UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

RISK COMMUNICATION ADVISORY COMMITTEE

Friday, February 29, 2008

The meeting came to order at 8:00 a.m. in the Grand Ballroom of the Hilton Washington DC North, 620 Perry Parkway, Gaithersburg, MD, 20877. Baruch Fischhoff, PhD, Chairman, presiding.

PRESENT:

BARUCH FISCHOFF, PHD, CHAIR
LEE L. ZWANZINGER, PHD, EXECUTIVE SECRETARY, DFO
CHRISTINE M. BRUHN, PHD, MEMBER
JACOB DELAROA, MD, MEMBER
ANNMARIA DESALVA, MEMBER
MICHAEL GOLDSTEIN, MD, MEMBER
DAVID MOXLEY, MSW, PHD, DPA, MEMBER
LINDA NEUHAUSER, DRPH, MPH,MEMBER
JOHN E. PALING, PHD, MEMBER
ELLEN M. PETERS, PHD, MEMBER
PRERNA MONA KHANNA, MD, MPH MEMBER
MUSA MAYER, MS, MFA, MEMBER
BETSY LYNN SLEATH, PHD, MEMBER
MARIELOS L. VEGA, BSN, RN, MEMBER
MARSHA YAROSS, PHD, INDUSTRY REPRESENTATIVE
GREGORY BAIRD, CONSULTANT
STEVEN GORELICK, PHD, CONSULTANT
DANIEL HANEY, CONSULTANT
MICHAEL WOGALTER, PHD, CONSULTANT

C-O-N-T-E-N-T-S

P R O C E E D I N G S

(8:11 a.m.)

CALL TO ORDER

DR. FISCHOFF: Let me thank you all for coming. I'm Brook Fischoff, chair of the FDA's Risk Communication Advisory Committee.

And we are going to begin with a statement of conflict of interest from Dr. Lynn Zwanzinger, the designated federal official.

DR. ZWANZINGER: Good morning. Thank you everybody, and good morning to all the members and consultants of the Risk Communication Advisory Committee, the members of the public, the FDA staff, and the press: welcome to this meeting.

The following announcement addresses the issue of conflict of interest with respect to this meeting, and is made a part of the public record each day of the meeting to preclude even the appearance of

such at a meeting.

Today the Risk Communication Advisory Committee is going to hear about and discuss presentations on, and then we'll discuss, the FDA's proposed template for press releases announcing product recalls with a view to incorporating recommended practices of risk communication.

Based on the submitted agenda for the meeting, and all the financial interests reported by the committee participants, it has been determined that no interests in firms regulated by the Food & Drug Administration represent potential for conflict or appearance of conflict of interest at this meeting.

We'd like to note for the record that Dr. Marsha Yarrows, industry representative on the circulatory systems devices panel for the Center for Devices and Radiological Health, is participating as a guest industry representative in accord with the charter of the Risk Communication Advisory

Committee.

In general participants are aware of the need to exclude themselves from involvement and discussion of topics where they may have imputed interests, and their exclusion will be noted for the record.

With respect to all other participants, we ask in the interests of fairness that they address any current or previous financial involvements with any firm whose product they may wish to comment upon.

We have a period of open public comment later in the day, listed in the agenda. If any persons who are not already signed up to speak wish to request time, please see one of my colleagues at the sign in table outside.

This entire meeting is being transcribed, and the transcript will be posted on the FDA's website. It can only contain what the transcriber can hear. So I would just remind everybody to please turn on and

speak into your microphones when you are recognized to speak. Turn them off when you are not speaking.

And I'd also suggest that all of us should turn off our cellphones and other communication devices or turn them to a silent mode.

Thanks.

DR. FISCHOFF: Is turning off our cell phones federally mandated? It's about time.

INTRODUCTIONS OF COMMITTEE MEMBERS

DR. FISCHOFF: We'd like to introduce ourselves and then we'll introduce the topics.

Again, I'm Brook Fischoff. I'm a decision scientist or cognitive psychologist in the Department of Social and Decision Sciences in the Department of Engineering and Public Policy at Carnegie Mellon University.

MS. VEGA: Good morning. My name is Marielos Vega, and I am a research nurse, a

staff nurse with the Department of Family Medicine at the New Jersey Medical School in the UMDNJ, the University of Medicine and Dentistry of New Jersey.

DR. MOXLEY: Good morning. I'm David Moxley from the University of Oklahoma, Norman, where I'm affiliated with the School of Social Work.

DR. SLEATH: Good morning. I'm Betsy Sleath, a professor of pharmaceutical outcomes and policy and research fellow at the Cecil G. Sheps Center for Health Services Research at the University of North Carolina, Chapel Hill.

DR. NEUHAUSER: Good morning, everyone. I'm Linda Neuhauser from the School of Public Health, University of California, Berkeley.

DR. PALING: Good morning. My name is John Paling. I used to be a wildlife photographer for National Geographic; learned about visual communication from that; and now

lecture to audiences about helping patients understand risks. And I'm glad to be with this group.

DR. PETERS: Good morning. My name is Ellen Peters. I'm a decision psychologist and a senior research scientist at Decision Research, a not for profit research institute in Eugene, Oregon.

MR. BAIRD: Hi, my name is Greg Baird. I'm an independent consultant in communications and public relations.

MR. HANEY: I'm Dan Haney. I am a former medical editor of Associated Press, and currently a medical freelancer.

DR. WOGALTER: Good morning. My name is Mike Wogalter. I'm a professor at North Carolina State University in the psychology department. My area is human factors, ergonomics.

DR. GORELICK: Hi, my name is Steve Gorelick. I'm a sociologist; also trained in criminology. And I'm a professor of media

studies at Hunter College in New York City where I am also interim director of the graduate program in integrated media arts.

DR. OSTROVE: Good morning. I'm not on the committee. I'm Nancy Ostrove, the senior risk communication adviser with the Food & Drug Administration.

DR. YAROSS: Good morning. I'm Marsha Yaross, Vice President for Clinical Quality Regulatory and Health Policy at Biosense Webster in Diamond Barr, California; which is a Johnson & Johnson company.

I am industry representative to the circulatory system devices committee, and industry representative for today.

DR. GOLDSTEIN: Hello, everybody. I'm Michael Goldstein. I'm a psychiatrist and internist. I'm associate director of the Institute for Health Care Communication in New Haven, Connecticut, and an adjunct professor of psychiatry and human behavior at Brown University.

DR. KHANNA: Good morning, my name is Prernamona Khanna. I'm an internist and specialist in public health and preventive medicine, as well as occupational and environmental medicine.

I'm the medical editor for the website, ICU.com, and then adjunct associate clinical professor at the University of North Texas Health Sciences Center.

MS. DESALVA: Good morning, I'm AnnaMaria Desalva. I lead the global health care practice at Hill & Knowlton, the global public relations firm.

DR. DELAROSA: Good morning. I'm Jacob Delarosa, heart surgeon, Idaho State University.

MS. MAYER: Musa Mayer. I'm an author and patient advocate on breast cancer research advocate as well, currently working with the Department of Defense breast cancer research program, Center of Excellence in Brain Metastasis.

DR. BRUHN: Good morning, I'm Christine Bruhn, University of California at Davis. I'm in the department of food science and technology, director of the Center for Consumer Research.

DR. FISCHOFF: Okay, let me thank you all for coming, and let me thank the FDA staff as I did yesterday for putting together really an excellent panel and an excellent program today, and just for getting us all here together.

DR. FISCHOFF: As you all know, our topic is communication about product recalls, which are communication about the risks of products that have benefits and effective communication will put those in perspective.

The success of recalls has health implications for consumers and patients, which depends on how quickly they receive the recalls and how well they understand them.

The success of recalls also has economic implications for the firms whose

products are involved, both for those products directly involved and others that are involved by implication.

It has social implications for citizens' trust in our public and private institutions, as well as for relations among those institutions. And the need for recalls has diagnostic value for the adequacy of the voluntary and regulatory risk management systems from which they emerge.

So there is a lot riding on getting the content of these notices right; on getting them into the right hands; and on ensuring that they are understood as intended.

Our task here is to offer advice, nonbinding advice, on their content and their comprehensibility, in order to allow these notices to do the best job possible within the system within which they are embedded.

And the program that we have is -- we will begin with a review by Captain David Elder from FDA's Office of Regulatory Affairs

for communication about product recalls.

Then we are fortunate enough to have five experts telling us what the research and practice has told us, one internally, Amy Lando from FDA, and then four special government employees, external consultants.

After that, we'll have a break. We'll have some discussion from the committee, then an opportunity to hear from members of the public, and then we will continue the general discussion after that.

So thank you very much. And let me introduce Captain David Elder from FDA.

COMMUNICATION ABOUT PRODUCT RECALLS

CAPT. ELDER: Good morning.

It is a pleasure for me to be here with you all today. I'm humbled to be here in the presence of this committee. Your credentials are so impressive that it's very fortunate, and I compliment Nancy and Lee for the job that they did in selecting you all to be a part of this committee.

The depth and the breadth of your experience is really remarkable. I was struck yesterday by the thoughtfulness of your questions, the precision of many of your questions to get right at the heart of the issue, and the level of interest that you have in helping us in this truly important subject, and you all seem to have a passion for it.

So with that in mind, I brought snacks. I think you see a theme in the snacks.

I think every speaker yesterday covered what FDA does, our mission, the products that we regulate. I did a quick inventory. It is 8:20. I've already used 14 FDA regulated products this morning. I suspect many of you have done the same or even more.

We didn't speak too much about the FDA organizational structure. But yesterday - I've got a very simple graphic; it's not that simple in real life as you can imagine - I

have a very simple graphic up there. But I'm part of the Office of Regulatory Affairs. You haven't heard from our office yet.

You heard from representatives from each of the FDA centers, biologics, drugs, devices, foods and veterinary medicine yesterday, and you've heard from representatives of the office of the Commissioner.

ORA is essentially the field organization. We have over 160 different offices across the country. We are the investigators. We operate the FDA regulatory laboratories. We have a management structure, and we have a headquarters component; I'm part of the headquarters component here in Maryland.

I think you might have noticed yesterday when the center representatives were speaking to you that they too certainly had a passion for their subject. And you can see how the different communication and outreach

efforts were somewhat unique by each of the centers. When we had the Center for Biologics telling you what they were doing, and how they do it, and the Center for Drugs and Devices, Foods and Medicines, you see a lot of uniqueness, which is appropriate, because the products are unique.

You saw some similarity across the different approaches. You heard some differences, where some people do a newsletter; some don't. Some put it electronically on the web; some do it through other forums.

ORA as the office of the commissioner is a cross-cutting organization. We do work in all programming area. We interact with all centers. We interact with all industries out in the field.

We are involved in domestic operations, foreign inspections, import operations. We get heavily involved in the conduct, the monitoring of recalls as we are

here to discuss today.

But I think you'll notice in the proposal that we gave you as part of the background and the template, and as this discussion progresses today, the idea that we are proposing here with a press release template is cross-cutting. It isn't center-specific. It bears the FDA brand rather than a particular center brand. It doesn't bear the ORA brand; it bears the FDA brand.

We would like at least in this proposal - the press releases issued by FDA - to alert the consumers directly through posting on the Internet, or indirectly through servicing the media that picks up our press releases and reports on them, to do so in a clear consistent manner, whether the recall relates to spinach, peanut butter, pet food, toothpaste, or a myriad of other products that we regulate.

I was also struck by one of the questions posed yesterday: what is the FDA

brand? And one of the respondents was a representative from the Center for Drugs, said "FDA approved." And I think Dr. Bruhn appropriately pointed out that if that was asked of the Center for Food Safety the answer would not be the same. FDA approved does not really translate to foods as it does to devices as it does to drugs as it does to some veterinary medicine products and biologics products.

So I don't think there is any two-word answer to define what the FDA brand is. Like the sides of police cars often read, "To protect and to serve," might be a little closer. But to advance and protect public health is really the cornerstone of the mission. And to me that is the brand.

So I want to get into a little bit with you about what is a recall. I think we all know the common and usual name. But it does in FDA have a legal definition.

FDA is a science based, science

driven, science led - whatever the first two right words are - but the last phrase is always, law enforcement agency. We are a law enforcement agency, a regulatory agency. And the term recall does have a legal definition. It's codified in the Code of Federal Regulations; there's a reference there.

But it is a firm's removal or correction of a marketed product that is in violation of the law, and against which FDA would initiate legal action.

That's the real definition of a recall.

How do we learn about a product that may be appropriate for a firm to initiate a recall action? The answer is, through a variety of ways.

Recalls, with very, very, very few exceptions, are voluntary actions initiated by firms that we regulate. There is a proposal through the food protection plan to give FDA mandatory recall authority in the area of

human and pet food. We don't have that yet.

We have some very limited mandatory recall authority in other programs, and in my memory have exercised it on very few occasions.

But the sources of information that leads to a decision to recall is almost as varied as the products that we regulate. There could be recalls initiated by some type of FDA action - an inspection, a sample collection, a follow up to a consumer complaint that the agency heard.

We could get information from our partners in oversight of this industry, from our state partners, from other federal agencies, from foreign governments.

Certainly the regulations that exist that firms must follow have provisions in there where they are expected to uncover their own problems. They are expected to have a system to receive and analyze complaints that are received by them from their customers

of their products.

They are required to submit adverse event reports to the agency, or field reports associated with new drug applications.

We could get some information from third parties, from some competitors, from interested consumers, or consumer based organizations. Centers for Disease Control certainly gives us a lot of information when products in the marketplace are associated with some type of outbreak, a food-borne outbreak, or an outbreak associated with a drug or a device. So it can come in through a variety of sources.

What does a firm do after the initial shock? They certainly are going to review and analyze the product - the product, the problem associated with it, certainly discuss and debate internally. But often it leads to that decision point that the product must be removed from the market.

After reaching that point the firm

must then decide what is the scope of the recall. Is it a particular lot? Is it a particular product line? Is it everything ever produced? Is it within a certain bracketed timeframe of production?

What is the strategy? How are we going to actually execute this recall? How are we going to get the product back off the market? How are we going to reduce the risk fo consumer illness or injury from these products?

There is a notification to the agency, which again with some exceptions is not a mandatory notification. Firms can initiate a recall and not tell us. We find out and do our thing at the right time, but there are some requirements where firms notify us, and in other cases there is no requirement for FDA to be notified.

And then there is the execution of the recall, the actual bringing the product back through the distribution system.

There is a requirement of verification that firms must assure that the recall is conducted appropriately.

And then if there is an analysis done at the end, which we think is a great idea, there is an opportunity to learn from the execution of that recall, so when faced with a situation like it again, the conduct of it can be improved.

I just ran through these steps. I think we can skip it on the slides.

And then what does FDA do? FDA, when we learn about a situation - again, the recall could be initiated through some type of FDA action like an inspection or a sample analysis, but we could also learn of it through a firm contacting us, they are about to initiate one, or through those other ways where FDA learns about it.

But certainly the first thing we are going to do when we are aware of a recall situation is to assess it, to obtain the

recall-related information, like what is the product, how is it labeled, where is it distributed, what evidence exists to demonstrate that it is a product that is in violation?

How could it affect public health? What is the risk associated with it? What testing exists, etcetera?

We are going to investigate. We are going to think about this perhaps on two tracks that are somewhat parallel but also cross, and that is, not only do we want to make sure that we get that product off the market that presents a risk of illness or injury, we want to find out what went wrong. What happened that caused that product to become in violation of the law, to pose an injury or illness risk to the people or the patients in whom it is being used, and what steps are being taken to prevent recurrence.

So this is where we get into the investigation to find out what went wrong. We

are exercising our regulatory law enforcement responsibilities. And then ensuring that steps, corrective action, is taken by the recalling firm to prevent recurrence of the same or similar problems.

We want to evaluate the firm's scope of a recall and their strategy to get the product back. We may not necessarily agree that a firm's scope is one lot. WE may think, no that's not right. We think it should be more. And we get into these discussions with responsible firms, again, without the legal authority to require it. But it is a negotiation and firms are receptive to work with us by and large to make sure that the risk posed by any of their products is reduced, and a recall is effective.

Look, firms do not like the idea of initiating a recall with a very limited scope, and then having to expand and expand and expand as more information comes in. But you

also have to appreciate that this is a very fast moving process. When I said that a firm's initial reaction may be shock, it may very well be. Because there is, all of a sudden, "Hey, I've got a product on the market. It could be my biggest product. It could be my most lucrative. It could be the one that really exemplifies my brand."

Peter Pan peanut butter, for example: there is a brand. Everybody knows Peter Pan. There is no Peter Pan on the shelves, so I had to buy Jiff this morning. But it is a brand, and a recall could damage a brand.

So it's a very important decision that a company has to reach when they decide to recall a product. It has implications directly, and it has implications in the future.

But we do try to work with the firm to identify the proper scope of the recall, what should be recalled, and the proper

strategy to get it back.

FDA also initiates the process of conducting a health hazard evaluation. We have our medical experts in the product centers review the available information. Often we have to get additional information so their review can be comprehensive, and determine what is the risk of this particular problem with this particular product at the target population in which the product is used.

That health hazard evaluation leads to a classification, and I'll get into classification a little bit.

After the - as the recall is progressing, FDA also initiates audit checks. We go into the firms' wholesale, retail, customer accounts, and determine if notification was received and proper action was taken in response to the recall.

The level of our audit checks is proportional to the level of risk of the

particular incident, and the level of risk is deemed by the classification.

So we have three classification levels for product recalls, one, two and three. One is the highest risk where there is a reasonable probability of serious adverse health consequences or death from use of the product subject to recall.

Class two is a medium risk. It may cause temporary or medically reversible adverse health consequences, and the probability of serious adverse health consequences is remote.

And class three is the lower risk where the likelihood of adverse consequences of unlikely.

That classification, like the definition of recall, does have a legal term. It isn't just a term of art; it is a legal term. And it is based on the health hazard evaluation. The definition of classification is found in the code of federal regulations.

And it has a meaning to us, because the classification of a recall also dictates the level of oversight that FDA is going to give in the conduct and the execution and the overall attention of the recall.

We are more concerned with class ones than we are with class three, obviously because there is a higher risk.

When is a recall classified? It's basically classified when our medical experts in the product centers have enough information on which to complete their health hazard evaluation, and the recall unit in the product centers is then able to initiate the final classification decision based on the health risk assessment, the health hazard evaluation.

In practicality it's as soon as possible. In the terms of real days, ti can vary based on when the information is available and other considerations. It could be as quick as a day; it could be as long as a month. It depends again on the information

available, and the other workload constraints.

What we do though very quickly is an initial assessment that will point us in the direction of which classification it may be. We may know very early in day one of an event that this is going to be a class one. We may not have the health hazard evaluation completed. We may not have the final classification decision on record. But all of the action and all of the oversight that we are giving this particular situation is commensurate with what we ultimately believe will be a class one decision.

When a recall is put into the class one or class two categories, there is primarily for the class one, but to some degree for class two, there is an opportunity for FDA, perhaps even a necessity for FDA, to ensure that the message is out as quickly and effectively as it can. And in the code of federal regulations again there is an option for FDA to issue a public warning at the

reference site.

We also have an industry guidance document that has been in existence since the mid or late `90s that advises the industry of our expectations in terms of public communication fo recalls. And it has our expectations, so the issuance of press releases, public notification in certain recall situations.

When we are dealing with a class one recall - and again the class one, there is a likelihood of serious health consequences or death; it's a serious situation - we need the communication to be as clear and as timely as possible to reduce consumer risk, patient risk fo suffering these adverse health consequences or death.

The press release is one vehicle to further that communication. The conduct of the recall again is a firm initiating a recall and pulling the product back through the distribution chain. If they have five

wholesalers who sell it to 25 distributors who sell it to 150 retailers, the conduct of the recall is pulling the product back through that distribution chain. It's notifying the wholesalers who notify the distributors who notify the retailers.

In something like peanut butter, that is sold in virtually every store in the country, I think there are estimates that there are about 200,000 retail stores in the country, you can imagine that that communication chain, that pulling of the product back through the distribution chain, isn't going to be as quick as we need it to be in a class one recall situation.

And that's the idea of, let's further those efforts by a blast notification to the public, through a press release. A firm could issue a press release. FDA could issue a press release. They are picked up by the media. They are posted on the FDA Internet site. And there is a number of other

vehicles that we use to get that press release out once issued.

In the class one situation when we do a press release - and just to give you a ballpark, there are several hundred class one recalls of FDA products each year. And we do as I said get it to the media outlets, post it on the Internet. We disseminate it through a blast e-mail to all of the state public health agencies in the country; to various organizations - I think it was the representative from the Center of Foods yesterday who gave you a few slides of the places that they notify; foreign governments, when our products are distributed internationally, and there is a likelihood of foreign distribution, we notify our foreign government counterparts so that they are aware that a product distributed or likely distributed in their country is affected.

And then various other stakeholders.

One example is, there are quite a few recalls of food products each year for undeclared food allergens. And we have come out with a list of the top eight food allergens that people are most sensitive to, things like peanuts, milk, wheat, shellfish, eggs, et cetera. There is a list of about eight.

One of our key stakeholders when we are communicating a food allergen recall is FAAN, the Food Allergy and anaphylaxis network. They operate a listserv, so people who are afflicted with severe food allergens can be on their listserv and get an e-mail when they send out a notification.

Well, we make sure any food allergen recalls get to FAAN. And then those people, those true stakeholders who have allergies - because frankly, if I see a recall of a product for undeclared peanuts, I don't care. I am not allergic to peanuts. So I will probably still eat that product. I'm not

going to return it or destroy it; I'm going to eat it.

So - but the people who are afflicted by it, those direct stakeholders of that recall can be connected to FAAN, and can get these direct communications. So that's one of the places that we make sure that we reach out to in those situations.

I mentioned here the Washington Post. I've got a couple - the next couple of slides are clippings from recent Washington Posts, but just the last two days on the - not everyone is from the D.C. area, and I'm not sure if your local papers do it, but the front page of the business section of the Post, in the bottom left corner everyday has product recalls; not just FDA. This particular one - this is today's Post - product recalls, heparin, details, Baxter International is recalling all remaining lots and doses of blood thinner heparin. Defect: there is a risk of serious allergic reaction.

The next item is cribs, and it's talking about a recall the Consumer Product Safety Commission is initiating on cribs where the crib height is not low enough so the child can fall over the edge of the crib.

Yesterday, we have a recall on Ford Mustangs, and also, General Mills is recalling steak and chess Hot Pocket sandwiches.

The Washington Post reports recalls the same way whether it's a food, a car, a crib, an electric blanket, or whatever it might be; the Washington Post does it the same way. They pick details, defect, and what to do.

You will see some similarity in the press release that we proposed. So I feel like if the Washington Post can do it for every category of recall for everything that happens, why can't FDA do it for those categories of products within our jurisdiction?

As I mentioned, and as the

commissioner emphasized I believe yesterday, the timeliness of the public communication is critical. But we also have to have enough relevant information to enable people to know what's going on. What is the product? What is the concern? What do I need to do?

And in a recall situation it's often developing. New information is coming in. Facts could change. When we get into the manufacturing plant, we might find something different than we initially though we might find.

In the case of spinach, when we first - when we issued our first public health advisory, September 14th, 2006, it said this: Based on current information, FDA advises that consumers not eat bagged fresh spinach at this time.

That was a shotgun right there. That was - we told people to stop eating spinach, fresh bagged spinach. It was later, as this developed, that we isolated the farm

from which the contaminated spinach was produced. But our first warning, which did not hold us in very good favor with the spinach industry, was don't eat spinach.

And as the commissioner I believe said, the consumption of spinach dropped precipitously.

We didn't have the information at the time of this warning to be able to isolate the case. We continued our tracebacks and working with CDC, identifying -- doing the epidemiological work to identify and pinpoint and do the analytical testing, the farm that caused the spinach outbreak.

We got there, but this was an issue. Did we need to bring out the shotgun at this time? Or should we have held back a little longer until we had more specific information?

And the next couple slides are a couple of other examples from recent Washington Post articles, recall notices on

food products as a vehicle; another food product; drug patches; here's a sketch book by Consumer Product Safety Commission. Again, the product contained excessive lead and is used by kids.

So the Washington Post, again, has started this, and this is a fairly recent attempt that they are doing. I noticed it; I don't know when they started it, but I noticed it a half a year or so ago that they started doing this in the same place everyday. And it seems to be very effective to me. Again, three basic categories: details, defect, and what to do.

So we do have some legislation and some new initiatives that are connected to what we are bringing before this committee.

Section 1003 of the Food & Drug Administration Amendments Act has some provisions in it that deal with enhancing the quality and the speed of our communication with the public in recall situations. And it

directs us to post information on our website in a way that is easily understood by the public.

Part of that was initiated by the concerns with the pet food recall for melamine last year. Let me throw a disclaimer out: these are not necessarily recalled products. My dog just finished eating this bag of pet food. So it wasn't recalled. But that brand, that Nutra was actually one of the canned foods that was affected by the recall.

But there were 5,400 different products under recall in the pet food situation. Can you imagine a consumer, a pet owner, being able to filter through that to determine whether or not the product they were feeding their animal - and of course every pet owner is immediately looking for signs to see if their animal could have been affected by this. But also looking at the dozens of cans they may have in their cupboard to see if it's an affected product.

Well, we tried to get a consolidated list of all the recalled products, but this section of FDAAA is really directing us to probably do a better job at it.

It was hard to prepare to update a list of 5,400 affected products, and to make it searchable and usable to consumers.

I think we did better as we went through it with the next major outbreak involving chile sauce by Castleberry's. And we did the same thing. We don't do this for every recall, but we had a dedicated web page where we listed all of the products that are affected. And in that case it was about 90 or so products that were affected, 90 different brands and labels and players. And we had another web page dedicated to Castleberry's.

During this past summer, there was concern with toothpaste. Certain brands of toothpaste, apparently counterfeit, came from China, some of which bear the Colgate label.

And there was a concern of contamination with diethylene glycol. And there was a lot of scientific discussion about what is the risk posed by the level of diethylene glycol that we are finding in this toothpaste product when you don't normally ingest the toothpaste. You might ingest a little, but for the most part you spit it out.

So when we were doing that health hazard evaluation with our scientists at the Center for Drug Evaluation and Research, we are doing the health hazard evaluation, you can imagine it's a different decision than whether diethylene glycol was in a food product that you consume. This is something you spit out, so how much are you going to get? It shouldn't be in there; that's not a question. It'd adulterated; it has a contaminant in it. But what is the level of risk associated with it? How concerned should we be? What are the side effects? What is going to happen if someone consumes some of

it?

And again, it was - there were apparent counterfeits as well, people making product labeled as Colgate.

The food protection plan - also an agency initiative versus a congressional mandate - directs us to improve food protection communication and the timeliness of food protection messages; better inform consumers and other stakeholders during food-related emergencies. The import safety action plan, part of this includes - this is a department or government-wide initiative. Part of this provides FDA - it doesn't really provide FDA; it suggests that we obtain it - mandatory food recall authority. Congress would have to give it to us. And to develop best practices for the use of technologies to expedite consumer notification of recalls; another area where I think this committee could play a major part in providing advice to us on what are those best practices? How can

we do better in these situations?

There has been a lot of congressional oversight, oversight within the Department of Health and Human Services through the Office of Inspector General, the Government Accountability Office. And the concerns have been clear and consistent as far as I'm concerned, that there are concerns about the timeliness, the clarity, how effective we are in the communication.

As the commissioner said yesterday, we can deliver it, but how is it received? I have a - I'm not sure if anyone is expecting a call. But I think about the messages when we are delivering this, how is Edith Elder, who is a lovely 80-year-old lady living in Cape Cod, going to receive the message?

I've known her my whole life, and when she gets a - when she hears about a product recall on Peter Pan peanut butter, sometimes Edith will stop eating peanut butter by any brand, and sometimes she may not read

it, and sometimes she is going to say, did you hear about peanut butter? Does that mean jelly is bad too? No, mom, it's just peanut butter this time.

So there is - we have to think about the audience of these consumer notifications that we send out, these press releases. Because as FDA is a scientific agency; it's a law enforcement agency. That means we have doctors and lawyers reviewing everything that we do. The press releases that we issue are going to be perfectly medically sound and legally justifiable, but we also have to think about that other aspect of it - how well understood are they, and can people take the action that is appropriate in response to them? That's the other piece that we need to get to.

So how can you help? Well, you can help us a lot. In the briefing package that we provided to you in advance of this meeting, we provided you with an idea for a press

template, a template where we could issue the same type of press release in the same type of format under headings with information blocked with answers to questions; whether the product we're recalling is pet food, toothpaste, spinach, peanut butter, a blood glucose monitor, or anything else that comes under FDA's jurisdiction where FDA determines that a public health notification through a press release of this recall is appropriate.

It's an entirely different question about what gets us to that decision, when we think it's appropriate. For the purpose of this step in this process, we're asking for your advice on the content of that release, on the structure, the content, and whether or not it will be effective in getting the end result of reducing risk to consumers and patients from products that are subject to recall.

We'd love to hear about your - we'd love to get your feedback. If there are some best practices that we can improve upon in

terms of clarity, we believe having standardization will actually help us with our timeliness in getting it out.

Overall the usefulness, the effectiveness. Like are the messages there? The Washington Post had defect details and what to do. We have categories that are similar to that. We try to block out the section on what consumers should do, just trying to capture our rudimentary understanding of risk communication practices, information mapping, etcetera.

And some of the key questions: would standardization be appropriate across all FDA products? Is that something that consumers would benefit from if a press release by FDA on a device look the same as it did on a food as it did on a pet food as it did on a prescription drug, an over-the-country drug or cosmetic? Does it make sense for it all to look alike?

The substance and the format, the

blocking, the information mapping, and the draft template.

I'm sure that there are some recommended communication practices that we haven't thought of, that in your expertise you know about and can advise us on.

And I think we'd be receptive also to the idea of other recommended communication practices beyond the use of the press release template. As I mentioned some of the legislative mandates and agency and government initiatives in food protection and import safety and FDAAA, and concerns of Congress and the inspector general of HHS and the Government Accountability Office.

There are a number of other pushes for us to see what we can do to improve. So we'd be interested in hearing about any other recommended communication practices that you have in terms of posting on the website, getting the information out in a different way.

Sometimes in these breaking situations we hold a media teleconference rather than a written - or in addition to a written press release. We also have a media call. We did one yesterday on one of the recalls that were mentioned in the Post today on the heparin. We did a media teleconference yesterday afternoon describing the recall, but also a lot of the interest was in the status of the inspection at the Chinese heparin supplier. So there is a lot of information on that.

We did it virtually every other day in the pet food situation at one point, and oftentimes in the peanut butter and spinach. So is that an effective way? Again, it hits the media. But we rely on the media to further the message, to get it out to all the readers, viewers, listeners that the media impacts.

One thing I'll mention in terms of best communication practices is during the

Castleberry recall we found that the Washington Post picked it up very well but the Cape Cod Times didn't.

There was a lot of national attention. It made it to CNN. It made it to NPR. It got into the major print and broadcast media. Except when we went to a small store that happened to sell these products we still found it on the shelves.

Not everybody heard about it who weren't watching the major broadcasts or reading the major print media.

So is there an opportunity, is there a way that we could get this message out down to the user level, more local? Are there any practices that we can do to improve in that area, and that was a real-life situation from not that long ago.

So I think that is the end. I appreciate this opportunity to speak with you. I can pass around these snacks if anybody is hungry. And I will be I think sitting over

there to answer questions, or address questions, at whatever is the right time for that.

So thank you. My pleasure to be here, and thank you very much for being on this committee. It's fantastic. Thanks.

(Applause)

DR. FISCHOFF: Thank you very much. Very helpful, and obviously appreciate all the work that you all are reporting on.

Let's go on to our next speaker, who is Amy Lando from the Center for Food Safety and Applied Nutrition.

LITERATURE REVIEW

MS. LANDO: Morning. And thank you for letting me speak with you today.

My name is Amy Lando, and I'm a consumer science specialist at the Center for Food Safety and Applied Nutrition at FDA.

Nancy Ostrow had asked me to look into the literature related to recalls of FDA-regulated products. And I'm going to share

the results of my review with you.

I started the review this past December, and I've continued looking through this month for any additional articles.

And I focused my search on four databases that are listed on the slide: Web of Knowledge; Science Direct; PubMed; and ScopeIt.

I also received help from my colleagues, and these include Nancy Ostrow, Allen Levy, and Michael Wogalter who is here today.

They were very helpful in pointing me in the right direction, providing some useful articles, and discussing the FDA recall process.

On the next two slides I have listed some of the search terms that I used. And as you can see, most of them use the words, consumer, and FDA recall.

On the second slide you can see I tried putting in drug recall and consumer,

drug recall and press, drug recall media; I tried all sorts of permutations.

The results indicate that there are few articles that are specific to consumer understanding of FDA recalls. The most relevant articles that I found were related to food borne illness outbreaks.

There is however a very large body of work related to recall and safety warning label effectiveness of consumer products in general. And this work is very well summarized in a review that was conducted in 2003 for the U.S. Consumer Product Safety Commission.

That literature review provided a framework for organizing the broad recall and warning label research. And their framework had five components, which are listed on this slide. And I'm going to very briefly try to go over these five components.

The first has to do with initial receipt and recognition of a safety-related

message. And this area of literature has to do with the recall notification techniques for reaching a specific audience, such as direct notification, a press release, media, a video news release, Internet and other means.

It also has to do with the factors that influence consumers' initial decision to pay attention to a recall. Why should a consumer pay attention to this specific recall warning versus all other messages that they receive?

The third area - or the second area has to do with message reading and comprehension, and this is where the literature on the idea of the use of pictures and symbols to help with comprehension of a message or recall, and the importance of physical layout and the use of consumer friendly terms is mentioned.

The third area has to do with storage and recollection of instructions for compliance. And this area of the literature

often deals with memory limitations fo consumers and information overload that may hinder consumers from following a recall warning.

The fourth area has to do with consumers self-evaluation, and the benefits and costs of complying with the recall message. And this has to do with consumers formulation of risk perspective, which is often related to the hazard severity of the recall; issues of controllability; dreadedness; the irreversibility of the negative outcome; catastrophic potential; and the immediacy of the negative outcome.

And finally the last area of the literature has to do with the actual compliance with a message, and why consumers may or may not actually comply. And issues such as social acceptability of compliance, task overload, stress and time pressure are mentioned in this area of the literature.

And some of these concepts are

evident in the three food examples I'm going to be presenting next.

The first example from an FDA product is a home delivered ice cream product that was recalled in 1984 due to contamination with salmonella. And unlike food sold in grocery stores, this ice cream was a home-delivered product. So unlike other food manufacturers, this manufacturer had a list of customers that they could contact directly. And it was one of the main methods that they used to let their customers know about the recall.

Additionally they had press releases, and instructed their delivery people to tell their customers; and also relied on friends, family and word of mouth.

A consumer survey was conducted in one state, in Georgia, to assess the effectiveness of this recall, and the results indicate that most, 91 percent, heard of the problem. But many who heard of the warning

still thought the product was safe to eat, and 10 percent were not sure.

And 22 out of the 72 households that had the implicated ice cream when the respondent first heard of the warning, a household member subsequently ate the product; in 20 of these households the respondents had not believed that there was a problem with the ice cream.

The author of these articles speculate on some of the reasons why the recall was not as effective as it could have been, and they mention that only 6 percent of news stories stated that the product should not have been eaten, and that the manufacturer reported mailing letters to all of their customers but only 21 percent of the people interviewed recalled receiving a letter.

The second case is an outbreak of listeriosis involving 108 culture confirmed cases with 14 adult deaths and four miscarriages or stillborn in 22 states; this

was in 1998. And on December 22nd of 1998, one company announced a national recall of nine brands of hotdogs and deli meats.

A consumer survey as part of CDC's FoodNet survey was conducted in seven states. The results indicated that half of those surveyed had not heard of the recall; and 25 percent who heard of the recall didn't know that the product was unsafe to eat. And most reported hearing of the recall via television.

It was interesting to note that shortly after the survey started the company took out full page advertisements in more than 80 major newspapers across the country. The survey results indicated that more people had heard of the recall after the advertisement ran.

Again the results suggest that press releases about the recall should highlight that the product should not be consumed.

And finally the last case I wanted

to talk about today was the recent E. coli and spinach outbreak in fall of 2006. On September 14th, 2006, FDA issued an advisory not to eat bagged fresh spinach, and it was expanded the next day to include all fresh spinach.

On September 22nd, FDA advised the public that they could eat spinach grown outside of the three implicated counties in California.

The results of a national consumer survey indicate that most, 87 percent, were aware of the spinach recall, and most learned of the recall through television.

Also, most knew that bagged fresh spinach was recalled, but consumers were less sure of other types of spinach; in fact only 68 percent knew that loose spinach was recalled, and 22 percent incorrectly thought that frozen was recalled; and 16 percent thought that canned spinach was recalled; and 13 percent who were aware of the recall and

ate spinach prior to the recall, reported having eaten fresh spinach during the recall. And 75 percent of those said they knew of the recall when they ate it.

Also there can also be a spillover effect from the spinach into other bagged produce, and I think there was a drop in purchasing of other bagged lettuce and other products.

From the food examples I've presented, a few ideas of barriers to FDA recalls for food are evident.

First it's difficult to convince consumers not to use a product that appears to be in a good condition, and press releases and media should emphasize that the product is unsafe to eat.

Also it can be difficult to identify a specific product involved in a recall, especially food. You have meat codes, you have sell by dates, you have lot numbers. And consumers have varying motivations to

search for a recalled product.

Also consumers may have expectations that a recalled product has been pulled from a retailer's shelf.

My three examples have been from the food side of FDA, and one question that came to mind was whether there should be different recall approaches for different FDA products such as drugs, vaccines and devices.

In a focus group study on medical devices that was conducted by the Center for Devices and Radiological Health, participants suggested that they preferred to be notified about recalls by manufacturers, health care providers, and also via the media.

In the case of medical devices, the media was less important to consumers as a way to find out about a recall. But since focus groups are qualitative, and these groups are not representative of U.S. consumers, additional research should be done to see if consumers of different FDA products preferred

to be notified of recalls via different methods.

In conclusion, there is a broad literature on recall effectiveness and on general warning label safety. But there is really scant data on consumer responses to specific FDA recalls. And all the articles that I have mentioned are in your handout and also on the next two slides; you can see them.

And I don't know if I can take questions now or if I can take questions later, whatever.

DR. FISCHOFF: Why not - you'll be here, right?

MS. LANDO: I'll be here.

DR. FISCHOFF: Yes, why don't we go through the presentations; people take notes; and then we can have kind of a - because I think the presentations are sufficiently interrelated that that might be most productive.

So thank you very much.

(Applause)

DR. FISCHOFF: Now we will hear from four consultants to the committee, the first of which will Michael Wogalter from North Carolina State University.

COMMENTS FROM CONSULTANTS - MICHAEL WOGALTER

DR. WOGALTER: Good morning. It's very nice to be here. I'm very lucky to be a consultant.

And today I'm going to talk about a small research project that a graduate student of mine did, I think it was last summer. Her name was Jennifer Cowley, and she did it as part of her first year project.

I'm going to start the talk off just giving some general things, and I'll be quick about it. My area is human factors ergonomics, and a lot of people wouldn't know what that is. They might have heard about ergonomics, and they think of chairs.

But there's actually a cognitive ergonomics, and human factors actually came

from human factors engineering. It deals with persons and products and how they interact.

And my particular area is on warnings and hazard perception; or at least most of my research has been on that. And the purpose of warnings are to basically to inform and convey information, to promote correct behavior and reduce inappropriate behavior, and to prevent or reduce injury, health problems, and sometimes property damage.

And there is - they are a type of safety communications, and they can be communicated in a variety of ways, different media and different modalities; most of the time it's visual and auditory.

And the warnings research - and there has been a lot of research, and a lot of it is published in the Human Factors and Ergonomic Society. Part of the aspects that have been investigated is that warnings should attract attention, and you can do various features and characteristics to help draw

attention to a warning such as print size, color, symbols and so forth.

Another factor that has been examined is enhancing understanding; giving the hazard consequences; the instructions that you are supposed to do to avoid those consequences.

And then there are other aspects that have been investigated such as how warnings could affect beliefs, motivation and behavior; and I just listed a few up here that have been looked at such as giving injury severity information, or potential injury severity; cost of compliance - basically what that is is how difficult it is to adhere to the instruction in the warning; and then social influence and how other people could influence whether you comply and your beliefs.

The differences between warnings and recalls is that basically warnings are usually given on or with the product or associated with the product at the time of

purchase, and recalls tend to be after the product has left the manufacturer; it's already been marketed, or out.

I'm going to start with what I'm doing with this research that I'm going to tell you about. And warnings has looked at various kinds of wording, the major investigations at least initially were on signal words. And they sort of title the warning. It gives information about the hazard level, the - and it also attracts attention. A danger warning and caution are often used, and they are kind of standardized by the American National Standards Institute as having three distinct levels of hazard.

But if you were to ask people most people don't know the difference between warning and caution, and they standardize it before investigating whether people do distinguish between warning and caution. Almost all people think danger is higher than the other two.

Researchers looked at some alternative terms. You can see the extreme, deadly, to notice. Sometimes they are not appropriate.

Also researchers looked at other aspects of wording, such as recently looking at instruction statements where you could add emphasis terms, like it's extremely important that you do this, or absolutely necessary that you do this, versus just the word important, or necessary, or no emphasis term at all.

And you could imagine that there might be some differences between saying this is mandatory versus this is recommended or optional.

Also researchers looked at explicitness; that is, saying specifically what the issue or instruction is as opposed to giving a general statement like, hazardous to your health.

The current research that I'm going to talk about applied some similar methodology

for names of recall notifications. And we used a variety of participants. We had undergraduates from two universities, but we also had a nonstudent adult population in North Carolina, many of which work at a flea market in the state fairgrounds.

Then there is another part in here that had just a variety of people, mostly students. And they have the odd different majors and backgrounds.

Part one basically, what we did is, we pretty frankly described the scenario to participants. Imagine you are in charge of notifying the public about a product which after having left the manufacturers is discovered to be potentially unsafe. Assume it could be a food product, a medicine, or a medical device such as contaminated canned meat, substandard antibiotics, or a defective blood sugar meter.

And they are also told that the FDA was putting out the recall, or a manufacturer

which was called generically Company X. Participants were given 61 potential names of recall notices, and then they rated them on a nine point scale from zero, not at all appropriate for a recall notice title or name, to eight, extremely appropriate.

And there were a couple of random orders that they were presented. And here are those results, plus what we had as titles. So they are ordered from the highest rated to - and the next slide actually has the remaining ones, but these are the highest rated.

And looking on the left hand side, names such as FDA urgent recall notice; or FDA public safety warning. Or if you go down, you see certain recurrence of words, such as urgent and recall and product in danger, and so forth.

And if you look over to the right you see some other things. Company X kind of comes into play on this slide. And here is just the remaining ones. They are lower

rated.

You see that the means over here, a lot of them are very similar. They are probably not significantly different.

But things to note, terms like FDA advisory, or FDA bulletin, are relatively low rated. And alert or advisory are relatively low rated.

What we did also was to go out and get another set of participants and have them rate individual words and components that might go into the name of a recall notice. And here's the ratings. They use a similar rating scale.

You can see that once again just as components they were selecting or rating high urgent, recall, FDA danger warning, so forth and so on, and advisory and bulletin are sort of down the list.

Here just as a graph we had so many different words and variations, we took the ones that were paired with either FDA or

Company X, and then some other words such as FDA bulletin, or FDA warning. And so forth. And Company X with the same root word.

And you see across the board that FDA when it was present was always rated higher. Of course Company X is not a real company, so had it been a real company maybe it would have done something different. It was just given a generic name, and not even a nice sounding name, not Company X.

The other aspect that I think is maybe also relevant to this study, this panel and committee, is what do you do about surgically implanted medical devices? One concern that was mentioned yesterday was, well, do you want to scare people? With a surgically implanted, it's not like you can return the device and discard it. You need to do something, maybe even another surgery, and it could cause some panic or anxiety and so forth. Because you just can't get rid of it.

So we were pretty frank with

participants, and told them what if it was a heart pacemaker and it was implanted, and then it was found to be possibly defective. Should you use the word recall?

And so we had them rate on whether they agreed with using the word recall. Actually we gave them three statements, and they rated them on whether they agreed to use one of the three. And the top one there it says, use the word recall for everything. Just standardize it; use it across all products.

The second one there, use the term, recall, for everything except - use a different term for a surgically implanted device.

And the third one there, don't use the term recall at all. Find some other term that fits all products, including surgically implanted ones.

I don't know if you have any guesses as to what came to be the highest

rated, but here's the results. Once again the scale was zero to eight here.

And the highest rated one was to use the recall for everything except use a different term for surgically implanted devices.

And the second one was to use recall for everything.

So they apparently liked the word recall for most things.

And so quickly to kind of sum up here, there are certain words that were highly rated to be used as a title to maybe capture attention. It's sort of like the signals words idea.

And certain names were highly rated. I put the top six up there that were highly rated. One could go down the list . These are just suggested things.

If one wanted to use a very brief two-word name, then urgent recall is up there once again. It's the highest rated individual

words.

And participants indicated that something other than the word, recall, for surgically implanted medical devices was permissible.

But this particular study wasn't designed to determine what that word or name might be. It means another study for finding out what is appropriate for surgically implanted medical devices.

But one of the aspects that I think comes from this is that even though you might desire to have a fully standardized title, it may be appropriate to have some exceptions where it may be necessary and could give the wrong impression.

And the last thing I mention up here is some simple testing to date and risk communication decisions.

That's it.

DR. FISCHOFF: Thank you.

(Applause)

DR. FISCHOFF: It would have been good to have the audience guess what the answers were going to be. Because once you see the answers it looks obvious; you didn't really need the test.

I don't know if anybody saw the news this morning. CNN used "recall" for the process of bringing Prince Harry out of Afghanistan where he had been serving. So I guess your subject would have approved of that use, because he wasn't surgically implanted.

(Laughter)

DR. PALING: He wasn't a rejected member of royalty.

COMMENTS FROM CONSULTANTS - GREGORY BAIRD

MR. BAIRD: Good morning. My name is Greg Baird. I'm the independent consultant in public relations and communications. And I will not be presenting any hard research as you've just seen. Rather, it's experience-based judgment. And I would quickly caution you on a risk communication advisory that it

comes with all the strengths and the frailties of just that - experience-based judgment.

In the more than three decades I've worked in the health care industry I've had the opportunity to participate in a wide variety of risk communication scenarios from inside and outside, companies in the pharmaceutical, biotechnology and device industries.

From as early as the Tylenol tampering to current black box warnings and withdrawals, they have reduced confidence in the ability of several blockbuster products and categories to safely deliver the clinical benefits that many patients have come to rely on, and the consequent expectation of better risk communication.

But at this point just what does that entail? Most of these recent risks or adverse events have only become apparent after years of post-marketing surveillance in vast patient experience. Apparently some of these

drugs may not have been meant for as broad a patient population as was first identified by the pivotal trials that led to their FDA approval and their labeling.

For the most part these didn't reflect any major error or miscue. At best they were subtle trends or unanswered questions in the data. But they evolved into headline news.

I bet some of you are wondering just what categories of drugs I'm talking about, and what does that tell us? Is Baird referring to Cox-2s? Breast implants? Heart valves? Maybe he means those anemia products that are going to before a safety review in the next few weeks.

Or could he be talking about the ADHD medicines that some critics call kiddie cocaine?

No, I bet he's referring to antidepressants and their suicidality. Wait, he's more likely referring to those IBS drugs

that were withdrawn from the market.

You get the picture. There is a growing crisis in confidence in the ability of our system to provide adequate protection from harm. The first do no harm axiom has been sacked too often to retain patients' once high level of trust and confidence in markets products and devices.

And biologics are proving just as frail as pharmaceuticals from a range of angles including clinical side effects, promotion that is too broad - to too broad a patient population, and pricing sensitivities.

That combined with the din of what I would call official health advice that often seems to contradict its own previous messages, many consumers are confused and increasingly cynical.

Paired with the simultaneous skyrocketing increase in the costs of co-pays for these same medicines, you have an emergent consumer who is angry but not exactly sure who

to blame.

Trial lawyers typically answer the question.

It has become a situation in which it is unclear exactly who has greater regulatory authority, the FDA or the courts.

And who is really the approval voice, the definitive advice system that the American public relies upon when it comes to their choices of which medicines and devices they seek to relieve their symptoms and cure their diseases - the FDA, their doctor, their pharmacist, their local TV news station, the manufacturer of drugs and devices, Google, academic medicine, patient advocacy groups. Here a KOL, there a KOL, the opinion leader.

It's a provocative and important topic, and it's why we're here today. And I earnestly hope that the advisory committee can help FDA create more than a thought leadership position with new standards that have the power of clarity and regulatory authority.

I don't think you will find industry disinclined to receive clear guidance that is fact based and pragmatically sensitive to the various dimensions of this problem.

In fact such guidance would relieve a tremendous burden of ambiguity they are currently confronted with.

If a drug or device company were to approach the FDA tomorrow with a risk communication plan for your review, would the agency be fully ready to deal with it?

Hopefully this committee can help make sure you are.

So let me add some experience-based observations I can candidly offer that might help your deliberations, and then make a few recommendations too.

I'm going to borrow a page from the Letterman show here and call these Baird's Top 10 Challenges to Effective Risk Communications.

And I apologize in advance for just

citing the problems without necessarily all the solutions I wish I had in my pocket.

Number 10, after 30 years of looking around these industries your vision gets pretty keen. And I see at least three invisible animals in the room with us today: an elephant, and two 800-pound gorillas. Let me introduce you to them.

The elephant is what we hate to admit is with us today. It's a large animal, bull elephant by all visible parameters, and it's the color money. In fact, it is money.

The elephant is joined by two twin gorillas who have street names. One is Too Much to Lose, and the other is Too Much to Gain.

They apply the perilous force of magnitude, the ethical judgment and core values. And they challenge them in ways that can only be appreciated by the pounding pressure these apes are capable of exerting.

The point here is, how high are the

stakes, or how high do they have to become, before best ethics and values are corrupted? Tens of millions? Hundreds of millions? Billions?

Systems of checks and balances need to escalate as the stakes escalate. A one-size-fits-all oversight system doesn't work well enough in my opinion.

There was an old quote I always valued. It was George Bernard Shaw and the quote was, "The test of a man's or a woman's breeding is how they behave in a quarrel." It's easy to be well mannered when the stakes aren't high or it's not hot in the kitchen so to speak. What industries and corporations are continuously facing are high stakes, extreme heat in the kitchen, and it becomes very challenging to retain the types of core values you read about in annual reports.

And these are well-intended people. I would not at all characterize corporate executives in any way other than very

earnestly well-intended people. But you need to consider the environment that they can find themselves in on the matters of decision and judgment that they face.

Number nine, there is an emotional contract between patients and their medicines and devices. They pour their hope and desperation into that contract and hope for a winner, not a loser. It's an emotional process as much as an intellectual process. And as with all emotional propositions anger is standing by in case of disappointment or rejection.

Risk communications need to bring the emotional portion of this equation out into scrutiny.

Number eight, better stories sell newspapers. As diligent as the press can be in fact checking, they are vulnerable to the same forces of marketing. They look for stories that satisfy reader interest and needs.

New breakthroughs, new exposes, new heroes, new culprits, and if Oprah likes it, buy it and read it or eat it or wear it. But who really regulates for the state? Anybody?

Freedom of the press is a critical but complex concept, one that can make or break reputations merely by raising speculation.

Number seven, consumers are expert about probability - not. Not now, not ever. If consumers were expert at probability nobody would be buying lottery tickets.

But look at the similarity. With lottery tickets they just want a chance at getting rich, and with medical interventions, patients just want a chance of getting well.

But they aren't buying a chance of getting worse, because they think they can beat those odds.

Sad to say, some patients need to pay the price of that ugly little statistic, that small but real prevalence of a bad

result.

We need to amplify the reality of bad results that are in the statistics in ways that patients can understand and that is not with just numbers. Show them cases.

If VTC advertising can portray the happy results, then fair balance can show the unhappy results. And I don't mean by just a voice over while visual rolls about happy people doing happy things.

Number six, the truth, the whole truth, and nothing but the truth. But what about issues of verification and reliability, versus precipitous and inaccurate reporting? When is the truth ready for prime time, and who decides?

There are legitimate devices in the details of timing of release of negative information, and the extent of that release. Let's get better training in these gray areas. Online courses for corporate communications; mandatory seminars are part of certification.

I think it's time to think more outside of the box in terms of actually qualifying communications experts and working with them and empowering them.

Number five, best information is a moving target. What then constitutes due diligence by drug and device manufacturers in the collection, review and dissemination of all emerging information about their products? Who has shared responsibilities?

Eliminate as much ambiguity as possible. I think an example would be an unsponsored clinical study of a drug that the manufacturer has nothing to do with in Europe. Information emerges: what is their responsibility to gather that information, review it, assess it, and discharge it to a need to know audience? It wasn't their study but it's their drug, and these are the sort of gray area ambiguities I think that need to be resolved.

Number four, what is adequate

discharge of information? Putting a press release out on a business wire isn't it. It isn't really over until all people who have a need to know know. But is that realistic? And if so how can it be measured? And who can afford such a level of communication?

Research and answers should be developed on this key question.

Number three, we do live in primitive times. Everyone is a guinea pig. No matter how much evidence is amassed, there is always the risk that contradictory information could arise at any time.

Because of this every patient who takes any drug could be the first to experience a previously unreported adverse event.

Personalized medicine has not come of age. When we speak of risk we must address a vastly larger audience than the message is really intended for.

And yet by definition of risk

communication we must reach that minority population who is truly at risk. How do we not unnecessarily alarm the majority not at risk while we effectively reach those who are?

We need better communication research and standards in this area.

Number two, labeling schmabeling. I've always wanted to say that at the FDA. Sorry. (Laughter) It would be a very neat world if product labeling was the be-all and end-all of the discussion. But it isn't.

Labeling is to the dialogue of medicine what the dictionary is to language. For each the follow up reality dwarfs the scope of the original document.

How does the FDA hope to really regulate the dialogue of medicine, and should it try? Who should become FDA's partners, and in this regard, and in this process?

It's not going to get better unless this problem is better quantified and qualified, and practical answers are

developed.

Number one, patients with chronic diseases are part of the problem. They tend to be apathetic about considering risk. They aren't motivated to absorb risk communication as well as those with acute or life-threatening conditions.

So how do you overcome that hurdle with cost-effective communication? I think I gave an example yesterday of the pre-op patients who are extremely attentive because the risk is so immediate. It's that day or the next day. It's quantified for them. They are listening. They are signing waivers. They are making a very calculated decision.

These types of decisions are not made when an arthritis patient who is suffering from pain chronically turns to NSAIDs or Cox-2s because the risk of heart disease or NSAID-induced ulceration seems far removed an odd or a risk that they are willing to take or not even consider.

So these are some of the hurdles before you. But I have a few recommendations for your consideration too as you seek to create competent protocols for new risk communications guidelines.

The first is work closely with industry. They aren't the enemy. They are just as anxious to find a reasonable and effective risk communication standards as you are, and frankly, they may be in more immediate peril than the FDA if they don't.

Corporations are not nearly as comfortable or used to working closely with the FDA about communication matters as they are clinical development, and this interface needs to be upgraded and strengthened, and I really want to emphasize that, because I really do have a tremendous amount of experience on the corporate side. And the communications folks at corporations are not authorized or empowered to really be able to deal directly with the FDA as an agency and

partner to that corporation nearly as often probably as it would be good to have them do so.

To create a real and authoritative architecture for risk communications that empowers communicators in all sectors of health care to be deputized in this regard, communications need a stronger voice and better recognition within industry.

In particular create allies among them by having them join the effort and help be watchdogs of industry. By comparison to other divisions and disciplines within corporations, communications is the runt of the litter. It needs more stature and authority; a better and stronger voice. And the FDA can help them get this by modeling itself like it hopes corporations to model. In other words I think the press office of the FDA mirrors many times what you see in a corporation in terms of communications. It is sort of the reed in the wind of the powerful

divisions of FDA. Just as communications offices within corporations are for the powerful divisions of sales and marketing, legal and regulatory. And I think that voice needs to be strengthened. It can, but it probably best can be if FDA models itself the way they would help a corporation to do as well.

Three, create a special focus on the side effects of marketing within a corporate environment. I've seen it have a remarkably deleterious effect on corporate judgment.

It's not that marketing specialists are intrinsically or intentionally evil; they are not. But let me turn to a little humor to help make the point.

I once saw in an episode of "Rocky and Bullwinkle", and in it, in Frostbite Falls, where they hail from, Natasha and Boris had discovered what they call goof gas. And whoever smelled goof gas became stupid. I

remember in the episode they took a vial to Washington, D.C. Beware.

Anyhow by making a silly overstated point, what I'm trying to say is that marketing is comprised of very intelligent and well intended people. But they deal with their own information, and it becomes circular, and it can influence the need for there to be countervailing voices, such as communications folks within that enterprise.

There once was a saying, flattery is like perfume, you smell it, you don't swallow it. It would paraphrase that to say marketing is like perfume, you smell it, you don't swallow it. And I think organizations need to keep that in mind, and be empowered to keep that in mind as they go forward with critical decisions and operational decisions.

Number four, look to the financial sector for a case study in risk communication emanating from corporations. Build a similarly robust ongoing dialogue between

manufacturers and the relevant practicing medical community who prescribe their drugs and devices.

Risk should be considered material to companies, and therefore an essential and mandatory communication process that needs to be discharged in a timely and ongoing, and I emphasize ongoing manner.

And reciprocally the practicing medical community needs to keep abreast as part of CME and recertification standards. There should be no less ongoing communication from these corporations with the practicing medical community as there is with the financial community.

And then last, health education for the emerging health care consumer. Train them early and effectively. Becoming a discerning health care consumer is essential. How? Use the baby boom generation as you show the way to the audience for younger generations. Baby boomers have redefined so many aspects of

living for their generation, let this become their next opportunity to be the pathbreakers to better living.

In other words they are facing the health challenges and the risks associated with all the products, devices, that they now need and rely on, and let them become the exemplars to other generations of how to assess risk and get the information and be an informed consumer.

I hope the remarks have been helpful, and I look forward to answering any questions you have later.

Thank you very much.

(Applause)

DR. FISCHOFF: Thank you very much. We will do all four - the other two presentations. I think we could spend a long time with each of these presentations, so let's do them all together.

The next speaker is Steve Gorelick from Hunter College.

COMMENTS FROM CONSULTANTS - STEVE GORELICK

DR. GORELICK: Good morning, my name is Steve Gorelick. I am a professor of media studies at Hunter College in New York City.

I'm a sociologist who started by getting interested in crime and violence and how it affects the texture of social life and communities that are hit by sudden acts of often pretty catastrophic violence, or at least violence that sets off a great deal of anxiety.

At that point I realized that mass media and communications was central to this, so I am doubly trained in my doctoral work in both communications media studies and in criminology.

I've been sitting here through the meeting trying to realize why it is that of all the academic questions that I think about or write about, why these are the ones that are most engaging for me, and the most viscerally interesting for me. Why do I find

this so endlessly interesting?

And I actually remembered a story. In 1957 those of you who follow flu pandemics know that 1957 was one of the years. And my dad got it, and I got it, and then my mom got it, and then my sister got it, and here we were in a California suburb, four people pretty ill with not your seasonal influenza but one of the pandemic influenzas, and we had to have a nurse come to talk to us.

And I remember, and I was only six years old, but I remember vividly the disorientation of being altogether, all sick, and trying to figure out what was going on, what was the remedy, what should we do. And it was a very formative experience.

And that led to a lot of my early work which had to do with how communities are affected by acts of violence; specifically in one case a large community study of how communities deal with an allegation of child abuse and such.

So that's sort of a background about the things that I do.

Rather than having a prepared presentation, I made a list of not necessarily in order of points or thoughts that all of the last two days made me think of. And I just thought I would share them. I actually, after Greg's quick presentation, I thought I'd give numbers to them also so they sort of make sense.

But they are just things that will less be answering questions than raising them.

The first of them has to do with this occasional thing that has come up about the extent to which people mistrust or bash national news media.

At one point one of the major news networks asked me to take a look at the question, why do they hate us? Why don't they trust us? And I spent a long time doing an extensive literature review, and found out that among social institutions the media was

not rated among the highest, and yet when it came to usage, and behavior, mass media was used extensively.

So there is a lot fo moaning about mass media, but be careful that you distinguish as a channel, moaning about a channel for sending out information.

And maybe there are better ways. Well, there are a lot of different ways in the new media age. But the bashing is often accompanied by continued attention to mass media.

The second thing I thought of was that I hope that as we move forward we will pay careful attention to the almost dizzying changes that are occurring right at this moment in news consumption patterns, where people get news.

In 1957 we had radio and television. I won't even go into all the ways that people now receive their news. There may be some of you who are at the point where you

are not using any paper, or newspaper; I don't know. There are differences of opinion as to whether that may happen at some point.

But please know that for things like RSS syndication, XML, subscriptions, online dues, cable, news by choice, newspapers that people design themselves in which they create a front page where they only ask to receive a newspaper designed with topics that they themselves are interested in.

All of these new things are happening, and the minute I dismiss one as sort of a fad of the moment, about three months later evidence shows that more and more