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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

FDA STAKEHOLDER MEETING

TALKING WITH STAKEHOLDERS ABOUT

FDA MODERNIZATION

Wednesday, April 28, 1999

12:50 p.m.

The Jefferson Auditorium
U.S. Department of Agriculture
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C O N T E N T S

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P R O C E E D I N G S

DR. FRIEDMAN: I want everything to remain on schedule today as much as we can. I'm Mike Friedman. I serve as the Deputy Commissioner in the Food and Drug Administration and on behalf of two others I'd like to welcome you here. One is Deputy Commissioner for International and Constituent Relations, Sharon Holston, and the Deputy Commission for Management Systems, Bob Byrd. We are glad that you can participate in this the Washington, D.C. site of the downlink for this teleconference with Dr. Henney.

We think today will be a special event. We want to give you an opportunity to directly share Dr. Henney's vision for the future of the Food and Drug Administration. This is designed to give FDA stakeholders a chance to tell the agency what they're thinking. In addition to the two-hour teleconference, the agency is sponsoring separate meetings in major cities across the country from Boston to San Diego. At each of these sites, like the meeting here today, stakeholders will be given

a chance to provide their concerns and provide feedback on five questions that have been published in the Federal Register announcement that form the central topics for today's events.

This process of talking to FDA stakeholders is laid out in the FDA Modernization Act and we take this very seriously. We started these meetings last summer, and they have provided a valuable source of information for the agency. Let me tell you what's planned here today. We'll start with a teleconference with Dr. Henney and with Dr. Suydam. The U.S. Senate confirmed Dr. Henney, as you know, last fall, and she became the Commissioner in November. While she's been meeting throughout the agency, industry and consumer groups since that time, this is the first time that she's holding a nationally broadcast interactive teleconfernece.

Dr. Suydam is the Senior Associate Commissioner for FDA. She coordinates a large number of activities within the Office of the Commissioner and she directly supervises the chief

mediator and ombudsman staff, the Office of the Executive Secretariat, the Office of Public Affairs, the Office of Orphan Products, Internal Affairs staff, advisory committees oversight, and the Office of Tobacco Programs.

The first half of the teleconference is slated to be an opportunity for Drs. Henney and Suydam to provide their vision for FDA over the next several years. The second half of the teleconference will provide an opportunity for you, the audience, to call into the FDA TV studio or to send faxes and direct your questions to them on the air.

This conversation is intended to focus on five critical questions that have been laid out in the Federal Register. You know what those questions are. Number one: what actions do you propose the agency take to expand FDA's capability to incorporate state of the art science and risk based decision making?

Number two: what actions do you propose to facilitate the exchange and integration of

scientific information to better enable the agency to meet its public health responsibilities?

Number three: what actions do you propose for educating the public of balancing risks and benefits in public health decisions?

Number four: what actions do you propose to enable FDA and its product centers to focus resources in areas of greatest risk to the public health?

And number five: what conditional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation and evolution of our modernization efforts?

You can certainly submit these comments or questions on any of these areas during the teleconference. If you want, there will be phones set up here for you to call the TV studio during the second half of the teleconference and direct your questions to them. Please, however, I ask you limit your questions to these topics. As many other interesting and important items as I'm sure

you want to bring to their attention, we ask that today you only deal with this handful of subjects.

After the teleconference is over, we'll take a short break, and then we'll begin a two hour meeting here in this auditorium. Perhaps a dozen or so individuals representing various FDA stakeholders have registered to speak. We look forward to hearing from them. There are a number of FDA officials here at this meeting who will form a panel and listen to those questions and comments. This is not really a question and answer system. Primarily this is an opportunity for us to hear the kinds of concerns, suggestions, comments and advice coming from our stakeholders.

The discussions--if our equipment permits --will be recorded and transcribed and entered into a general database of information being assembled from similar meetings all across the country. Questions that are not answered during the teleconference will be grouped into categories and answers will be provided on our internet site and subsequently in reports to Congress.

As I've said before, this is an important process. We take it seriously. We face a number of very important challenges as we enter the next millennium. Our responsibilities grow faster than our resources. The current budget request before the Congress provides for a substantial increase for the agency, but even so there will be responsibilities that we cannot fully meet because we do not have all the resources.

In addition, science progresses at an accelerating rate. The agency must strengthen its scientific base if it's to remain current with the scientific advances and make the decisions required before us. These are challenging times. They're also enormously exciting times. I hope that you will find this teleconference interesting, informative and valuable. We very much look forward to your discussions afterwards. Thank you all very much. I anticipate that in the next couple of minutes, the teleconference will begin. In the meantime, welcome again.

[Interactive satellite teleconference

convened for two hours followed by a short break.]

MR. BYRD: Dr. Friedman has already introduced me. I'm the Deputy Commissioner for Management and Systems with the Food and Drug Administration. We want to continue our stakeholder meeting this afternoon. These stakeholder meetings will be listening meetings as Dr. Friedman indicated. We'll be listening to 11 speakers representing three panels. We will continue our discussion on the Food and Drug Administration's Modernization Act and what we're doing to implement the act.

You've heard what the five questions are over and over again, but I think they deserve just one more reiteration by me. The five questions: (1) what actions do you propose the agency take to expand FDA's capability to incorporate state of the art science into its risk-based decision making; (2) what do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making; (3) what actions do you propose to facilitate the exchange

and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle; (4) what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health; and the last question, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?

As I've indicated, we have 11 speakers. The 11 speakers have all been given an agreed upon time to make their presentations. We ask that the speakers adhere to these times because we want to be fair to all of those who'd like to speak so we ask you to be very cognizant of the time frame under which we're operating.

Our first panel today I'd like to introduce is Tony Young, who is counsel for the American Herbal Products Association; Ann Fonfa from the Annie Appleseed Project. Ms. Fonfa is a breast cancer patient and advocate. Eleanor Vogt

is from the National Patient Safety Foundation. And Jama Russano is from the Children Afflicted by Toxic Substances. Who would like to go first? Tony Young.

MR. YOUNG: My name is Tony Young. I'm counsel for the American Herbal Products Association, the national trade association and voice of the herbal products industry. AHPA is comprised of small and large, domestic and foreign companies doing business as importers, growers, processors, manufacturers of herbal products. We are the principal raw materials supplier, manufacturer, and distributor beneficiaries of the Dietary Supplement Health and Education Act's inclusion of herbs and other botanicals within the definition of dietary ingredients. We appreciate the opportunity to provide input here with respect to FDA's modernization efforts.

On state of the art science and risk-based decision making, we support the concept of risk-based decision making and the incorporation of all available science including state-of-the-art

science into that process. In 1997, AHPA published the Botanical Safety Handbook which forthrightly describes conditions appropriate for the marketing and use of many herbs including potential adverse effects.

This handbook was based on the rich worldwide experience, tradition and reporting on the effects of herbs. We see that handbook as a takeoff point. The first edition of an information base and source that will be edited from time to time to include new and important information as it appears. AHPA and its members do not seek to hide from what is known about the safe use of herbs and botanicals. AHPA recognizes that many herbs are pharmacologically active and must be treated with respect.

We encourage FDA to provide information to AHPA as it becomes available so it can be considered for inclusion in the safety handbook. AHPA also recognizes that many of its products are used to treat conditions which FDA so far has said must be described euphemistically. "For men over

50 years old" sounds to us like a 1950s laxative TV commercial where the only word over three syllables permitted by TV sensors was "regularity."

Saw palmetto is used by many men who experience enlarged prostate, a condition as common to male aging as gray hair. The National Institute of Aging for one of our institutes has an excellent information piece of BPH including clear and concise descriptions of the signs and symptoms of BPH and the universally accepted message that those with BPH should see a physician.

State of the art science says men over 50 should have a prostate exam. Eight out of ten cases are simply enlarged prostate and two are much more serious. Is there any good and sufficient reason why the essence of those NIH authored statements, neither of which mentions saw palmetto, should not be included within saw palmetto packages so that men who have this condition can have the opportunity to ready them? Isn't that good sense, good risk reduction and good science?

With respect to the exchange and

integration of scientific information, we encourage FDA to promptly exchange scientific information with the botanical industry. When the plantain contamination situation occurred, some real science heroes in FDA's C Street laboratory did an extraordinary job in determining the contaminant and its source. FDA presented its position to industry and the industry, herbal products industry, cooperated in effectuating a recall.

We need that kind of interchange. Recently, an article in the American Family Physician reported on five botanicals which may interact with prescription meds. AHPA intends to address this information. We encourage the pharmaceutical manufacturers to address this information. FDA can play an important role by bringing articles like these to the attention of the herbal products industry so that we can integrate it into our database and recommendations for members.

We encourage FDA and staff to share technical input to industry efforts. In this

regard, we point out the value of having FDA staff on an open seat of the Institute for Nutraceutical Advancement, that is presently developing validated scientific methods, analytical methods, for botanicals. Those aren't necessarily in place yet and we know we need to get them and FDA knows that we need them as well.

With respect to areas of greatest risk, botanical raw material identification, as the plantain incident showed, is a very important area and it's the first step to ensuring the integrity of botanical products. FDA scientists are now working with AHPA and the American Herbal Pharmacoepia to provide training to members of the botanical products industry in basic botanical morphology and microscopy.

This follows the submission by AHPA members to FDA and its advisory committees of a botanical identification scheme. FDA input into these kinds of industry efforts focuses resources in an important area where our industry already has a momentum going and where we can both serve the

public interest.

Enhancing communication about modernization efforts, we encourage FDA to interact with AHPA members, staff, counsel, whenever there are matters of interest to be discussed. AHPA has taken the initiative of inviting FDA staff to our committee meetings, and we are pleased to have them present at those meetings. Modernization should also include open lines of communication. Passing along information to affected industry should not be considered engaging in policymaking. FDA and its staff should not be so shy that they cannot informally communicate information to the industry it regulates so that we can begin promptly to take action where necessary. Thank you very much.

DR. FRIEDMAN: Thank you.

MS. FONFA: My name is Ann Fonfa. I was diagnosed with Stage 1 invasive lobular carcinoma in the left breast January of '93. I found it while doing my monthly breast self-exam. I chose not to have radiation after the lumpectomy. Dealing with a very slow growing cancer, I also

chose not to take chemotherapy. I knew that most breast cancer patients in common with many other cancer patients did not benefit in survival terms. I've spent the last six years educating myself on issues of importance to the cancer patient community.

I speak for myself and a large number of cancer patients concerned about treatment options and standards. We need to know about all the trials that are available. The PDQ is way too limited. We want you to make the information available on all trials to all of us. There are no secrets among the industry. Let us into the club.

We also want you to publish mortality data. This is very important information for cancer patients. It's what we care about. Give us access to drug data before we're asked to comment on approval for a particular drug. We want to focus on relevant issues. We need the facts. Let us meet and speak to FDA officials informally before a meeting. We have lots of questions. We don't understand very much about your agency. We

need to know.

Oncologic advisory meetings can be confusing and intimidating. When a speaker raises issues, they're not necessarily responded. There is no dialogue. The audiences in the back of the room sometimes cannot even hear the proceedings and they hardly ever know who is speaking. When the FDA advisory panel decision is made, the media often reports it in incorrect terms. I'm thinking particularly of the Tamoxifen approval which was approved for risk reduction, yet the media reported it as prevention.

In addition, standards for healthy people will need to be very different from those who are ill. We need to know if survival is impacted by the drugs being studied. Cancer patients need to know. The system is set up to facilitate research, but that may be not enough for us. We need you to establish quality of life as an important standard. Our plan is to aid patients and if we're to live or if we die, how we feel physically, mentally and emotionally is critical.

We call unwanted effects side-effects, but that doesn't reduce their importance to patients. They can be painful, sometimes long lasting, and should not be easily dismissed. To us, they are as central as any effect. Side effects are not aside.

Drug approval standards are both inappropriate and tertiary. Tumor reduction doesn't often correlate with increased survival. Robert Templeton of FDA has said that quoted in The New York Times. Speaking as a cancer patient, survival is our goal. So why do we use tumor response as a standard? The answer is usually that we can measure that. That's not really good enough.

This has resulted in those tiny incremental steps that don't seem to follow through with a survival advantage. I often think of it as crawling on hands and knees through a field of broken glass, and I'd like to take a running leap over that field.

As you begin to offer survival data to patients to patients, we will be demanding new

standards. I know this data is available. New standards might include disease stabilization. Angiogenesis drugs are said to work by that effect.

Our system obviously includes exploration of patentable drugs. If the answer lies in natural or non-toxic substances, patients will want to know that. Our tax money finances many studies in part or fully. We asked for human studies designed to look at total protocols as practiced in the real world. Many animal studies have shown the benefit of combining vitamin regimens for example. Indeed, we take antioxidants as a group, never alone. They've been shown to be useless, possibly harmful as isolated elements. Garlic, onions, green tea, soy, a variety of fruits and vegetables have shown anti-cancer properties. I know that cancer patients would be willing to participate in studies.

Our tax dollars would be well spent. Thank you for approving a trial of Tibetan herbs, even if it's being done in a westernized fashion which may limit results. In traditional Chinese

medicine, Ayer-Vedic and Tibetan systems, each patient receives a highly personalized prescription consisting of many herbs. They are designed to balance each other, eliminating unwanted effects. Chinese have been recording herbal formulas for over 4,000 years. Since breast cancer is known to be heterogeneous, the study of Tibetan herbs may yield some valuable answers.

At this year's meeting of the American Society for Cancer Researchers, there were again many studies on green tea. No matter. In the real world, no patient is going to go home to drink green tea by itself. We're going to combine it with other elements for a total protocol. It's this that we need to have studied. It must be looked at in a way that real patients do it in the real world. We're leading this, but you guys should be catching up.

Right now many patients, myself included, are spending our money and our precious time on substances that may not prove useful. That's why we need your data. We need your input and we need

those studies as soon as can be. I cannot wait another six years to see these studies begin. I have heard every year for the last six, well, we have no studies on that; well, we don't know anything because there are no studies. Well, start those studies.

Clinical trials often do not gain answers to patients questions. Too often the aim of the trial is simply to determine of a drug can get approval. You ask us to participate but ignore the majority of our questions. An example, as a result of last October's approval of Tamoxifen for risk reduction in healthy women, there were a host of seminars conducted around the country. Many shared the title "Estrogen, Tamoxifen, Raloxifene." At each forum, women raised many questions and all too often the answer was we don't know. Now researchers boast of thousands of women hours of data, yet we still don't know the answer to many of the basic questions about the drugs. This is bad.

Advocacy groups are constantly asked to help recruit patients for clinical trials. I have

just spoken of some of the barriers to that. Often physicians don't tell their patients about trials even if they're in their own centers. Or overloaded oncologists may not have time to consider each patient when a new trial is announced. A patient must learn to be an educated advocate. Well, it's hard to do. Many cannot and they shouldn't have to. We need to have all information on trials easily available.

I've heard it say that FDA and other responsible agencies focus on methods developed to fight infectious disease, especially the idea of the magic bullet. It's time for a change, a paradigm shift, to use a buzzword. As a non-scientist, it may be easier for me to see these gaps. Activists like myself watch you continue to look at the usual suspects in the usual way. You seek answers under the lamppost because that's where the light is. We can, therefore we do.

I've been told that if don't know how to look at something, it doesn't exist in scientific terms. That may be true from the limited

scientific perspective, but it offers nothing for the real world, and as I said, cancer patients are living in the real world. New ideas, new methods, new discoveries have to be encouraged. No more burning at the stake is allowed. We shouldn't be dismissing new ideas outside the norm. People with cancer continue to die in huge numbers and we don't seem to find appropriate answers. I urge you to study natural and non-toxic substances as quickly as possible using a total protocol that will matter. Neither finances, politics or old patterns can interfere with our need for real world solutions for cancer. Thank you.

DR. FRIEDMAN: Thank you.

MR. BYRD: Thank you very much. Ms. Vogt.

MS. VOGT: Hello. I'm Eleanor Vogt with the National Patient Safety Foundation at the AMA. I'm going to speak very briefly and very directly to question number four and offer a concrete suggestion.

The area of greatest risk and therefore the area for greatest opportunity for improvement

is with product use, the product and practice. Now as we move down the pharmaceutical safety chain from industry research and manufacturer to FDA approval to prescribing, dispensing, and ultimate end use, it appears that the availability of information for prescribing, compliance and monitoring falls off dramatically. So that the knowledge, the support and the resources both to manage risks and more importantly to exploit the benefits of the therapy in actual practice become more and more scarce the farther down the chain you are.

This is, I think, both ironic and tragic. Now the current situation is that the institutions and the companies involved in the research and the development of a therapy product are very rich sources of information not only about the product but about the disease state as well. And a good part of that knowledge gets passed on into the FDA, gets added to, gets analyzed, and new knowledge is generated as a part of the approval process.

But it's after this point, however, that

the flow of information in meaningful educational resources seems to slow down. So if we're to close the gap between what we do, what we know and what we do, then we must move that product information and knowledge down the safety chain and at the same time, of course, this has to be a living process in which we're adding to this information out of our own experience and from other resources.

And again it's to maximize benefit as well as to reduce risk. Now here's the key. The transformation of knowledge into practice calls for the overlay of a new model based on education and the communication sciences. This model actually evolved from the regulatory model which is based on law and the physical sciences.

And I want to make a differentiation here between regulation as a function and the regulatory structural model. And I think we can and should have a healthy debate about the role of regulation with regard to communication and education products, but what I will say is that trying to adapt the structure and the procedures of the

regulatory model itself do not work. It's not a good fit. It was never designed to that end. And what I'm suggesting is that we're going to measurably improve patient's safety, the next step we must take is the creation of a practice centered or a patient centered model, which is grounded in science, as Jane Henney says, but it's grounded in the social sciences, in education, and communication and behavioral change sciences.

So we need both. Here is my direct recommendation to you. The National Patient Safety Foundation is working very actively with the FDA right now in taking a systems look at the roles and accountability of all the players in the pharmaceutical safety chain. We're an appropriate neutral convener because we represent all the stakeholders. We have them at the table.

What I'm suggesting to you now is that we move on to the next step and we start addressing the development of this I call it a transformational model, a practice model, where we can start generating the next generation of

products that will serve to close this gap between what we know and what we do, which everyone has alluded to and everyone is frustrated by.

And I don't mean that we have to reinvent the wheel in the sense that there are models out there. Your own MedWatch program I think is a great example of bringing stakeholders together and developing and using the strengths of all the stakeholders. So I would recommend to you that you formally address the NPSF, ask, request the NPSF to serve as this forum to assist you and to assist all of us in developing this new model, again grounded in science. And this is the kind of a concrete action the agency can take to produce measurable improvements in both the safety and just as importantly the efficacy of care. Thank you for listening.

DR. FRIEDMAN: Thank you.

MR. BYRD: Thank you.

MS. RUSSANO: Hi. My name is Jama Russano and I'm the director of the children's nonprofit foundation called Children Afflicted by Toxic

Substances. At birth, I was born with a hemangioma tumor and due to the removal of that tumor, I never developed fully on my right breast and ended up having a silicone breast implant emplaced at the age 14. Mind you implants were never studied nor proved safe for young women like myself. To this date, they still are not.

I developed severe complications and I had two children that I breast fed that also developed severe complications. To add fuel to the fire, I also participated in a protocol drug study to help the esophageal motility disorder that I got from the implant and was part of Temple's protocol and really had adverse, again adverse side effects to it and was dropped from the study. To this day, I have never heard from the pharmaceutical company or Temple University to see if I was green, blue or if I was even alive.

I founded CATS out of the frustration of lack of information concerning the safety of medical devices and other products exposed to children. Seven years ago I started gathering data

on the health of children exposed to medical devices, specifically the children born to mothers with implants. There are close to a million children. Breast implants and other silicone devices, the data that I've gathered should have been conducted by the FDA and manufacturers.

I have learned a great deal about the ethics, the procedures and health issues across the board with the FDA, NIH, CDC, and other governmental agencies. First and foremost, the FDA is recognized as a safety net for consumers. For a safety net to be hold, the agency must place the consumer before the manufacturers at all times. Every time we the consumer sit down for a meal, take a bath, give our children a vitamin, we are affected by the FDA's work and decisions you the FDA holds the power to alter every person in this country's health and well being.

Yet this agency is grossly underfunded, understaffed, and underpaid, under power, and needs more recognition by Congress. Today's consumer must be a modern sleuth. They have to become the

experts in many cases. I have been in more instances where I've been before physicians and I know more about silicone and poisons that affect children and mothers than the doctors do. They call me.

We have heard it takes a village to raise a strong family and healthy children. I believe it takes a village to produce safe products. The village I see would comprise of a round table of experts from FDA, NIH, CDC, HHS, insurance companies that not only provide product liability insurance but also provide health care insurance, consumer advocates, physicians and manufacturers.

I will address the issues of adverse reactions as the products are rushed to market. Insurance companies that sell liability from one division while paying health care claims from another division of the same product. If this information is combined, it would give us a heads up on our particular problem with the drug or device. Our health care providers hold significant data on adverse reactions. Yet no one pays

attention to it or the number of occurrence.

A special division with the FDA should be set up to process and dispense this new information. If the number of adverse reactions on a drug or a device is equal or greater than the number of persons in the study approving the drug or device, then that product should be pulled from the market for further evaluation. The FDA should have brochures in every doctor's office. Every prescription drug dispensed should have a number or an access of a web site so that they can report a related problem, not that the problem just goes back to the manufacturer where it's not properly reported.

The FDA should charge the user a user fee from seven to ten percent across the board. This was mentioned this morning. Strong fines should be imposed when a product line has to be reviewed or taken off the market. The FDA should require manufacturers data on products to supply information pertinent to that product by complying or conforming the information on disk or specific

data programs within the FDA so that it makes the FDA's job easier.

The FDA should be able to go to Congress and ask for more funding when there is a large health crisis like second-hand smoke, silicone breast implants, just to name a few. A new department within the FDA needs to be formed focusing on children's products and products that are intended for children or products that children are exposed to, even labeling of products such a simple product like mouthwash that is not properly labeled, but if a child drinks it, it could cause severe harm to their liver.

All departments would send their data for review reviewing a child's exposure before any product would be reviewed or released for sale in the market. My 14 year old son recently brought Wow potato chips, not knowing it contained olestra and seeing the big words "Wow" across the bag. He was sick for two days.

Within the FDA, one department is researching adverse problems to a device or a

chemical while the other department has approved a new device or a product within the same group or chemical. And that has proved to be a problem. A special department needs to be established looking at the impact of strong widely used chemicals and combinations of chemicals and numbers of times one is exposed to various chemicals such as benzene, formaldehyde, Toluene, silicone, polycyloxin that are used in everyday food processing and everyday consumer items that you shower and eat and bathe and are exposed to. Layers upon layers of them.

The FDA should establish a new department reviewing researching patents. Dr. Kessler discovered vital information on tobacco and nicotine. I personally conducted research on 246 patents on silicone breast implants showing the adverse reactions and how identified problems were noted from manufacturers and researchers from 1963 to 1996.

This information was turned over to the FDA two years ago but nothing has been done yet. All products grandfathered into the FDA or continue

under the GRAS should be restricted until the manufacturer can prove their safety. New items containing these chemicals or products should be halted. The numbers of persons identified to those persons along with their social security numbers that partake in research studies should be constantly contacted throughout the years.

The average number of persons tested in this study to approve the safety of a drug or device range from ten to 400. Yet, it seems it takes hundreds, sometimes thousands of persons harmed before a drug is pulled from the market. If a device or drug fails and one is harmed and chooses to recoup their losses through the court system, the FDA seems to back away from exploring the device or drug in question.

As an example, silicone breast implants have never really been tested for safety in young women ages 13 to 21 or children who have been breast fed.

There are no epidemiological studies conducted identifying common adverse reactions.

Yet once the drug or the device is on the market, adverse reports start coming in, the manufacturers claim we need epidemiological studies to prove your correlation.

The manufacturer then goes to a university or a group of physicians and drops millions of dollars to state their product is safe. They have hired the largest PR firms. They use the media and newscasts that gives misleading information. The burden of proof it seems to be on the consumer, thus creating a David and Goliath effect. I as a consumer do not have the clout nor the finances to conduct such studies. This is a vicious cycle and I hope the FDA places this at he top priority. Most physicians get their information from the manufacturers, not the FDA. Thank you.

MR. BYRD: Thank you very much. Do we have any comments or questions for any of the panelists?

MS. COHEN: My name is Susan Cohen. In Asia, herbs are used a great deal, but there's a social science aspect to it. They believe in the

efficaciousness of the herbs. If FDA or anybody else does a study, what do you take into consideration in terms of the sociology or the idea that the herb is going to work because there is that factor in the positive reinforcement of believing what it's going to do?

Also, Ann, you said something that interested me, and you said it to me before. Living in Washington, we live in a very rarified atmosphere. But you said that you thought a lot of people didn't know about the existence of FDA. I wish you could comment on both of those.

MS. FONFA: Okay. I think, you know, it's certain possible that there is a placebo effect amongst populations used to using traditional Chinese medicine and herbs. However, the placebo effect is already factored into every study we do for everything, and as you probably know, it's as effective as almost any drug we have on the market. So, you know, there's two ways to play it.

The Tibetan study that I referred to is only using seven herbal protocols out of a vast

majority and there is 30 people in the study. I just hope that those 30 people qualify for those particular seven herbal formulas so that it's an accurate and effective direction.

In terms of FDA, what I said and what I mean is that most of us have no idea how FDA operates and I've been on the fringes of this for six years. And I still am not clear. Things that were referred to during the broadcast, you all know what they mean. Most of us don't know, and it's very hard for us. That's why I said, suggested we meet informally in ways so that we get to understand how the agency operates. I've no idea even how many divisions there are. You know it's never clear. There is always a new thing that I discover. In speaking to some of the audience members, I found out about new departments that I didn't know existed. So we would welcome sort of either chart or discussion and many of the advocacy groups would love to have somebody come and explain that. That would be very helpful for us.

MS. RUSSANO: Could I just add?

MR. BYRD: Thank you. Sure.

MS. RUSSANO: Most of the divisions, also within the FDA and NIH, CDC, they're all abbreviated. So people have no idea what CFAN means or FDAMA means so I think a good start would be to make a list of all the different divisions with their abbreviated names.

MR. BYRD: We do have a web page and a website if that might be helpful to any of you. It's www.fda.gov. You might want to visit that website. But I agree with you that we have to do more in order to educate our stakeholders. This is the first step of many steps that we hope to take to begin the dialogue and begin the type of sharing of information that I think and Dr. Henney thinks also is very valuable to the FDA and to our public health mission as well. Are there any more comments or questions?

I would like to thank the panelists. I really appreciate your comments. They were very thoughtful and very helpful and they will be recorded as part of this discussion. Thank you

very much.

Let me now introduce our second group of panelists: Dr. Bert Spilker, who is the senior vice president for Scientific and Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America, PhRMA; Dana Kuhn from the Committee of Ten Thousand; Anita Ducca, representing the Coalition for Regulatory Reform; and Dr. Sanford Chodosh from Public Responsibility in Medicine and Research. Dr. Spilker.

DR. SPILKER: Good afternoon. My name is Bert Spilker and I'm the senior VP at PhRMA. I'd like to address questions one, three and five from the Federal Register. On question one, the first point to make is that risk-based decision-making should never be undertaken except in comparison to benefits. Therefore, the term "risk-based" should be modified to read "benefit-risk based decision making."

Secondly, PhRMA supports FDA's desire and the need to have the most scientifically well qualified and competent staff possible. We support

their efforts to recruit and retain such staff. We believe that setting aside some time every week or perhaps up to a half a day for career development activities is a high source of motivation and will serve to attract and retain high caliber candidates. While some physicians at FDA already utilize this time for clinical activities, non-medical scientific reviewers should also be encouraged to participate in projects, possibly at NIH, AHCPR or local universities.

These specific activities that FDA could offer staff and potential candidates is a matter for FDA to consider. Medical decision-making has become a specialty and can be a very useful guide in making benefit risk decisions. Relevant FDA staff should pursue training in this area as well.

Lastly, we encourage the FDA to have their reviewers visit industry to learn more about our perspectives, operations and processes of drug development. While this has occurred from time to time, particularly among the FDA chemists and statisticians, we believe that an ongoing

permanent program should be organized for relevant professionals in many scientific disciplines. The length of these visits can be discussed with industry but we believe that short visits of one to five days will enable the program to provide such opportunities to a fairly large number of FDA staff.

Benefits are substantial. And include greater understanding of each other's perspective. Other advantages include learning about current and future technologies, information systems, and current state of the art research and manufacturing equipment.

On the third question which states what action do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making, our answer has two parts: addressing messages and approaches and processes. We believe that both FDA and industry should educate the public as to the following messages: drug safety is best viewed as a balance of benefits and risks. The benefits of

prescription medicines far outweigh their risks. Continued monitoring by all stakeholders in the health care system helps assure that an appropriate balance is maintained.

There are many other specific points on benefit-risk. They're in the handout that was given. And I'm not going to read those in the interest of time because that will take a substantial period, but I would suggest that people do look at those.

The approaches that we suggest that could be used to educate the public might include (1) public service announcements on radio, TV and in print media such as magazines, newspapers; (2) the FDA could establish a speaker's bureau within the organization from both headquarters and district offices to present FDA's perspective to public groups, industry and others; (3) information could be and should be placed on the FDA's website; (4) information could be and should be sent to other government agencies such as the CDC, the AHCPR, NIH Health Find, and HCFA, for them to place on their

websites; (5) there would be live or taped radio talk shows.

These could even be done as a joint FDA/industry activity. (6) Brochures could be sent to a large mailing of federal and state legislators, federal and state health officials, patient associations, organizations, requesting publication in their newsletters and on their web sites including such groups as the AARP; (4) professional medical associations, managed care organizations, pharmacy associations, and others and requesting widespread dissemination. And lastly, publication of a series and periodic reminders in the FDA consumer magazine.

As to question five about additional actions for enhancing communication processes, the FDA, the pharmaceutical industry and other stakeholders have had very productive, very positive procedures for working together over the last several years. This interaction has led to important benefits that directly improved public health and the lives of many patients through more

rapid availability of drugs to prevent or treat diseases including improvement in existing therapies that make them better tolerated.

Senior management within the agency has also been much more willing than in the past to appear in public forums such as at DIA, PhRMA forums, other meetings, PERI courses, and meetings such as this to present its positions and progress on issues. This activity should be encouraged and expanded to include additional constituencies such as medical societies, possibly in concert with industry spokespeople when appropriate.

The current open dialogue and free exchange of views between FDA and industry needs to continue and there are and will always be situations and issues where it's appropriate and beneficial for industry and the FDA to work together for the public good. Examples of such activities include recent Biostatistics Workshops, the Joint Forum on Industry/Government Year 2000 Preparedness, PhRMA's Information Management Working Group working with FDA Information

Management Board and the International Conference on Harmonization or ICH, to mention just a few.

PhRMA welcomes these and other opportunities for dialogue and an exchange of views on regulatory policy and management. We look forward to continuing these and other forums where the public health is served. Thank you for the opportunity of addressing you today.

DR. FRIEDMAN: Thank you.

MR. BYRD: Thank you. Dana Kuhn.

MR. KUHN: I would like to thank the FDA and Commissioner Henney for this opportunity to present our concerns and our issues with you all today. My name is Dr. Dana Kuhn, and I am a person with hemophilia, coinfected with HIV and HCV. It has been approximately 12 years since the first anti-retroviral drug for treatment of AIDS was released by the FDA. However, if you recall, it was only released by petition.

The waiting period was approximately three weeks and I personally know this as I had to petition the FDA for the use of this product on

behalf of my wife who in 1987 was diagnosed with AIDS. Unfortunately and to no one's fault, the antiretroviral did not arrive in time and my wife died before she could use the product.

Since 1987, due to the demand from antiretrovirals and the pressure from many activist groups, the drug manufacturers and the FDA have worked quickly to fast track the needed AIDS drugs through the prescribed phase trials. For this, we are very grateful. However, the area of FDA operations which we feel has importance well beyond its current funding priority is post-market surveillance of adverse reactions to the AIDS drugs.

Our community, people with hemophilia, who have contracted HIV through contaminated blood products, is particularly susceptible to side effects. Some of these are documented and some are not. A personal friend of mind died recently from an adverse reaction to AIDS drugs. I myself was sent to the emergency room for a deathly reaction to a newly fast track drug called systeva of which

the symptoms that I suffered were not documented in the drug insert description of the side effects.

We understand that the FDA loses sanctionability once a product is licensed and released to market, but we feel strongly that the American public deserves to know that the agency is staffed and in place to monitor newly released pharmaceuticals and biologics. We also realize that the pharmaceutical companies conduct post-market surveillance through reporting. However, we do not feel that this should be left up to companies alone.

Suffice it to say many of us infected with HIV through blood products are a little skeptical of the surveillance of this type alone and some feel that we may not have been infected if surveillance was not left up to industry alone. Given the known harsh adverse reactions of some of the AIDS drugs, we believe post-market surveillance and medical studies necessary to track these effects are taken a back seat due to a lack of financial resources.

It brings us to the point that in trying to educate Congress, we have helped them understand that post-market surveillance raises questions of FDA resources and personal power and we have met with and discussed with this question with Chairman Skeen of the Agricultural Appropriations Subcommittee of the House Appropriations Committee. We are also continuing to educate members of the Appropriations Committee in both the House and the Senate about the need to provide the FDA with resources to do post-market surveillance of HIV/AIDS.

We supported the need for fast track of AIDS drugs and new therapies in the late 1980s and early 1990s. However, now with the wide range of choices available in the marketplace and the cocktail drugs, we believe a healthy and intensified focus needs to be directed toward post-market surveillance of the existing AIDS drugs.

Obviously, this will cost money and again we are working to educate the relevant congressional committees about what we believe is a