break a double-blind code after the study has been completed. Yes, it is true. Don't shake your head.

Five, feedback of results to participating subjects is almost nil. In many areas of drug and device development, the required to demonstrate equivalence to a comparative drug or device is the general rule. Comparator agents are often selected to satisfy marketing concerns, not selected because they are the gold standard for the group of drugs being tested.

The FDA allows and industry capitalizes on using investigators of variable scientific capability. What are the results of this state of affairs? Positive drugs and devices may well get approved in a faster way. On the other hand, the data collected to meet minimal standards often does not conform to good scientific methodology. Studies designed to demonstrate equivalence usually

results in inadequate numbers of subjects to show anything but equivalence. And the selection of outcome goals and methods that are used are not as objective as they could or should be, and I can give you many examples of that.

Lacking good scientific design, most of the investigation's resulting data which is very unlikely to pass muster in a good peer review journal. Unless a publication can be produced to help the marketing of the drug, the results will likely only be referred to as data on file and therefore not subject to any peer review beyond the FDA, but usable in advertising. The results of the study do not flow back to the investigators, the institution or the human subjects.

I think this raises some important ethical issues. The subjects generally are led to believe that they are taking risks so that scientific information will be advanced. I think that in general we've missed that our subjects. Most investigators are disinterested in the results because most companies are very upset when I ask

for a report of the study, because no one else has.

Why then should they be considered ethical or even legitimate investigators? Institutions do not insist on seeing the results of such industry oriented research. Shouldn't IRBs consider that their part of their responsibility is to see that the studies they approved were actually carried out appropriately and expect to see results. What can be done?

Well, I think you need to change the rules. Drug studies should be reviewed by the industry, FDA, IRBs and investigators to ensure that the best science is being used to evaluate a new drug or device. Quite frankly, that often is cheaper than the way this goes right now. Because if you really design a study properly, you probably do not need as much work on it frankly.

You need to have true scientific advisory boards. That is that are very specific for the topic for the drug being studied, and IRBs need to consider these as if they were NIH proposals. Very often, most IRBs will get industry sponsored

studies and say, well, these aren't that important. You know let's look at this NIH study. That we're going to pick apart.

FDA should change its acceptance of equivalence testing as the desired outcome. I think they should be looking to see differences if they exist. The methodology used should be the best objective measures of what is expected of the compound. Surprisingly, that doesn't always occur.

It should be required that the results of these studies be made available to science and society. This may require some new type of journal or register. Currently journals should accept more responsibility for considering publication of negative results. It's just as important to know something doesn't work.

However, if studies can pass peer review scrutiny, the results should also not be accessible for obtaining new drug approval. So it all goes around and around. If you plan good science and do good science, you'll probably come up with answers that are meaningful.

Require industry to give results back to the investigators and the investigators should find means of relating the information to the subjects that were in the study and to their institution review boards. The FDA should require that industry not use their marketing departments to dictate publication policies and details of publication.

In summary, the FDA needs to set a higher standard for the science which I think Dr. Henney obviously agrees with of the drug and device approval system. Industry needs to reassess their responsibility to develop therapies that are properly tested and reported and are scientifically sound. Human subjects must be provided the dignity of knowing what they were involved in by being given outcome results. All significant studies should be reported to the scientific community and to society whether positive or negative. I thank you very much for this opportunity to present.

DR. FRIEDMAN: Thank you.

MR. BYRD: Thank you. Are there any

comments or questions from members in the audience?

MS. RUSSANO: I have a question. First, I'd like to applaud the gentleman that just--

MR. BYRD: Could you identify yourself, please, for the record?

MS. RUSSANO: Jama Russano from Children Afflicted by Toxic Substances.

MR. BYRD: Thank you.

MS. RUSSANO: I would like to applaud the gentleman that just spoke for his truthfulness and his stand on this situation because I fully agree with it. I want to ask the woman from the Red Cross about blood bags and donating blood and if the Red Cross and the FDA have taken the position on accepting blood from people with immune deficiencies or severe allergic reactions like having a silicone device and then being allergic to silicone and what they're doing about it?

MS. DUCCA: We have an extensive donor screening process that occurs before any donor can donate. It tends to focus in on questions as lifestyle and transmissible diseases. For the

specific types of toxic transmissions that you're speaking about, I'd have to go back and speak with our medical department and find out if that very specific level is in there currently, and if you'll give me your name and your phone number after our discussion I'll be sure to get that information back to you. But right now it is focused primarily on the transmitted types of diseases.

MS. RUSSANO: Also, do you work with consumer groups like myself and other groups, maybe MS, or diabetes, to understand that you have searched all the questions that do need to be answered?

MS. DUCCA: That's a very good suggestion. We do work with such--well, we participate in the meetings that are held by FDA, primarily the Blood Products Advisory Committee, and I know, for example, there's a member of the Committee for Ten Thousand that is on that committee and we participate through that particular forum as consumer groups also participate. Again, though, for your specific kind of question about your

particular groups, I don't remember them specifically participating in these BPAC meetings.

For example, I certainly see no reason why they would be particularly excluded, but again that would be something that we can certainly explore with you and I welcome the question.

MS. RUSSANO: Thank you.

DR. FRIEDMAN: Thank you for your question.

MR. BYRD: Thank you. Any more? I'd like to thank this panel, too. Thank you very much.

DR. FRIEDMAN: Thank you, all.

MR. BYRD: Again, your comments and responses will be recorded. Thank you. Let me introduce the participants in our third panel. Michael Doneo from the People's Medical Society; Susan Cohen, a consumer representative; and Brian Meyer, who is from the American Society of Health Systems Pharmacists. Mr. Doneo.

MR. DONEO: Thank you, Mr. Byrd, and thank you, members of the FDA for inviting my organization to be at this session today. It has

certainly been enlightening and very informative and I'd like to say that I really appreciate the comments that the other consumer members have made. Ann and Jama and I think Dr. Chodosh were really right on target.

My organization is a national health care consumer information and education advocacy group. And we're generally supportive of the FDA modernization act. Insomuch as it does get things that are needed to certain populations. However, we do have some reservations about the expediency of perhaps bringing some items on the market, primarily because when there are adverse incidents, there are reactions. We are the ones who pay the price in more ways than one.

So I don't think we want to see any more repeats of the Dalkon Shield, the Shively heart valve, the silicone breast implant--thank you, Pamela Lee Anderson--and things such as defective pace makers. The other thing that I think was raised here today and we are also concerned about it is the fact that at the present time the

scientific stream seems to be things that the manufacturer funds and the types of studies and the reports and we don't know if these things are published in things that the manufacturer owns and then they're presented to the FDA as being fact.

I had raised an issue earlier about tracking side effects. We've heard Commissioner Henney mention that while we know in these studies there are certain side effects from medications, but I think it's also important to know what happens when you put that medication or that device into the general population. Are there certain population groups that are more vulnerable, who might have other reactions? And we need a mechanism for getting that information back to the FDA because if there is something that needs to be done, they could pull it back.

I'm not going to address items one and two because I don't think--we are not a scientific group. We are strictly a consumer group, but I do want to address question three. And I think that something that's very important is that we need to

particularly uninformed about the risks associated with medication use. Drug products after they enter the marketplace leave the artificial situation of controlled clinical trials and they're placed in the hands of ordinary human beings--health professionals who strive to maintain a thorough understanding of the product and patients who may not be well informed about their role in ensuring the best use of the product.

Without fully comprehending the benefits and the risks associated with taking prescription medications, consumers may have unrealistic expectations of their medication therapy. There is a real need for public education in this regard and ASHP would like to assist the agency in developing a program to educate the public about what safe medication use is all about.

I say assist because we recognize that both, both health professionals and the agency have a shared responsibility to educate the public. And as front-line practitioners, pharmacists along with doctors and nurses are safety managers, learned

professionals who help patients safely manage the risks of their medication therapy.

ASHP has been an advocate and a leader in the safe use of drug products. In the first precept of our leadership agenda declares the top professional objectives is to foster fail safe medication use in health systems. And among the key assumptions that we have made is the belief that patient risk associated with medication use will increase as drugs become, drug therapy and drugs become more complex. And the recognition that safe medication use is a growing public concern, as reflected by news reports and the scientific and professional literature.

ASHP has a number of practice guidelines that our members use. I'm just going to highlight a few. One is a minimum standard for pharmacies in hospitals and it states that patient education coordinated with medical nursing and other clinical staff should ensure that all patients are given adequate information about the medications that they receive.

We also have a guideline on adverse drug reaction monitoring and reporting. And it suggests that health systems develop a comprehensive adverse drug reaction and monitoring and reporting program that includes patient involvement. And finally, we have a guideline on pharmacist conducted patient education and counseling, and it states that the pharmacies profession has the responsibility to provide patients with information to improve patience adherence and reduce medication related problems.

And that has a goal to partner with patients in managing their own care, which is the very essence of patient practitioner collaboration and safety management. And that is to ensure the therapeutic effectiveness of their medication use.

And a final guideline that we have deals with the medication errors and preventing them in hospitals. And it contains a section entitled "Recommendations for Patients and Personal Care Givers," and states that health care providers should encourage patients to take an active role in

their drug use by questioning and learning about their treatment regimens.

Earlier this year in January, our organization and our research and education foundation brought together a group of interdisciplinary experts to discuss medication misadventures with the goal of developing a set of ideas for generating concrete action plans to foster this fail safe medication use in health systems. Among the major ideas identified by this group was one that would use patients and consumers as allies. Patients have the greatest interest in understanding drug safety.

They also have a high level of trust in pharmacists. Consumer representation should be designed into projects formulating public communications such as public service announcements about the benefits and risks of medication therapy. Our members also have an ongoing commitment to safety management in their day to day practice. Every interaction with a patient is an opportunity for the pharmacist to educate the public about drug

safety. We encourage FDA to take advantage of the pharmacist role in reducing medication roles but also recognize that FDA has some responsibility to educate the public.

ASHP stands ready to assist FDA and other organizations and research projects designed about safe medication use. One area that needs research is the incidence and causes of medication errors in the outpatient and ambulatory setting, and home care setting. The error free prevention value of collaborative drug therapy management, arrangements in which pharmacists, prescribers, nurses, patients, and others work closely to ensure the best therapy and safety also needs further study.

And ASHP is eager to begin a partnership between FDA, pharmacy, nursing, medicine and patients to conduct such research. In March of this year, at a policy forum on drug safety sponsored by the American Enterprise Institute, CDER Director, Dr. Janet Woodcock, stated that risk management of drugs once they're approved is not under FDA authority. But that the agency has a

role in preventing medication errors through its regulatory requirements for product packaging, labeling, and distribution. ASHP believes that under packaging and labeling the FDA has an obligation to quickly review and revise its procedures to eliminate medication errors that occur due to sound alike names, similarities in packaging, and other labeling and packaging problems.

As noted earlier, patients should be considered the allies of health care professionals in eliminating medication errors and should be involved in providing input into the safety design of drug product labeling. ASHP would also add advertising to Dr. Woodcock's list of aspects of FDA's role in drug safety. Specifically, we think FDA should be reviewing the concept of direct to consumer advertising much more critically.

Direct to consumer advertising may induce patient demand for a product that is not in the patient's best interest. We suggest that FDA thoroughly research the risks and benefits of

direct to consumer advertising and its contribution to increased reports of adverse drug events. We appreciate FDA's hesitancy in getting involved in the safety management of drug products on the patient level. Health system pharmacists, however, expect the problem of medication misadventures to get worse as products and more potent products enter the marketplace, and as these products are prescribed for more patients.

But this hesitancy must not lead to a renunciation of responsibility. We believe that the issue of safe medication use provides us all, health care professionals and the agency, with an opportunity to work together to provide better patient care. Thank you.

DR. FRIEDMAN: Thank you.

MR. BYRD: Thank you. Are there any comments or questions? Please.

MS. HAIRE: My name is Doris Haire, and I'm president of the American Foundation for Maternal and Child Health. I have been chair of the National Women's Health Network and several

other organizations of national prominence. First of all, I'm very pleased that this meeting has been held and I must say I agree with all of the statements that the consumers have made at this meeting. One of the things I think is so terribly important for people to know, and it is such a simple statement, that most people do not know that only--let's see--I'll have to do this again--that only those doses approved for specific conditions mentioned in the indication section of a drug's package insert are FDA approved uses of the drug.

I learned that from Dick Krout many years ago. I have never heard it repeated in any FDA publication and it is such a simple thing for people to understand. So I would like to see the FDA make that a prominent message in the future.

I'm also concerned that when Dr. Henney was speaking today and talking about what needed to be done at he FDA there was not a single mention of the fact that the FDA has no written guidelines to evaluate the safety of drugs given to pregnant women. All drugs given to pregnant women cross the

placental and enter the baby's brain, and the FDA is still using a 25 year--it's over 25 years old guidelines. It's not really a guideline. It was passe when it was produced and it's even more so today.

So I would like to see that the FDA take upon itself to immediately initiate a program to evaluate the safety of drugs given to pregnant women. We've seen drugs can alter dendritic arborization and cause life long problems for the child. Thank you.

MR. BYRD: Thank you very much. Are there other comments or questions?

MS. FLYNN: I'm Rosemary Flynn from the Gray Panthers and I have some comments. By the way, I appreciate the comments of the panel and some of the other panelists, believe me. But I want to comment on the fact, and I don't think I'm mistaken, that no physicians group has been represented on the panels and I think--I don't think it's an omission in that FDA wouldn't want them so I don't really know why they're not. But I

think it's very important to consider the interaction of the pharmaceutical salesman and the physicians after the use of medications, after the introduction of those medications, and just how much information the pharmaceutical company, the salesman gives to that physician, and it couldn't be dealt with because there is no one here to speak to it that I know of. That's all.

MR. BYRD: Thank you. Please.

MS. COHEN: Can I make a comment and ask a question? I was in a physician's office and a detail person came in from a pharmaceutical company and I kind of grabbed here and I said do you have any concerns about the job you do? She said to tell the truth, my concerns are that when there's a new medication, we really don't know how efficacious it is or what the side effects are or the risks are, and I get a little concerned when I'm so to speak bringing these free samples in and we have say a year's time and we really don't know what's going to happen.

I just had a quick question. Is there any

they want to have that flexibility there.

MS. COHEN: Thank you very much.

MR. BYRD: Thank you.

MS. RUSSANO: I'm Jama Russano from CATS, Children Afflicted by Toxic Substances, and I'm very happy to hear that the pharmaceutical--or, not the pharmaceutical, that pharmacists would like to take a more active role, and I'd certainly like to be a part of that, but one of the areas that we really seem to focus today was the drug aspect of all of this, where we really haven't focused much on health and beauty aids, cosmetics, which are a part of the pharmacist's role and people do inquire about that and I think that it's important coming from a cosmetic background that maybe your group might be willing to participate with the FDA with the cosmetic companies along with health and beauty aid companies.

Because many people do have adverse reactions to cosmetics, shampoos and various things on the market. That's just one suggestion. The other thing is again in pertaining to children and

what is happening, I think that the FDA needs to really focus on the amount of chemicals that these young children are absorbing in their bodies from this processed food.

You know there was an article in the Houston Chronicle this Monday about the amount of chemicals that our children are exposed to and how it changes their immune system and changes their mental chemistry, making them more violent, making them more aggressive, and that issue after we've seen what has happened cannot be ignored.

And I went to my inlaws 60th anniversary this weekend and a 100th birthday last week, and they never been to MacDonald's once or a fast food restaurant. I think that has a lot to say about something. But it is important and even though drugs and devices are top of the list here, I agree. We still need to look at that and there needs to be more consumer groups working with the FDA on these issues.

MR. BYRD: Thank you.

MR. DONEO: One other point I'd like to

make very quickly and I think it was the fact that consumers need more information and my group recognized this. About 12 years ago, we put together a publication entitled "How to Choose a Pharmacist" because we recognized early on that when you look at the health care delivery team, it's not just the physician health practitioner, but it's also the patient and the pharmacist very often because you're getting a prescription, and we have given a lot of suggestions on questions to ask about the different medications that are being prescribed, not just the medication itself, but also any side effects, any interactions with other medications you may be taking, whether they are prescription, OTCs, vitamens and minerals, because this is all information that you can convey to your practitioner as well as the pharmacist to help give you some guidance.

Another thing, I was glad to hear you mention is the fact of tracking and reducing hospital errors. We did a seminal publication several years back entitled "Medicine on Trial"

where we examined what was written in professional publications about medication errors, about surgical procedures gone awry and what have you. We work with a pharmacist in our area who heads up an institute known as the Institute for Safe Medication Practices and he and his partner are both hospital pharmacists that have done great strides in trying to reduce. You probably know Michael Cohen who was excellent.

He will work with hospital pharmacies to try to reduce areas where accidents and mistakes can occur and he also works with manufacturers in trying to change the labeling and packaging so that when something is prescribed it's pulled from the shelf, that you're not going to get a drug that is only injectable or should be mixed accidentally given to someone. But they came up with a formula that in an average size hospital, you could have up to 300 medication errors per day, which is what we told consumers early on. When that pill comes in, ask who ordered it, what are the hours, what's the shape, what's the size, the color, whatever you

need to do, make sure you know you're getting the right medication. So we have to work together on this. I don't think it's just any one. It's a team effort.

MR. BYRD: Thank you very much.

MR. MEYER: I guess maybe slightly to respond if I may and maybe to conclude and it is striking a balance between both the patients and the health care practitioners and regulatory agencies to get a good understanding of risk and benefit to achieve the best outcome here.

MR. BYRD: Thank you. I'd like to thank this panel. I really appreciate your very thoughtful comments. I'd like to thank all of the panelists again. We appreciate all the comments. They were all recorded. A lot of the comments suggested the need for the agency to do a number of new things and to do a number of things better. And it also recognized the agency's need for additional resources. We particularly appreciate those who recognize that need. We hope that people in the audience and others who are part of our

panel will continue to support the agency and particularly the agency's budget request.

I would be remiss if I didn't make that comment. We also, before we conclude, Ms. Sharon Holston, who is the Deputy Commissioner for International and Constituent Relations, will provide closing comments and a wrap-up for today's stakeholders meeting.

MS. SMITH HOLSTON: I should say I was going to provide closing comments until Mr. Byrd just provided closing comments and a wrap up. So this isn't going to take me long at all. I think, first of all, I also would like to express the appreciation of the agency for those who have come to be with us this afternoon and who have been supporters of FDA for a long time and many of you are individuals with whom I've had the pleasure of working many times in the past, and I appreciate the fact that you continue to come out and support us and to give us the benefit of your opinion.

One of the things we heard today is that I think our stakeholders really do want FDA to make

decisions based upon the best available science, but they also want us when we have information available to us, to find better ways of communicating that information to those individuals, organizations that are affected by it. I heard that from consumers. I heard that from the industry. Everyone wants to have as much information at their disposal as possible and they're looking to FDA to figure out mechanisms for sharing that information.

I think there are concerns. I heard concerns expressed about the fact that we are approving drugs at a fairly rapid pace, and although I think most people out there who need the drugs, want them available to them as soon as possible, there's still concerns about the agency's ability to do adequate post-market surveillance of drugs, particularly with the limitations that we have on our resources.

There is concern that we do more education about the benefits and risks of drugs. That consumers need to understand that there are

tradeoffs and that some of the decision making about whether to use a drug or not to use a drug, for instance, is dependent upon a consumer making informed choices about their own benefit-risk equation and we need to help by providing them with sufficient information to make that decision.

I think everyone is interested and supportive of two-way communication process, between FDA and a particular stakeholder group as well as between FDA and among stakeholders. There's an interest in having stakeholders work together with FDA, and finally just to repeat again what Mr. Byrd has said, there is some recognition of the fact that FDA has limited resources and that there are many organizations and individuals who want to help us become adequately resourced to do the tremendous job that we have to do.

Again, we want to thank you for spending the time with us this afternoon. We will be having stakeholder meetings again in the future, not only because of FDAMA, which mandates that we do this kind of activity, but because for those of you who

know the agency, you know for many, many years, it has been a part of the way we do business that we do reach out to consumers and to other groups to try to get their input into the agency. So we look forward to our next opportunity to hear from you and thank you again for being with us.

[Whereupon, at 5:04 p.m., the meeting was adjourned.]

CERTIFICATE

I, **VICTORIA S. McLAUGHLIN,** 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.

Victoria S. McLaughlin

VICTORIA S. McLAUGHLIN