people are using it. It's important to know how that is changing now.

The third I won't say almost anything about, but it was something I mentioned yesterday, which was, I think it's important for the FDA to think carefully about who it is and what kind of an entity does the public believe it is getting news from when it gets it.

These releases go into a sort of a social zeitgeist in which - and I can't say I fully understand how it's perceived - in which the FDA is ultimately seen in some very special ways.

And I use this buzzword that I hate, and know I have to hear it for the rest - about branding. But what is the - how do people feel about this as a place from which they receive news?

The fourth thing has to do with checklists and your template for a press release. I would have had nothing to say

about this were I not to have just read some recent articles in medical journals. I don't know why I saw them, but a whole host of journals, articles, showing that check lists and hospitals and sort of protocols and stuff just solve all sorts of problems when it comes to infection management.

I'm not saying that this is a transferrable concept, but normally you know, I guess in my generation, if you tell me I've got to comply with a list, I'm saying, let me be creative and so on. And yet I read more and more about how in many occupations they are simply less forgotten. Messages are crafted with much more attention, and things aren't left out.

So I would ask some of you may be aware of this literature about check lists, but they tend to be enormously helpful, indeed as I fly back to Newark Airport tonight, I'm hoping that the guy in front might be using one also.

The other thing is that was sort of striking to me that some of the people here said, who are health care providers, that fits with my own experience, is that - and as Greg said - it's almost never ill intentions, but it is amazing the extent to which actual retail health care providers, physicians, often don't get the information that you need.

I have to travel occasionally to go follow my son around the world on the job he does, and it's often to places that require me to see an infectious disease doctor. And I was in a strange position of seeing this wonderful infectious disease doctor who saved me from all manner of things, and being the one to tell her about CDC travel alerts. And I felt a little strange about that; this was an infectious disease physician.

And it just means that our work routines are such, people's lives are such, that things often just pass us by.

I would count the next one though

as one of my really important ones. And it also comes out of my own work.

I think you can't underestimate the extent to which all of these well crafted, well pretested communications are launched into a world that is an absolutely crazy miasma of rumor, urban legend, what I call noise. Your message has to make its way through - first through the legitimate news sources, and a well skilled AP reporter will write a great story. That news then goes into a world very much on the street level in which it is competing with some of the sort of scariest and craziest yet rapidly spreading rumors, and legends, about the efficacy of various medicines; about what causes disease and illness; and about where HIV virus - and on and on.

I've studied these things, and what I really think might be important is, if you are going to be sending out such deeply important health care messages, to have a

group of people or a unit that sort of monitors this world, sort of a nonsense monitor.

Other institutions and agencies do this, pay careful attention to all of the street level misperceptions that are mitigating against their message being taken seriously.

And there are actually ways that this can be done. A lot of it happens on the Internet. It has to do with monitoring press reports. It has to do with monitoring school districts where notices are sent out for children not to - to make sure they don't eat Pop Rocks at lunch because their mouth will explode or something.

There are a lot of interesting ways to monitor this world, but I would suggest that this is the world in which these well crafted messages are going out, and it's important to be aware of that.

Finally, and this came up in a few

of our discussions after the meeting, those of you who are communications people know that a lot of the earliest research on how messages get through from crafting to people were voting studies that were done in the `30s and `40s about how you get - how they got people to vote for Franklin Roosevelt of all things.

What was fascinating about these studies is that some of the findings, while now refined with multivariate analysis, still pretty much hold. And it's not exactly stating anything earthshaking to say that everything can work. Everything can work.

The message can be pretested. It can be crafted elegantly. It can be crafted with intention to multicultural differences, to the potential anxiety of the recipient, depending on what the nature of the incident is. Everything can work.

And it comes up to a point where either the person - right at this point where either the person does the behavior you want

them to do or not. So I'm saying that it's very important to focus on the messages that are taking place here, but it's also important through focus groups, field studies, community studies, the kind of qualitative research, what happens at that moment that leads the person who is right ready to do what you want them do, not to do it?

What made me, and I'll end with this, there is no good answer to this, what made me spend the fall teaching and talking about health communications in a class and how you get people to do things, what made me do everything but get the flu shot, and then get one of the strains that was covered by it.

There is no good answer to that. Why didn't I take that - so sometimes I think, in sum, that that line between persuasion and then the behavior might as well be a chasm sometimes, and it's very - that's the thing that always interests me. How do you get people to just make that last jump.

And so those are some of the observations from listening to you.

It has been an enormous privilege to people who say things and have thoughts that have been deeply interesting and fascinating to me.

Thank you.

(Applause)

DR. FISCHOFF: Thank you very much.

And our next speaker is Dan Haney.

COMMENTS FROM CONSULTANTS - DAN HANEY

MR. HANEY: Thanks very much for asking me here.

I don't have PowerPoint slides, so I'm sorry to say for the next few minutes you won't have anything to look at except me.

It seems as though over the last couple of days we have been taking an aerial view of the subject of risk communication. We have been looking at it from 50,000 feet up. And we've gotten a great overview, but I am going to try to bring us down to earth and

talk about something very specific, which is the FDA's proposed format, template, for press releases having to do with recalls.

This is the first specific proposal that the FDA has brought for this committee to give them advice on.

My point of view is as an old news guy, and I worked for Associated Press, as I mentioned a couple of times, for a very long time. And during that time as a reporter, I never wrote a press release, but I probably have read tens of thousands of them.

First, I should say that I think the FDA is taking a step in the right direction with this template. I think it will help the agency do a better job of creating press releases that recognize the changing audience for these documents.

I don't know how much you all know about the use and function of a press release over time, but for most of the 20th century press releases were written in the form of

newspaper stories, and they were aimed exclusively at the news media. The idea was a publication could simply print the press release as is.

Of course that didn't usually happen, especially at larger publications. So instead reporters used them to find the basic information they needed to create their own stories.

The most important change in recent years is the audience for press releases has changed. They are no longer seen only by reporters. These days most press releases, no matter who puts them out, are posted on the Internet where of course they can be read by anybody.

So I think the FDA's new approach recognizes the dual purpose that press releases serve. This format is intended to give the news media that facts they need to prepare news article, and it was designed to provide a better organized and more readable

format for anybody else interested in the subject, particularly those who are directly affected by the recall.

My initial impression is that the new format succeeds on both counts. Reporters I've talked to say they would rather not search through fake news stories for the information they need to prepare their own reports. They'd prefer to work from a document that organizes the facts into logical categories, which I think this format obviously does.

And I think consumers will also find the format much easier to navigate.

The new approach should also make press releases more consistent in the content they include. As was just mentioned, check lists are now proving to be a very reliable way to make sure the right things get done, and this format gives FDA writers a check list of the points that should be covered in each section of the news release.

It seems to me that this will ensure that the press releases don't omit important information.

Most of these recall releases will never give rise to news stories in the national media, as Captain Elder mentioned. They often end up in lists, in - of recalls in newspapers, or on web sites.

However some of the releases will trigger full-fledged news articles, depending on whether the media decides they are newsworthy.

The main elements they look for when making that determination are the size of the recall, the number of people at risk, and the magnitude of the potential harm.

All of these things should be quickly apparent from reading the recall news release.

But often they are not, either in the old format or this new one. To make sure the releases are complete, and that they

convey the importance of the recalls, I think the template should be more precise in several areas, and I'm going to make some suggestions here, some very specific ones.

In particular I think the two sections should be fleshed out with more - I think two sections should be fleshed out with more specific items that need to be included in most cases. These are the categories headed, what is the problem, and who is at risk, and other important information.

Reporters tell me that the single most glaring deficiency in their view of recall releases is that they often fail to say how much product is being recalled. I hope you have read the garbanzo bean release, because I'll use that as an example.

It says a canning company is recalling five years worth of green beans. Well, I know that sounds like a lot of beans. But any reporter would want to know the approximate amount. Are we talking about a

thousand cans, a million cans? There is no hint in the release.

I think all recall releases should provide this kind of information because it tells us the magnitude of the health threat from the news media's perspective a big recall is usually more newsworthy than a small one.

Furthermore, we know that beans don't last forever. How much of the inventory is still thought to exist in warehouses and people's kitchens? I think a realistic estimate of how much product needs to be thrown away or returned should be included in all recall releases.

Next, how serious is the health threat? Were any of the cans of beans actually tainted with botulism? Did anyone get sick?

This information was included in the bean release, but it isn't required by the template.

And some of the other releases in

the meeting packet, such as the heparin release, never mentioned whether any illness was associated with the recall products.

This is something the media will surely ask, and I imagine anyone affected by the recall will want to know.

For consistency and readability, I think the first real sentence of these releases - I'm talking below the headline - should give the name of the potential illness associated with the recall product before it gives the technical name of the pathogen.

For instance, the bean release would have been more effective if the first sentence said that eating foods carries - that eating these foods carries the risk of botulism. Instead the first sentence only lists the name of the bacterium which I doubt will mean much to most readers.

I think that most people who read these releases will want to know how the problem was discovered. For instance, did the

bean contamination come to light during a routine inspection? Or because cans of beans exploded on store shelves? Or was it because people got sick?

Sometimes this information is disclosed in the sample releases in our packet, but again, it isn't required of a template.

The template should also list what regulatory actions have been taken, and what the practical impact is likely to be. For instance we know that the green bean company has stopped shipping all product. But often we are left to guess whether the problem has been resolved and production restored, or whether the regulatory requirements will result in shortages.

The press releases the deal with drug recalls have some unique requirements I think. For instance I believe a release should list all of the common uses of the medicine being recalled, including ones that

are off label.

People are likely to think the recall doesn't apply to them if the release doesn't mention the conditions in which they are taking it.

Also I think releases on drug recalls should routinely list alternative medicines that are available; and they should say how long the recalled drugs have been sold. This will help people figure out whether they have taken the recalled drugs in the past.

It's especially important that the releases about drug recalls include the amount of product affected as well as the approximate number of patients who take the medicine. For instance the heparin release tells us that all lots of pre-filled syringes are being recalled, but it doesn't say how many lots that amounts to, or how many syringes are in a lot.

And perhaps most importantly, it

doesn't tell us what proportion of the nation's heparin supply is being recalled. Will it mean shortages of this drug?

I'm almost done, but I want to mention two other points. One is word choice. These releases should avoid unfamiliar jargon, both the legal and the medical kind. For instance, the new release on Encore Cabs (ph) calls the drug an analog and says it has, quote, a similar pharmacological and adverse event profile as another medicine.

Since a release is meant to be read by ordinary consumers the FDA should find a way to say these things so that anybody can understand.

And finally a comment on timing. It seems obvious to me that these releases should be written as quickly as possible so the public is alerted to recalls that affect their health. Just as one example, the heparin recall began on January 18th, but the press release was dated January 25th, so why

does it take a week to get out a 200 word press release?

Maybe a standard format like this will help speed up the process.

Most of what I suggested is just fine tuning. I think the FDA has made a good start toward creating recall releases that are better organized; that are more informative; and that do a better job of communicating with the media and the public.

I understand that the goal for now is to use this template only for releases that are written by the FDA staff. However I think the agency should encourage companies to use this format as well when they are making any announcements about recalls.

Thanks.

(Applause)

DR. FISCHOFF: Thank you very much.

Let's take a 15-minute break, and we will start promptly at 10:20.

(Whereupon at 10:05 p.m. the

proceeding in the above-entitled matter went off the record to return on the record at 10:25 a.m.)

COMMITTEE DISCUSSION: RECOMMENDED PRACTICES FOR PRESS RELEASE TEMPLATE ABOUT RECALLS

DR. FISCHOFF: One of the nice things that the FDA has done with this initiative is provided an opportunity for people who don't always, or ever, perhaps, get to talk to one another to get them together in a room. So it's a bit of a shame to stop the breaks, but that's my job.

So let me once again thank the -- thank our speakers, and reflecting on what -- on the comments that we have heard. One way to think about it is we've had comments perhaps on three levels. One is sort of a philosophical level about, what is the world we are functioning in, how is that world changing, and how is FDA's leadership in conjunction with the Congress trying to adapt

to that leadership, which in some ways is going to -- somehow shaping the contract between the American people and the -- and its government.

Secondly, these questions that we had about, how are we managing risks in our society, both within industry, and within government, and where does risk communication fit into that risk management process? Is it integral to how we shape our relationships with our consumers, how we design processes, or is it an end-of-the-pipeline patching up when things go wrong?

And if it's -- and then, what is the best way to use it? If it's at the end of the pipeline, is communication being asked to do the impossible? And are we perhaps foregoing opportunities to design better risk management systems by thinking perhaps of risk communication as a way to get to know your consumers and your patients so that we have, you know, fewer and better recalls, if you

will; that is, we get better information there, you know, to the front, have better products, and we are right on top of it when we need it.

And third, how do we actually deliver the best possible recall notices at times that we do, thinking about the complex technical details there is necessary to do the best job possible, but it's also necessary to sort of feed upward to say, what can you actually accomplish with a recall, and in the end, that's an empirical question, and we'll have better answers to the empirical question to the extent we have -- we'll both do the best job we can, but also that we do a good job of evaluating our effectiveness.

And I think our speakers in interlocking ways addressed all of those levels. So now we have a chance for an exchange between the committee and the panel, and perhaps we should start with -- well, we could go in any direction, but perhaps we

should start with clarification questions, things we want to make certain that we understand, and then we can have a general discussion in which we would invite our guests to give their opinions, too.

So who would like to start?

MS. VEGA: I have two questions linked together for Captain Elder.

I would like to know, what is the role that the FDA has from the moment it approves a product, a device, a medication, to the ongoing life of the product? Is there a monitoring, for example, like heparin, it's been on the market for a long time. It was once approved; now we heard that it is recalled for the medication. The company, it was in the news that the company had held in terms of releasing this to the public for a little while, because they wanted to make sure there was enough supply of a product like heparin for hospitals.

Is there a monitoring for products

after they are approved?

My other question, which is kind of linked to it is, do companies have a time frame to do their recall process from the time that they identify the problem to the time that they report to the FDA, particularly if it is a class one?

It seems to me that this is a lengthy process that goes on, but in the meantime, the products are still on the market.

CAPT. ELDER: Thank you.

There is a continuing role for FDA after a product is approved for marketing. FDA's role in its most simplistic terms is, there is a premarket component. That is where the, in certain categories of products, clinical studies occur.

There is, in the area of devices, there are investigational device exemptions under which clinical studies occur.

In the world of drugs, there is an

investigational new drug, there is investigational new animal drugs, there is a variety of premarket activities that go on in which FDA is engaged in an oversight role, and a review of the protocols, and the conduct of those studies.

And then there is the postmarket world. And after a product is approved for marketing, there is a continuing oversight of FDA which involves inspections of the manufacturing facilities, monitoring adverse event reports that are reported by the company or by consumers, Centers for Disease Control obviously has an active surveillance program to spot trends in potential injuries, which, through our close working relationship for CDC, gets to us at a very prompt time when it involves an FDA-regulated product.

So through our ongoing surveillance of the manufacturing operations, we could identify problems in manufacturing, or adverse event reports that would have further

communication about within the agency, or we could get other signals from -- of concern from partners in health care, from partners at state agencies, from CDC, that would cause us to initiate an investigation on a more directed basis.

So I would say that FDA's role for our products is throughout the full lifecycle of the product.

In the area of food, the commissioner talks about it from farm to fork. In the area of drugs and devices, it's manufacturing to ultimate use.

So we do maintain that continuing role.

Your second question had to do with the time frame for the recall. And as I alluded to in my presentation that, when those signals are coming into a company from the variety of sources from which they can come, it is very much an evolving process from the time that that first signal came in about a

potential problem with a product on the market, to the time where it can be analyzed and determined that it is, in fact, a signal that requires action, or multiple signals come in.

There is a point in time where those signals come in, they are analyzed, and a decision is made to recall. In practice, the communication to FDA is very prompt by a recalling company when they reach that point of deciding that a recall is appropriate.

The actual conduct and the execution of the recall again is a -- it's in a company's best interest when they reach that point to do it quickly to mitigate any additional risk of injury or illness to the public associated with their product.

So it's certainly in a company's best interest to do it quickly. It is in our best interest to encourage and provide any support or direction that a company needs to execute it quickly.

We want the scope to be defined properly up front, and we want the recall strategy to be effective to most effectively reduce risk of consumer injury or illness from these products.

If you are asking for a set time frame, like you have to do it within 24 hours, that doesn't exist. But the idea is that it will have to be as prompt as possible to -- in the interest of public health.

DR. GOLDSTEIN: I want to thank all the presenters for the information and background you provided.

I have a question for the captain again about the other kinds of devices that are used to alert, particularly, health professionals about the recall, beyond the press release.

Can you say something about what's currently in place for that?

CAPT. ELDER: Well, the press release is just one additional notification

step in the process.

The actual conduct of the recall by the recalling firm is, as I described, of pulling the product back through the distribution cycle. It's a written communication letter. It could be a phone call, a fax, an email, a certified letter, to the company's initial distributors, to whom they know that they shipped this product to distributors X, Y and Z.

They notify those distributors in the most expeditious way possible, often it's a phone call. It could be a fax, or an email, or a letter saying, we are recalling these products. You need to pull it back from whomever you distributed it to.

And then the next level of communication occurs until you get to the point of pulling all of the product back off the market.

That's the conduct of the recall. I mean, that's really how it's executed.

The public communication through a press release is another step. It's a step that maybe gets the communication to that lower level sooner than would have otherwise be achieved through the chain of the distribution process.

DR. GOLDSTEIN: I'm thinking particularly about pharmaceutical agents, and the roles that health professionals could play in responding to the recall.

CAPT. ELDER: May I say that there are other steps that include, that perhaps involve the press release with some other method of communication, is the MedWatch system, where that gets blasted out to the members of the MedWatch community.

We also notify our state regulatory counterparts through a blast that hits all of the 50 state health agencies that can also get down to the local agencies as that communication vehicle continues on its path.

We notify foreign governments, so

when we have a -- and information gets posted on the FDA website, as well.

So I think there is a number of ways that a health care provider can obtain the information in addition to the formal recall notification process that is initiated by the company.

DR. GOLDSTEIN: And I just want to point out, I think it would be useful for us to think about templates for that process, as well, or assistance for that process, as well, beyond what we are considering today, the press release, because I'm not sure that those other strategies that you mentioned are getting to the health professionals in a timely and effective way with information that could help them communicate more effectively with patients when they bring their concerns to them.

So that's something for us to consider beyond, I think, today's discussion.

DR. YAROSS: Yes, and following up

to that, I can say, from my own experience, that often, say, with surgical use devices, firms may frequently contact the professional societies, and ask them to disseminate to their membership. So there are a number of additional strategies that are used by firms.

On a separate note, also, again, for Captain Elder, what is FDA's thinking on the use of these templates by industry, and in particular, what is the problem, and who is at risk? There is a second paragraph that talks about the information to put risk into perspective, and in the past, it's been at least the perception of industry that FDA did not want recall notifications to say anything that would appear to downplay the risk.

So your thoughts on that would be helpful.

CAPT. ELDER: Yes, certainly we don't want the risk downplayed, but we want it characterized appropriately. So defining the risk is an important element. We don't want

to downplay it; we want it to be accurate.

Currently, we are at the point of asking this distinguished committee to provide us advice on how FDA can do a better job with our press releases. If we get to the point of starting to use this template and adjust it however is needed based on the advice of this committee, it would make sense to me, personally, to take that next step, and advise the industry that we think it would be a good idea for you to do it this way, as well.

There is an additional process that we would have to go through to get to that point. That would probably be in the form of an industry guidance document that would have to get posted and, et cetera.

But right now, I think for the purpose of this, step one for us is, please advise us how we can do this, whether or not we are on the right track, and what adjustments we need to make to get it on the

right track to begin doing this for FDA releases.

DR. YAROSS: And further to that, in our own practices, we often look at, not only the risk of the defect, but the risk of the harm, and is that a reasonable differentiation to include.

CAPT. ELDER: Could you explain that just a bit more?

DR. YAROSS: Yes. Often you will have a product, firms sometimes will go forward with a recall because there is not necessarily a trend of injury, but a trend of a malfunction that, in and of itself, could possibly cause or contribute to harm.

And in trying to portray the appropriate level of risk, the data that you have may only suggest the incidence of the defect, but there may be modeling approaches to translate that into risk of harm.

CAPT. ELDER: Yes, I agree that there would be approaches to be able to

characterize that when you have a defect which could be severe, but a likelihood of occurrence, which could be low.

And that likelihood is captured, I believe, in the FDA recall classification system, where a class one is a significant defect, which is also likely to cause adverse health consequences or death, and a class two is that same type of defect, but perhaps the likelihood of occurrence is remote. I believe that is captured in the classification system, and is appropriate to characterize as such in these communications.

DR. DELAROSA: Captain Elder, I just have a couple of investigations.

Number one is, how many investigations are ongoing currently with the FDA with different products you all regulate? Number one.

Number two, is there a website that you all have currently running that shows who is being investigated or not?

And the third question is, how many are on your staff, how many staff members do you have on your investigational committee?

CAPT. ELDER: If I could answer that last question first, there are about 1,300 FDA investigators in the country. All of them are busy. I can't tell you all of them are in a manufacturing facility at the moment, but there could be several hundred ongoing inspections across the country right now, not all of which are responsive to any type of illness or outbreak response. We do a lot of surveillance work. We try to get into companies on a surveillance basis as often as our resources allow.

Often, we get pulled into emergency situations, and have to dedicate a significant amount of resources at one particular site until that issue is resolved to the point of being able to move on to the next thing.

We do not, as a law enforcement agency, as a regulatory agency, we do not

publish ongoing investigations or inspections, because the result of them could be some type of regulatory action. Violations of our law can put people in jail. We are an enforcement agency that has that type of statutory responsibility to initiate actions when we find problems.

So people who violate the main law that we regulate, the Food, Drug & Cosmetic Act, can go to jail for doing so. There are also other civil provisions involving seizure of products, and injunction of people and companies to prevent them from continuing to violate the act.

So with that in mind, and also operating under the disclosure requirements that we have to operate under, we wouldn't have any interest in posting identifying ongoing inspections for a number of reasons. And there are, as I said, several hundred probably ongoing right now.

DR. MOXLEY: Thank you for your

presentation, Captain Elder.

The email blasts that go to -- I'm assuming they go to public health authorities?

CAPT. ELDER: The ones that we sent to the state, sir?

DR. MOXLEY: Yes.

CAPT. ELDER: Yes, they go to the public health -- states are often comprised of primarily two main agencies that we deal with are the Department of Agriculture, and the Department of Health. Sometimes there's a Department of Consumer Protection, or something like that, but it's usually Health and Ag.

DR. MOXLEY: Do those follow a template?

CAPT. ELDER: Well, if we issued a press release, that is the thing that we would send to the state health agencies. So if we went to this template, that would be the thing that we would start sending to the health agencies.

DR. MOXLEY: To what extent do you think those messages get to food pantries, and community feeding programs, and community kitchens when it involves a food product recall?

CAPT. ELDER: You know, it's a concern. And it was a real concern, we found, during the Castleberry's chile sauce recall this summer. And we actually -- I actually made a phone call to the president of Second Harvest and advised -- it was the vice president, I'm sorry -- advised her of the recall, and to make sure that the communication went to all the Second Harvest and affiliated pantries in the country. And she assured me that they were aware of it, and that they were communicating that.

And our Center for Food Safety did something very similar to a number of stakeholder organizations, because that was a recall where the severity of harm was significant. It was botulism, and we

confirmed botulism in canned products, so it was significant. And there was also some likelihood of occurrence, because four or five people came down with botulism, and were in critical condition in the hospital.

So it was so significant that we really activated the communication network on that one.

DR. MOXLEY: To what extent do you think those messages go to food pantry entities that are not part of franchised oriented social services? Because Second Harvest is sort of a franchise model. It's not the local, maybe church or food pantry, and then, would you consider timing of those messages to be important in terms of, you get heightened utilization of those pantries at the end of the month. So people may be weighing the risk of the message versus their actual hunger in terms of making a decision about whether they're going to actually use canned goods or bottled goods that are in food

pantries that are not -- there isn't a lot of oversight in terms of the inventory.

And the inventory may actually be past expiration. And they may receive it in that way. Do you disseminate those email blasts, or do you think there is a capacity to send those to social service organizations?

CAPT. ELDER: There is a -- if we had a list of such organizations, there is the capacity to do that, and we'd be happy to do it.

DR. MOXLEY: Say ones like Lutheran Social Services, or Catholic Social Services?

CAPT. ELDER: We'd send it to anybody. We'd send it to anybody who had an interest in the issue. I'd be delighted to have such a list, and to use it in these situations.

DR. MOXLEY: I think that's an important connection.

Thank you.

DR. KHANNA: Thank you, Captain

Elder, for your presentation.

Over the past two days, we've heard from yourself, and a number of others involved with FDA groups that have told us about their systematized efforts to reach others, whether it be through websites, emails, phone trees, the Health Department, et cetera.

My question is, do you know of any quantifiable data that we might have telling us how much of a problem it is in terms of, after the information has gone out, that there still are people who don't know about the recall data?

Because we are hearing a lot of anecdotes, and I'm really trying to get at, what is the extent of the problem? Because it seems to me like you have a very comprehensive system.

CAPT. ELDER: Well, it is. But I'm not going to sit here and tell you it's perfect. Our system is good. I think we have learned a lot recently; I think we are doing

better today than we did just two years ago.

I think we would like to add some more structure to the system, and we are working toward that. And some of those legislative and agency department initiatives that I mentioned are giving us the impetus to do that, because there is concern that the message isn't getting down to every level that it needs to get down to.

So we are very much interested in making improvements to that, and sometimes it may be as simple as doing what we're already doing in a more systematic way. Other times, it might be doing that as well as more to figure out how we can best get the message out.

Quantifiable data to be able to determine whether or not all who need to have the information gets it, there is, at the -- what we call the termination phase of each recall, and the termination isn't, you know, a week or two after the recall is done, it could

be several months down the line. But there is a termination phase where we would assess the overall recall effort, and determine what we could consider to be the effectiveness of it.

Because, as I mentioned in my discussion earlier, FDA, as well as the recalling firm does a series of effectiveness checks, of audit checks, at the customers of the firm initiating the recall. We would go to the wholesaler, the distributor, the retailer, wherever it might be down the chain, at a certain statistically significant percentage level based on the risk of the product, based on the classification of the recall.

So there is some data available about the overall effectiveness of it through our audit check program.

I can tell you that, again, just this past year, in the Castleberry's recall, and again, it's probably more anecdotal than real hard data, is that we were hearing that

the product was still being found on the store shelves a week or two after the recall was initiated, which gave us great concern, and we continued to try to get our message out through whatever vehicles we can.

And I mention this, too, it was getting it down to the level where it needs to be communicated, to the remote stores, and the distant towns, and the communities where the products were being offered for sale, but the communication hasn't gotten there yet.

And that is -- it is a concern, and we'd be eager to get some advice about how we can do that better, how we can get the communication out as wide as possible to make the recall as effective as possible.

DR. KHANNA: So the answer is, all the evidence we have is anecdotal?

CAPT. ELDER: No. A lot of it is, but, as I mentioned, there is a level of effectiveness of a recall based on FDA's audit checks of that recall. So when a recall is

terminated, we do have a level of effectiveness that we consider when making that termination decision. There is some data.

DR. BRUHN: Thank you.

In regards to the distribution, you mentioned the press releases sent to the State Health Departments. And indeed, I've received them from the State Health Department.

But are they also sent to the grocery store or restaurant organizations? Because they might also participate in sharing the information to their groups, whether it's a national group like Food Marketing Institute, for example, or even within each state there's the grocers' association, and that might get some of the smaller people, the restaurants, as well, because there is a National Restaurant Association, there is probably local groups there where something like the Castleberry product might work.

So the first question was, are they

sent there? And then the second question is, do you have any feel if the electronic systems are such that they can actually track who buys something? You know, if you are a member of some supermarkets, they have your frequent shopping card, and they know what we buy, and they use it, and Nielsen has it. And if it's a product that has a serious class one type of a recall, they've got a can of botulism in their cupboards, it would certainly be worth a letter, and maybe a letter more persuasive than what Swan's used, but at least the effort. So do you have a feel for the capacity in that regard?

CAPT. ELDER: Second question first again. Yes, many supermarket organizations or buyers' clubs, like Sam's Club or Costco, I believe have the ability to actually know whether or not you purchased a product that is under recall by the UPC code.

So if it's a certain lot of product, and not the entire category of

products that bears that UPC code, they are not going to know that. But they are going to know that you bought a certain UPC code of product that is subject to recall.

If they have that information, they could send you a letter directly, and let you know that you have purchased a recall product. That recall communication could be no more personal than that; I think that would be great.

Some of these organizations have actually done that. Costco, for example, sent several hundred thousand letters to customers who bought recalled product this past year in the Castleberry situation. Some other supermarket chains have done the same. We can't mandate it, but I believe they have the -- hard to say they have the capacity, because, like anything, sending several hundred thousand letters isn't easy, and having the people to be able to pull the information and get it out there isn't easy,

so I would say that they have the technical capability of doing it. The capacity might be another question, except FDA is not able to mandate that they do so.

But there is an opportunity there. We do send the notifications. I didn't try to cover everybody we send it to, but when our presenter from the Center for Food Safety spoke yesterday, she did have several slides of organizations that we commonly interact with. And depending, again, on the severity of the hazard, we would initiate direct communication with Food Marketing Institute, Grocery Manufacturers Association, those are examples of companies that we do have frequent interaction with, and I'm fairly certain would have gotten the communication on a recall like Castleberry's directly from the agency.

Again, I think, as I said a minute ago, I think we can work toward being more systematic about our approaches when initiating that type of communication.

DR. NEUHAUSER: A follow-up question about working at the state level, because obviously, this is too big for the FDA to get down to the very granular level in the various states.

So I'm wondering what your relationship is with ASTHO and NACCHO, the two national associations of state public health officers. And also, with the public health information officers at each state. And more specifically, my question would be, have they gotten together with the FDA to get trained on ways to react to press releases, and perhaps contact organizations that the states might regulate, restaurants, and so forth, because they have those lists. Probably they could get them down to the level of the pantries, which are probably 501(c)(3) organizations that the state would know.

So I just wonder if that might be a strong approach, rather than figuring the FDA has to do all of the communication, and have

it work out perfectly.

CAPT. ELDER: I think those are good ideas. I can tell you, from my experience, those are not two entities with the states that we, as far as I know, interact with on a routine basis. It's the state Health and state Ag agencies that we more commonly interact with, and the public health officers, perhaps, do more interactions with the Centers for Disease Control, and doing epidemiological investigations.

We interact more closely with the health -- with the regulatory bodies in the state agencies. We -- if there are other state entities with whom this committee thinks should be on our list for dissemination of information, we are delighted to obtain it.

DR. NEUHAUSER: Just a further comment about the state public health information officers. When I meet with them, they often comment that they are not as connected with various bodies at the federal

level as they could be.

And obviously, these are trained communication people, so they would understand press releases, and they would also understand how to take a press release and get it out to the state media rapidly and effectively, because that is mainly their job.

CAPT. ELDER: I don't have a further comment, except I would also hope that the state agencies are connected, at their level, with that entity. If FDA is not connecting directly, I would hope that the state Health and Ag agencies are connected with those folks, and I just don't have experience dealing with them myself.

MS. DESALVA: This is also a follow-up. I was involved recently in the recall of a medical device where the data was fairly ambiguous, but the company wanted to take a conservative action, and FDA really supported that action.

And there was actually very good

collaboration, I think, between the company and the agency in terms of how to communicate the risk. Because in that particular instance, the risk of explanting this device was far greater than the risk of doing nothing.

And I'm wondering, and this has come up already, but is there an opportunity for us to better define and standardize best practices of collaboration between the agency and companies. Because, were it not for that kind of collaboration, the quality of that communication would not have been that good or that effective.

And frankly, with the activity of the plaintiffs bar, with the trial attorneys many times seizing opportunities to agitate concern around some of these recalls, it becomes even that much more important to be able to neutralize that, and make sure that is an adequate characterization of risk, that, in that particular instance, was supported by a

very good collaboration.

So in terms of -- in terms of best practice, is there something that this committee can consider? Or is that a step forward in terms of looking at what's worked, and the possibility of standardizing that?

CAPT. ELDER: In terms of the risk communication mandate of this committee, I think, to the extent that collaboration with the recalling firm leads to clarity, timeliness, accuracy of the risk communication material that is disseminated, I think that is -- comments in that area would be helpful.

Standardization of interaction between FDA and a company, to me, is a little bit different. We certainly -- FDA doesn't conduct recalls. Recalls, 99 point something percent of them are voluntarily initiated and conducted by the recalling firm. So ultimately it's - we - since we can't do it ourselves, it is a collaboration. It is a partnership. It's making sure that the risk is minimized to

consumers and patients from products that pose a health risk, that are in violation of the law. And ultimately, we still have to get back to the legal definition of a recall. It is a product that is in violation of the law. It's a product that FDA would initiate action against. And through the classification process, the degree of risk is determined by the agency through the health hazard evaluation classification.

So our interest is getting the product off the market, not used, and reducing any further exposure of consumers to products that could hurt them. That's our interest.

Doing so as effectively and timely is truly a collaboration between the firm that is conducting the recall, and FDA as the regulatory oversight body.

DR. FISCHOFF: Steven?

DR. GORELICK: Do you have any idea how, through opinion studies or other means, how the public views post-purchase attempts by

manufacturers -- and I know this applies often to consumer goods -- but to the attempt to get them to register?

Because there are a lot of privacy concerns that people have, thinking about today, that weren't even thought about awhile back. And when it comes to using various medications or products, there are some areas of the economy where it's assumed that the seller will always know the people who bought the products.

That can't be the case with medications and with other -- always with medical devices. And yet I'm wondering, when it comes to a device, are people offered a chance to register as people who have received stent X? And if so, is there any resistance to doing that?

CAPT. ELDER: There are certain requirements applying to devices that require tracking to the user level, certain implantable devices are an example of that,

where the manufacturer actually has to know, down to the user level, in whom the product is implanted. This was a change in FDA law and regulations several years ago requiring device tracking.

To that extent, it certainly facilitates the communication of a recall, but it's a small category of products that that regulation applies to.

Products for home use, like a blood glucose meter, there is no FDA mandate, no requirement, to track such a product. Certainly the manufacturer could offer something to have it registered with them, so they could know the users, but it's not within FDA's regulatory schema to require that.

DR. GORELICK: One reason I ask is that a number of pharmaceutical companies have very informative websites about their medications - no secret about that - and offer people the chance to register if they are users of a given medication.

And even though I'm not someone who demonizes that industry, that's not what I'm into at all, I can't say that I didn't think twice about saying, oh yes, I'm using this statin drug, even with the assurance that it was going to be for sending me any new findings about the drug.

I can't say that marketing and advertising and sort of other things weren't at least a little bit in my head, even with my generally positive stance towards the people who wanted the information.

CAPT. ELDER: I think what you could get to if something like that ever got into play is that you could have some direct communication with a certain population, but it wouldn't alleviate your need to communicate more broadly for all the people that you don't know who have the product.

I'd also like to just mention that we have two of our long time recall experts with the Center for Drugs, and the Center for

Devices here in FDA, Mike Smedley and Mike Verdi. And I'd invite them to comment at any time during this discussion, if they'd like to. So I just wanted to throw that invitation open, too, if we get into any real specifics with these program errors, that they can either correct me, or add their own comments at any time.

DR. YAROSS: Yes, I was going to agree that manufacturers in many cases do welcome that contact with the ultimate users of the product. And obviously, we can't mandate it except for those specific track devices. And for those devices, manufacturers are actually required to keep track of those users, which is a tremendous undertaking that they do to be able to provide updated safety information when needed.

MS. MAYER: Captain Elder, there are, as you know, many websites that have specific patient communities, and many websites for general health information, that

are very widely used by the public. Some surveys have suggested that as many as 60 percent of the U.S. population goes online to search for health care information.

I'm wondering if you have anybody at FDA who is devoted to communicating with these websites, either disease-specific websites, or general websites, like WebMD, and also with physician websites that are devoted to continuing medical education, like -- well, there are many.

But it just seems to me that you've got -- you may be preaching to the converted; in other words, to the people who would already be likely to have found this information in other places, and that might be a problem there. But it seems to me that, for a relatively small investment of time, you could be disseminating information in the appropriate form to very widely reach, and perhaps even persuade these websites to have a standardized way of presenting recall

information, as you were pointing out, the Washington Post seems to have developed.

I mean, it would be really wonderful to have consumers sort of routinely think about, oh, I'm going to look for this, when they go to these websites.

CAPT. ELDER: Your comment is clearly a good one, that there would be an opportunity, I think, to direct some of our communication on category specific issues to such websites that cover that category.

The short answer to the question about whether or not we have anybody dedicated to reviewing it is, I don't know. There very well may be, in the various offices within the Agency. It's not within my office. I don't believe anyone in the Office of Regulatory Affairs is routinely doing it, but we have a number of, within our product centers, and within the Office of the Commissioner, there very well could be. I just don't know the answer to that question.

DR. FISCHOFF: Let me ask one question about how the system works, which is, do you need to coordinate with the commissioner's office before you initiate an action? Are these decisions all made within the Office of Regulatory Affairs? Or are there some that you need to check with --

CAPT. ELDER: The -- kind of depends on the specific nature of your question. With regard to recalls, specifically, a press release initiated by FDA would go through a formal clearance process, which includes staff at the Office of the Commissioner.

The idea of whether or not a recall is appropriate, and what level of classification it will be, and those types of things, is Office of Regulatory Affairs, and the involved product center.

So it's not at the Office of the Commissioner level on classifying a recall, or scope, or strategy, but, by procedure, press releases are cleared, through staff at the

Office of the Commissioner, as well as ORA, product center, press office, et cetera.

DR. FISCHOFF: Are there any other -- yes.

MR. HANEY: I mentioned earlier that reporters often want to know the amount of product that's being recalled as one way of assessing the news-worthiness of the recall.

Is there any barrier to obtaining and releasing that information? Because it essentially is sales information. So can FDA -- if FDA writes the press release, can you include that information? Or is there some constraint on that?

CAPT. ELDER: There is a constraint on releasing what would be considered confidential commercial information, and I think that would be something that we would have to apply in each unique recall situation.

It may not be confidential commercial information to be able to say that a company is recalling lot #123, and there are

7,000 cans of product in lot #123. I don't think that would necessarily be protected information, and if we had that information at the time, I don't see any reason why we couldn't say it.

If, however, a company's -- if a company is recalling all of the production that they did over a year, and that production is 12 million cans, that possibly could be. But that's one of those issues that we would just have to decide on a case-by-case basis.

We often, if we have that information available we -- I'm just thinking of the, not just of the written press releases, but the number of follow-up questions that we often get from the media after a press release; that that is often a question that we'll try to get the information together and be able to answer.

So there may be a hint of a restriction there, but I don't think it applies, except in a few circumstances.

DR. PETERS: Just a quick follow-up on that. In at least some types of consumer goods, product lots would be going to particular parts of the country. So maybe the product lot #021 is only in the Pacific Northwest, for example. Is that something that could also be included? Because that bears both on who cares in the media, and on the consumers who are actually at risk or not.

CAPT. ELDER: It definitely is, and our -- I think the template that you have indicates the flexibility we have to call something a worldwide recall, a nationwide recall, a regionally-specific recall, a statewide recall. That is something that we would want to be able to characterize in a certain way. If the distribution of a recall product was so limited that it was only in, say, one state, we would be focusing on the media outlets in that state, and call it a recall of product X in Massachusetts, and focus on the media outlets in Massachusetts to

get that message across.

So that is -- that is definitely possible, and actually, we often do it. Sometimes, if we know that it went to seven states, we'll name those seven states. There is always the opportunity -- you know, sub-distribution that we may not know from, you know, if it went to wholesalers in seven states, they could easily sub-distribute it to retailers in all 50 states.

So it's only when we know that we can confine the geographic area that a recall product may be located in that we would take that step of trying to do that.

DR. SLEATH: I just had a quick clarification question. Are your releases going out in multiple languages, or are you relying on others to then translate them?

CAPT. ELDER: Routinely, I believe they are -- they go out in Spanish, and perhaps some Asian languages. And again, it might depend on the location of the product.

Obviously, if we have a release of a product impacting Puerto Rico, we have to make sure we get it into Spanish quickly.

I was looking for my friend at the press office, who isn't sitting there right now, who would know more accurately about the way the releases are disseminated in other languages. I know that we do have a - I'm still looking, I don't see her - I know we do have a policy of doing it when it's in populations that would need the release in another language. DR. SLEATH: Actually, I was thinking of that myself, because I consider myself a little savvy in computers, and I was looking for them in Spanish to see what they looked like, the press releases, and I couldn't find any of them from the Food and Drug Administration.

And I know one of my biggest concerns is, then, we would rely on others to translate those documents, we know -- then the message starts from the FDA in one way, but it

might end up in a different way when somebody else translates this.

And today we heard a presentation where we heard about how important terms are. So I think it's very important, it should be very important that these press releases, including the template that we have under review, be translated also so it can be pilot tested with those populations.

Because, in my field of study and work, we cannot use an instrument unless we have pilot tested that instrument with our target population to make sure they understand. And I know this is directed to consumers, patients, health care providers and others. Have those press releases, or this instrument, is it planned to be pilot tested with these populations, or has it been pilot tested?

CAPT. ELDER: It has not been pilot tested. I think -- I know we are eager to get the advice of this committee to get us into a

better shape to begin doing it this way.

But the thought is, we've been issuing press releases for years, and we've been issuing press releases that are often a one, or two, or three page narrative.

We aren't talking a significant difference in the overall content; we are talking about a difference in the organization, and in the clarity, and in the consistency across all product areas.

So I would say I question, I guess, whether or not it would need to be -- if we are comparing what we used to do to this approach, would it need to be pilot tested if, at least internally, and on the advice of this committee, the expert opinion is that this is a better way than we have been doing it?

DR. SLEATH: I also, when I had a -- I wanted to know what the reading level of this document was. And I know it's 12th grade level, so it still would not reach -- if it's in other languages, it still would not reach

that sector of the population, that is very large, and those who either speak English, or read English, but I don't know at that level, then they can't understand the document.

So that is why I was talking about the pilot testing to be very important.

CAPT. ELDER: I didn't recognize that the template, as currently prepared, was at any particular grade level, because it really hasn't been filled in; it's really just headings with what would go under the heading.

I think what we put under the heading would have to be certainly written at the appropriate level. I don't know if this -- I don't know what that appropriate level is. Inferring from your question, 12th grade is too high, but I don't know what the recommendation to us would be for what level is appropriate.

DR. FISCHOFF: We have one more comment, please.

MS. MAYER: This is a follow-up on

that.

It occurs to me, as I follow press releases, and then read what the media does with them to disseminate information, that often, press releases are quoted word for word by the press, by members of the media who simply do not have time to write in-depth information, especially short pieces.

And I wonder, if there isn't a need to really follow up, to give a really simplified version of -- and shortened version as, again, the Post did. I was really impressed by that, as a part of this, not to replace the entire thing, but sort of like a consumer abstract, if you will, of the information that really is crafted very carefully at a reading level that is accessible, to be then followed by the more complex and detailed information.

CAPT. ELDER: I -- one of the premises of your question was that the reporters take it verbatim when writing their

stories. And I don't know, Mr. Haney, may have a comment on that from his 30-plus years as a reporter and editor. I don't know if that's true or not.

MR. HANEY: Well, I think it depends on the publication. Certainly at the national level, I don't think it ever happens, or very rarely. I think it does occasionally happen on smaller publications, like weekly newspapers, and trade press, occasionally. But trade press is going to want to be reporting at a very technical level, I think, and not a simplified level. So I can't really think of an example to illustrate what you are talking about.

MS. MAYER: Okay, I'll tell you, I follow most of the media around emerging research of cancer drugs. And I go to the major conferences, and I pick up all the press releases, and then I follow how the press covers the conference.

And I very frequently find, even in

large national media outlets, that information is conveyed word for word. Now it's not by AP, and Reuters, and the major news services, clearly. But it happens more often than you would think that large, undigested paragraphs, and un-attributed from press releases, are presented as news.

It's very alarming, really, because there is no analysis of the information.

I mean, that's, of course, getting very far away from the issue at hand in terms of recall, but if you are really talking about wanting information to get down to the local level, to get local newspapers to reprint it, you've really got to, I think, give them something in a form that they can use, and not expect their reporters - especially since this is time-sensitive information - to have to extract something for the reader.

I mean, it's a golden opportunity for FDA to do that, I think.

CAPT. ELDER: I appreciate the

comment. It's certainly something that we should think about.

I can tell you that one of the goals of the proposal as presented was to do what you're suggesting. Maybe it didn't go far enough, but it was to reverse the procedure of a one, or two, or three page narrative, and to put the information in a more usable way, to chunk it, to map it, to have distinct headings where people could go pull out that information to enable reporters to accurately report it on a quicker basis than trying to pull out those elements of relevance from a more of a narrative release.

So I think one thing that we tried to do was to address the point you're making, and perhaps the point is, maybe you can go even further, and that's probably something we should think about.

DR. FISCHOFF: We have public comment.

If I could ask the two members of

the public to -- I think we are having a productive discussion, and let me just push down the public comment until we get through this round of discussions. We will certainly get it in before lunch.

MR. BAIRD: Captain Elder, just a question. When you sit down with corporations to discuss the communication of serious adverse events, or risks, or recall, how often do the corporations bring the head of communications into the room to discuss that with you?

CAPT. ELDER: I guess I should say, in my 20 years with FDA, 15 was in the field in the Boston office. I had lots of direct communication, in person, or on the phone, with companies, including in recall situations. And it was common practice to have whomever, and smaller companies don't have somebody by that title. But when companies do, that person is always involved in the process. They are the ones, you know,

really crafting the release, and of course, it's going to go through the legal department, as well.

So in the companies that have such a person, they are involved.

MR. BAIRD: That wasn't the marketing head, or another person in the company? Because it just conflicts tremendously with my own experience that, typically, the communications heads are left back at the office.

And the only reason I even questioned the point is, I think that the discipline could have a salubrious effect on the discussion. And I'm just wondering if it isn't an under recognized opportunity.

But I'm hearing it's not, and I think that's great, if that, indeed, is the case.

CAPT. ELDER: Yes, again, to the extent a company is large enough to have somebody who is the head of communication,

head of public relations, head of public affairs, my experience has been that person has been involved, at the table, I don't know, but working on the actual language of the press release.

DR. NEUHAUSER: This is a follow-up to your question, Captain Elder, about what would be the appropriate reading level. And it's a question that would require a fairly long answer, so the committee could think about how to deliberate on this, and how to look at the research.

But I'll just summarize very quickly a response, and that is, number one, there is no national standard for reading level recommendations. However, the NIH does recommend that information be put into 4th to 8th grade level, with the preference on the lower end of that. And many people think that the average American public reads at about a 7th or 8th grade, or about three levels below the last grade completed, and that includes

some people that have completed college.

So 7th to 8th grade is many levels below the usual 12th grade level of most of the press releases that I have seen.

These things can be tested using computers, and so forth. And then to the question of -- and I just have to qualify that to say this is for English; among Spanish speakers, the level of health literacy is lower than among English speakers, and then, among various other groups, it would have to be assessed. There are some groups that don't have a written language, like the Hmung, so there are other issues there.

You asked about pretesting, and the short answer would be that, if you want something at an accessible reading level, understandability, reading level is only one way to try to get there, and you would still have to pretest in order to assure yourself that people can actually understand it. Those people, the people that you are testing it on,

would have to be tested for their level of health literacy to make sure that they are low health literate.

So a 7th to 8th grade level, but the assumption would be it would still miss about 20 percent of the English speaking population, and more of the Spanish speaking, who might read around a 5th grade level.

MS. VEGA: I just wanted to clarify to Captain Elder that, when I did the reading -- assessed the reading level, it was not of the template that we have in front of us, but we were provided with a larger package that had examples of the template with actual information on recalls that have been done in the past. And those were, some of them were to the 12th grade level, with actual information.

So it was not of this template, and it still doesn't have information from actual recalls, with actual information.

CAPT. ELDER: Thank you. We had

never issued a press release in the format of this template. The working examples we prepared was taking press releases that we had issued, and just taking that same information, and dropping it under the heading that we found appropriate. And so it would have been, if it was a 12th grade level on the template, it was a 12th grade level on the initial press release. We didn't adjust the information to put it into the template.

DR. NEUHAUSER: This is in follow-up to the comments, or the research presented by Mr. Wogalter, and it was very nice to see the surgically implanted devices broken out as a separate category.

There are certainly other categories of products, including devices, that are not typically removed or discarded during a field action. And so the question would be whether or not -- I saw the template talks about correction. But that's, again, a technical term from the regulations.

Is there thinking as to what range of additional terms will be used, or is that something you're looking for input on today?

CAPT. ELDER: I think we'd be looking for input, and we appreciate hearing the detailed Dr. Wogalter's presentation.

The template, as we had crafted it, had been standardized for the way that we had been communicating, and titling such press releases for a number of years.

Mike Verdi is here from the Center for Devices, who perhaps may want to talk about the history of the way we've been using it.

Mike, do you want to say anything? You'd have to come up to the mike.

DR. FISCHOFF: I officially recognize you.

MR. VERDI: Thank you, David, thank all of you.

I'm Mike Verdi. I'm the senior recall coordinator, probably, based on age, at

the Center for Devices. I also served 10 years with the Center for Drugs as their recall coordinator.

We're well aware that there is some information on implant recall items that may need to be handled differently. It's been addressed for a number of years. If you've been around as long as I have, 31 years with the agency, it's been a wonderful job for me, you realize, you see things come and go.

Back in the `70s, this same issue had come about. And the Commissioner, at that time, when the FDA recall guidance was published in 21-CFR, which Captain Elder has mentioned is sort of our Betty Crocker cookbook, it's not a regulation, it's a guidance document. And it was issued so that both industry and the agency would have some uniformity in what was said, and we would both understand how we were to say things, and how we were to conduct the recall.

And part of that was, we realized

that a small portion of products, medical devices that are recalled, probably less than one percent of the number of recalls in a year, might be implanted. And an even smaller portion of those might have already been all implanted. But for the most part, there are products that are waiting to be implanted, and those that have been implanted. And the commissioner understood this.

And in the comments to, what we call the preamble to that regulation, he covered that idea. And he said that the first part of the announcement, the word "recall," was to alert the public, and the doctors, to be aware of this situation, and then following in the body of the documents, were the risks, and all the other categories you see, were to explain the differences, because, in fact, a recall is a violative product. And for the majority of the part, as Captain Elder said, that product really should come off the market.

But we understand there are scenarios, health risk scenarios, and as was mentioned here, Dear Doctor letters, where that risk can be explained, and the patient and his doctor make that determination as to whether they want to return that product.

And so the idea that the word, "recall," appears at the front, that's to get everyone's attention, call his doctor, see his doctor. And then the other information that the agency and the firm have gotten together, the risk, the use, the other explanation, follows in the body of the document.

DR. YAROSS: Thank you, I appreciate that.

I think what I'm trying to add to the dialogue, though, in addition, is the category of products other than implanted devices, such as capital equipment, MRI machines, et cetera, where the form may not be removal or recall, but perhaps a software upgrade, things of that nature. So I just

wanted to make that point, as well.

MR. VERDI: If I could have one second to address that, and then I'll get away? I'm a terrible person when you start me talking, and I continue to talk.

But there are four big reasons why we want to try to stay uniform. The public is familiar with certain words. The worldwide nation is familiar with certain words. There is a uniformity when we address companies to issue the recall letter, so we want the recall letter to match the press release, so we don't confuse the individuals reading both documents, because they probably will see both.

Again, the commissioner, who was very smart back in the `70s, said, that's correct. We may -- a recall is more than, or less than a recall. The word, device correction, which I believe is part of that header, has been codified, is well known across the world, and it includes - correction

includes, not removing the product, but fixing the product as an X-ray machine. You certainly don't want all of those to come back. Or patient monitoring, correction is patient monitoring, where the idea is that doctors will monitor their patients.

So I think that template tried to capture all the scenarios, recall, correction, market withdrawal; tried to cover all the things that are not nationally and worldwide known, so that when we issue a press release, the Europeans will know what these words mean, and so will the public.

Thank you all.

DR. FISCHOFF: John, and then Ellen, and then we'll go to our open session.

DR. PALING: I would like to try and put the work that you are doing in the broader context of the FDA as I currently understand the situation.

Yesterday I had the insight that for my simple mind I could divide risk

communication within your agency into two primary categories: those such as yours which are primarily involved with warning the public, appropriately, speedily, at a level of language and reach and with a logistic reach through the distribution chain in a way that is effective.

Clearly that is risk communication. It is very appropriate that you have asked my colleagues to give you their input upon that.

I however distinguish that between - from the fact that many areas of communication to the FDA involve carrying forward data, your expert hazard knowledge, in such a way that the public, the media and all other citizens can make their own decisions.

To repeat my simple sentence, what you are doing is reporting on your decisions. And I would like to say immediately something that has not been overtly said, I think this template system is very good.

I compliment you on, A, your

continuing efforts, and what you have done before, with a group of academics that are used to marking papers, this is more of a Rorschach test for them. You can almost test what people's little agenda is according to how they would deal with these same words.

More important to me is the fact that I suspect legally you have to have consistency through the FDA.

So how you are dealing with class one, class two, probably should resonate and be identical to the way people discussing drugs, talking to the media, communicating with the public, are also discussing risks.

This is a theoretical conceptual thing I will offer you now. If we were to ask you and your colleagues, which I do not think it's appropriate that you do, to think of risk communication as being some, as best we can make it, factual explanation of the probabilities and also another factual explanation of the consequences, as you know

well some blend of these makes a big risk.

What I am finding as I read your material is that it is excellent as a warning document. And that's what it should be, and that's what in my opinion you should concentrate upon.

I think that it should not apply in the same way with the same terms - let me withdraw the "same terms" - with the same lack of information about real probability and real consequences when we look at the broader responsibilities of the FDA. And I'll give you two specifics.

One is in the European Union, because I used to be European, I'm well aware of their regulations, they have defined very carefully what the agencies may use by way of words describing probability.

Most people here, it's a big risk, a small risk, likely, remote. When I looked through the various demonstrations of past press releases that were presented to us,

there were all manner of words. And that's fine; that's the way the public thinks.

My suggestion would be that sometime you or this committee should think whether there is a desirable trend to actually set, is it very probable, quite likely, or what do we mean in terms of probabilities? Because if I were to be trying to use your documents as exemplars of what might be put forward to the broader responsibility of letting others make their decisions from your data, then I would very much wish that there was such a definition of words with likely probabilities. That's one thing.

I could provide my version of them, but there was a gentleman who was the equivalent of the surgeon general in England called Dr. Kenneth Cowlman, and he being in the erudite and important position that he had, got these right through the English system and then almost through the European system.

I'm happy to provide those. I basically used his with one slightly different one.

I'm really trying to make the suggestion, and I will do that if that's appropriate, there is a need that what you do is paralleled by others who have a different responsibility from yourself.

The other is, I think there is a big difference between data and information, the way the public use those two words. If you haven't thought about this, you might like to. Is there a difference? Everyone says, yes, there is. What is the difference? In fact data I would suggest is typically just basic facts. It is only in my submission information when those facts are also provided in a context, in a perspective that makes the potential listener or reader have an ability to understand the data.

If you accept my broad definition, just listing side effects one after the other

after the other, is nothing more than a data dump, not unintentionally confusing, but because we have never tried to see the responsibility of risk communication as being communicating some meaningful probability and some meaningful consequences.

So what I'm trying to say is, I'd like you to be from one simple person very reassured. I think you are doing very excellent work, and I don't think you should be expected to be the ones who are defining what probability and consequences mean.

So my question, which I do have at the end of this is, to what degree do you think these three classes would be easily applied and useful to your colleagues in other centers who are providing data in a way that the public could make their own decisions?

DR. FISCHOFF: Let me ask you not to answer now. I'd like to ask Ellen to make her comment. I'd like to say something briefly, and then I'd like to go to the open. And

since you will be with us afterwards, we can continue the conversation after lunch.

DR. PETERS: I'd like to reiterate Dr. Paling's point that the template is actually quite good as it stands. There probably is some room for improvement.

I did want to follow up on Dr. Mayer's suggestion about having a little bit better sort of what I would call a fast facts section at the very beginning.

I do some work with the Eisenberg Center for Communications where we produce a set of products about different medical concerns, like the use of analgesics for arthritis or medications for low bone density. For consumers, physicians, and policymakers. So many of the same audiences that you are concerned with. You have more concerns besides that as well, but that is a subset at least of your interested parties.

What we've done is, we've developed a template over time, and it's evolved through

consumer testing. It's evolved through doing one-on-one interviews with physicians, doing focus groups with consumers.

And what we've ended up is where you are starting, which is having kind of a two to four page document that has an organized set of bullet points or thematic types of information in particular order throughout each and every one of our documents so there is consistency, so a physician looking at one is going to know about where to find that same information on the next.

But in addition to that we do a fast fact section at the beginning: what is the most important information for this physician who has 30 seconds to take a look at this, and really doesn't have the time to read through all the detailed information.

And the main purpose behind it is, do I want to spend my time to read further into the detail? If you interest me in that fast fact section, I'm going to go ahead and

spend the extra maybe two minutes now. That I didn't really want to, but now, yes, I'm interested enough, I'm going to do that.

So I just wanted to reiterate Dr. Mayer's point.

DR. FISCHOFF: I think this has been a very good - sometimes we've understood the system within which all this needs to perform, how you get the information, how it gets out, and so on, and I was gravitating toward the detailed design.

I'd just like to make one sort of personal comment. As I'm always anxious about expert judgment serving as a substitute for data. I mean I'd almost be reluctant to give an expert judgment if I thought somebody's life was going to rely on that. Even with all the rigamarole that you all have to go through with the Paperwork Reduction Act and so on, this is really cheap relative to probably most other parts of your operation, relative to the stakes, the consumers, the industry, the

reputation. This research costs basically nothing.

I trust my expert judgment. I probably trust the judgment now more than I would have trusted the judgments of me 10 years or 20 years ago. I trust my judgment more in areas where there has been research on particular topics and populations and communication channels.

I trust my judgment more when I have the opportunity to be beaten up by my colleagues. But I'd really be reluctant to give judgment as a substitute for data.

So okay. So we are now having our open public hearing. We are grateful for having three or four, well, three people speaking together to share their comments with us. We may have a little bit of time to interact with them now.

So I have a notification that I need to make, which is that both the Food and Drug Administration, FDA, and the public

believe in a transparent process for information gathering and decision making.

To assure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason FDA encourages you the open public hearing speaker at the beginning of your written or oral statement to advise the committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting.

For example the financial information may include a company's or a group's payment of your travel, lodging or other expenses in connection with your attendance at the meeting.

Likewise FDA encourages you at the beginning of your statement to advise the committee if you do not have any financial

relationships. If you choose not to address this issue of financial relationships at the beginning of your statement it will not preclude you from speaking.

So thank you.

We have three - from the Heart Rhythm Association, we have Donna Goldberg, and Joel Harder. After that we'll have Lisa Weddig from the National Fisheries Institute. And after that, Marcella Gaitan for the National Alliance for Hispanic Health.

And we welcome your comments and thank you for coming here.

OPEN PUBLIC HEARING

MS. GOLDBERG: Thank you, good day.

I'm Donna Goldberg. I have no financial disclosures to disclose. I manage the scientific and clinical documents at the Heart Rhythm Society.

There's been strong reason given to this committee for precise effective standardized templates that provide details,

defined effect, and tell what to do.

The Heart Rhythm Society believes this hasn't been done yet, and there is room for improvement. We have a template for your review, and will be happy to answer questions after our statement.

MR. HARDER: Hi, good day. I'm Joel Harder, director of quality improvement and outcomes, speaking on behalf of the Heart Rhythm Society.

The Heart Rhythm Society is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders.

We represent over 4,500 specialists in cardiac pacing and electrophysiology. When medically indicated electrophysiologists treat patients through the use of an implantable cardioverter defibrillator, pacemaker, or cardiac resynchronization therapy device.

The Heart Rhythm Society is the

leader in cardiac device post-market surveillance. Cardiac device performance and the communication of device performance after device malfunction are chief concerns of the Heart Rhythm Society membership, physicians, allied health professionals and the public.

The Heart Rhythm Society is fully committed to improving device performance communication, and would like to work closely with the Risk Communication Advisory Committee.

In 2005 the Heart Rhythm Society convened a policy conference cosponsored with