forth?

It's helpful to test memory also because people don't always have their leaflets handy, but what we get is a function of how we test for it. If we use a free recall procedure where we say, for example, what are the possible side effects that can occur with this medication, they don't do very well. That does not necessarily mean they don't know anything about it because if we switched and used a recognition experiment where we give, say, one side effect at a time and say could this side effect occur with this medicine; how about this one; what about this one, and so forth, then their performance goes up.

So what we get in terms of memory and then you'll see in a moment comprehension and everything else, it depends on how we test for it.

In terms of comprehension, there are a variety of paradigms we've used to test comprehension of text, pictograms, and so forth.

Problem solving tasks are essential because they go beyond the specific information given. So we can have various types of scenarios. What would you do if you were on this medication if such-and-such happened?

Search and find tasks are important. We've talked about that before.

Decision making is interesting. The decision maker is really the health care provider, to write a prescription for a given drug for a given patient.

However, when the patient gets this leaflet, can he or she look over all the contraindications and other information and say, "Yes, this seems appropriate for me, " or, "Ut-oh, forgot to tell my doctor that I have asthma," or diabetes or something of the sort.

So selection and de-selection in partnership with health care provider can be facilitated by these leaflets.

And finally, metacognition. In metacognition tasks, we can ask people how easy or hard was it to understand this information. How well do you think you understood it? Do you like it, an dos on and so forth?

But there's a problem here. Cognition is the process of knowing, while metacognition is the process of knowing how we know, being able to reflect on our own mental processes.

And what we find is there is often a very

big gap between metacognition and cognition. People tend to overestimate how well they understand information, and I think that's a part of the results that we heard this morning with consumers rating comprehensibility type measures, a high in some cases. I doubt whether they would really do well on a true comprehension test.

So we can take a look at all of these cognitive tasks. We can see how well people do in the actual cognition tests in the laboratory and also in actions out in the real world.

We can look at accuracy, and we can also look at errors. So when they get something wrong, what kinds of errors do they make, and are those errors likely to have serious health consequences?

So now that we know format is so important, how do we go about selecting appropriate formats? Well, obviously we start with the usual content, the indications, contraindications, warnings, dosage, side effects, et cetera.

But that's only part of what we need to do. There are other dimensions involved, and at least two others are worth talking about today.

Format. We have options for each chunk of information. Shall we present it in text? That's the

left to right cycling of words across the page, or a list in outline. Other types of representations we've developed in my lab, fans and trees, and so on.

The point being is that you can take the same information and when you present it in one format people might not do well with it. Okay? Why is that? Is it hard? Sure, but it might be the wrong format.

We have then switched formats and gotten dramatic improvement in people's ability to understand the information, and it sometimes is dramatic as an 80 percent improvement.

Finally, we have to make sure that we're serving all of the various types of cognitive tasks that people are going to do with these materials, such as being able to find and understand, remember and use the information, and it can happen that you have a certain combination of content by format, and that looks great, and you do a comprehension test in some way, and it looks like they understand and you feel good about it.

However, later on people might not be able to define the information, remember it or use it in an accurate way in everyday life. So how do we select a given format for a given chunk of information?

There's a tendency to start with a format

and stick the content into it. That's one strategy. Another strategy is to start with a content, look at it carefully. Is it descriptive? Does it have a list imbedded within it? Is the list long or short, et cetera?

Then go try a format. Does it fit into Format 1? If not, try another. Does it fit well in Format 2? Not so good. And continue until there is a good fit, and so cognitive accessibility is maximized.

So, in conclusion, there's a lot that we can do to insure that specific information is present in these leaflets, in the approved professional labeling on the Internet, on TV everywhere. We can make sure that it's physically present.

However, if people cannot find, understand, remember and use this information, then it is functionally absent. So in the year 2000, we get Dr. Svarstad to redo the study and so on. What would it mean if we used the current research methods which get us to a certain point, and we came up with 100 percent adherence on all the criteria, even if everyone put in and modified those criteria to everyone's satisfaction?

The information could still be functionally

absent. We must have materials designed based on cognitive principles and submitted to full comprehension testing.

Thank you very much.

CHAIRMAN GROSS: Ruth, thank you very much.

I think at this particular point questions can be asked of all of the presenters during the public hearing, as well as Dr. Day.

I'll start off by asking Dr. Ratto of First DataBank.

As an example of one of the DataBank vendors, how do you view the Keystone criteria? Are they used on a regular basis? Any comments on them?

DR. RATTO: Yes, the Keystone --

CHAIRMAN GROSS: Why don't you go up to the microphone if you don't mind.

DR. RATTO: When the Keystone guidelines ere established, we had incorporated information related to these guidelines. For example, we completed an enhancement in approximately April 2001 where we added the explicit warning section, whereby in previous editions of monographs we would have precautions and drug interactions, et cetera, imbedded in those various sections. We created an explicit section that essentially consumerized any boxed warning information

in the labeling.

We also created an overdose section. I'm speaking now to the original First DataBank product, which is what I'm here to address,a nd when we added that overdose section, we also added an other uses section, and we're in the process of segregating out off label uses from label uses.

So we had taken that into account. We have, in fact, since then also created an XML version, which stands for extensible mark-up language. We have that version which includes bullet points and some of the readability issues that were addressed. It includes the extensive customizability for our customers. They can basically choose from a number of different formats to display these monographs.

Unfortunately at least with the technology that I understand it at this point, the primary use for that would be as a Web, either Internet or intranet type environment, but there is no intrinsic reason that I know of that they couldn't be printed, other than the fact that they are obviously going to be longer in length just based on the fact that a number of the sections, most explicitly the side effects precautions and drug interactions, have bullet point list items within them at this time.

And that's a product that we just released several months ago that has not yet to my knowledge had any major user involved with it at this point, but we have been touting that.

CHAIRMAN GROSS: So your latest product is compliant with all Keystone criteria?

DR. RATTO: What I'm saying is that the latest product incorporates all of the formatting issues -- a number of the formatting issues that are in the Keystone guidelines.

What I'm saying is that we have our editorial policy structured such that we have incorporated to our view the Keystone guideline criteria, and what we need to do is we're going to take a look at the scoring guidelines that just came out with Bonnie's report and incorporate any additional information that needs to be added to those.

And what we need to do and what we're in the process of doing is going back to our monographs and populating that information through all of the monographs.

CHAIRMAN GROSS: So at the time Bonnie's study was done, however, maybe the information sheets, the CMIs, were not totally compliant?

DR. RATTO: Correct.

CHAIRMAN GROSS: Dr. Cohen?

DR. COHEN: Well, that's more or less what I was going to ask.

Currently, can you say that all of your materials -- you're probably the leading provider of this drug information to pharmacy computer systems. Can you say that all of your material would contain all of the black box warnings that exist, all of the important side effects, all of the prominent contraindications for drugs?

DR. RATTO: What I need to state first off is that we are -- when this study was done, there was a -- the information within the company was, as Bonnie had said, segregated into separate versions that depended on the Medi-Span products as well as the original First DataBank product, and there is currently a divestiture process going on within the company related to the Medi-Span product, and by FTC regulation I really can't comment on the Medi-Span portion of the database.

I am here to comment on the original First DataBank portion of the database, and I can tell you as we just alluded to that we did go through -- there was no way to get a comprehensive list from any one

source of all the individual products that have boxed warnings in the labeling. However, we made a good faith effort by going through the PDR, the GenRX source, and going through also at the time one other secondary reference source that had a number of the boxed warnings listed and tried to encapsulate every one of them that we could find.

So I'm confident that we have in the high 90 percent range, if we don't have 100 percent of them, already summarized, and we have -- what we are working on, as I said, is reviewing monographs that were created in the past.

CHAIRMAN GROSS: Well, perfection is tough, but pursuing it is certainly worthwhile. What would you propose as one of the major data vendors that all of the data vendors do to try to be as close to compliant with all of the eight categories and it subcategories to maintain this as an effective voluntary program so that there isn't pressure to remove the voluntary status?

DR. RATTO: Something that we have informally discussed with FDA and are pursuing now is dialogue feedback with the agency, and hopefully that will take the form of discussions with Dr. Svarstad and some of her groups. Certainly the entire group

would be a difficult procedure.

But we have some discussions that are set up for tomorrow. I'll be visiting FDA offices, and we want to -- from our perspective, we want to get this off the ground in terms of having constructive dialogue interchange, and we obviously are working towards implementing our current editorial policy through our entire database from our perspective. We'd like to bring other stakeholders to this sort of dialogue and point-counterpoint quality improvement efforts with the agency.

Obviously that's going to be up to whichever providers are out there besides ourselves, but we certainly would welcome the participation of everyone involved for the overall improvement of the quality of the monographs.

DR. SULLIVAN: I was just wondering whether you have what you currently have in place, what sort of quality assurance or quality control. For example, do you ever go back to the sponsor companies to check with them whether they think that's appropriate or do you just hand it out for peer review or do you have internal people that audit what you're producing?

DR. RATTO: Well, first of all, we've had at least ten to 12 years of field testing, if you will,

from the standpoint that all of our monographs, whether they are looked at in a physician office by a physician or a pharmacist or a patient. We have gotten feedback from those end users, if you will, and also our software vendors. Information is passed on through them, questioning either the information or perhaps the inclusion of additional information.

Basically any questions that are raised out in the field, whether they are validated or not, we will review them and take them under advisement. We respond back with information giving the reasons for the inclusion of that information or stating that we will consider that particular information.

With any off label uses, for example, we'll substantiate that with literature information usually through perhaps a secondary reference source, and I had earlier mentioned the AHFS drug information because they do authoritative literature searches for off-label information, but we are focusing on labeled uses in the uses section of the monograph.

We, along with that, we do monitor MedWatch. We do have information from manufacturers. We don't have a pipeline with every single manufacturer, but we do encourage their drug information pharmacist to send us information as early as possible if there is

labeling issues that they have in terms of, you know, upcoming changes to their labeling, that sort of thing.

CHAIRMAN GROSS: Jackie.

MR. LEVIN: Just a point of information. It is my understanding that it is not -- that the law does not permit the inclusion of off label use in medication guides or in whatever we want to call these things; that to be scientifically accurate, they have to represent the information in the product label. The product label does not include off label use by law.

DR. RATTO: Actually the way the action plan criteria are set up, to my understanding it is that you may customize a monograph with off label uses, which is why we have an other uses section, which is where we're in the process of segregating out our off label uses. So that that part of the action plan criteria will be met because, you know, we have essentially reviewed all of the criteria that were set up within the action plan, and again, we want to look at the scoring guidelines as well and make sure we've incorporated all of that information into our policies.

CHAIRMAN GROSS: Jackie.

DR. GARDNER: Can you enlighten us with the logistics of the process by which even a perfect monograph with all of the criteria gets to the consumer from you?

We heard today about the issue of the vendors being -- I beg your pardon -- the software companies being a black box that things go into. Can you tell us something about licensing from the standpoint focusing on the logistics?

If it leave you, it goes through the license. How frequently are they updated with the software vendors? What kinds of options do they have to make changes, things like that? So that we get some idea of what the process is and the time frame?

DR. RATTO: Well, the first thing that I would have to say is that I don't have all of the details on that, but I'll give you what I know at least as a skeleton, and we are working with Dr. Svarstad and the FDA in terms of trying to elucidate that information as much as possible because, frankly, we don't have all of the information as to what our software middle men, if you will, are doing with the data.

What we do have at this point is a contractual statement that says that they will not

alter that monograph in terms of deleting information. That's happened with all new contracts and contracts up for renewal. And that's our attempt, and I think it's, you know, basically an effective attempt to make sure that the information is being given to the consumer in the proper format and with the proper content.

Now, admittedly, that doesn't control the font size, for example, and that should be a concern for, you know, everyone in general, and that's something that is another story. I'm surprised to hear that most monographs came out of one page because when they're in the ten point font, which is what we send out, they certainly don't hit one page. So that is an issue.

What I would say is that as was mentioned earlier by Dr. Svarstad or actually I think it was John Coster who said that the monographs are delivered to either software vendor or directly to large chain pharmacies, depending on if they have their own processing system.

From that point, basically, you know, to be frank our control is not there in the sense that the control we have, if you will, is in the contracting, and beyond that we don't dictate. We do dictated in

the contract that they do not delete information, but we don't sort of, if you will, squire the monograph all the way down to the patient level. So --

DR. GARDNER: But you said delivered. How often are they updated if there are updates?

DR. RATTO: Oh, okay.

DR. GARDNER: What's the process?

DR. RATTO: Okay. Sorry. That's another point you made.

Our process is set up such that we have the capability of updating people on a weekly basis. What I mean by that is that is available to all of our customers, a weekly update for clinical data.

There are customers that receive that information monthly, and frankly, we don't know how often. I imagine there are a few cases. I think that was brought up again earlier where customers may not update them I think it's very infrequent, but I imagine there's still a few people out there that are only updating quarterly.

That's something, again, that's out of our directly control, but we certainly offer weekly updates and encourage people to go with weekly or at most monthly updates.

CHAIRMAN GROSS: Bill.

DR. CAMPBELL: That was the question.

We heard some comments about variability of the information product that will get to the consumer as in updated information weekly, biweekly, monthly, and so forth, based upon price to the pharmacy, the community pharmacy.

And we also saw evidence that the same vendors were providing leaflets that might be less than 5.6 inches, greater than 5.6, and so on and so forth.

So the question: is there a disincentive at the pharmacy level for providing full information to consumers based upon the price of the leaflets?

DR. RATTO: Let's see now. My feeling would be no just based on the fact that we -- I'm here discussing essentially the original First DataBank product. There's only one of them at this point.

We discontinued the short monograph product. So that particular product is available in its entirety basically at one rate, and to my knowledge, I don't know the -- I shouldn't say that I know. I don't know whether there's a difference in weekly versus monthly updates. There probably is in terms of pricing, but I don't know that for a fact.

Certainly the new XML format that I

mentioned, that's available at no extra charge. So I guess the bottom line is that the monograph that I'm referring to is basically a one price monograph, but again, I don't know what the pricing structure is for monthly versus weekly updates, if there's a difference there or not. That's in the sales and marketing area.

CHAIRMAN GROSS: Okay. Michael.

DR. COHEN: Yeah, I want to go back to something I asked about earlier or talked about earlier, and that is how rapidly you are capable of updating your own information system. Subsequently it would be made available to the others as we've just been discussing, but we've had a number of reports over the last few years of inordinate amounts of time to get important information into the system.

I mentioned cisapride. There have been other issues as well. When something is published in the literature, when there's evidence that there's a serious problem, it sometimes takes quite a bit of time to go through the process at FDA to get it in the actual labeling.

Are you able to respond to published articles where you believe that there is a serious problem or do you have to wait for a change in the labeling?

I've been told that that's the case. I've also been told from people in the database vendor companies that a report of a death, even though it's tied to a specific drug side effect or a drug adverse reaction is not enough to trigger an alert; that there would have to be multiple reports before something like that could actually appear in a drug information system.

So I'd like to get that cleared up because I think that's an important issue.

DR. RATTO: Well, for our system specifically, we do rely on FDA MedWatch and on labeling for updates primarily.

Now, if something comes up in the literature, one thing that we did want to explore with the agency is if we notice in the course of just reviewing, doing continuing education, whatever, looking at a journal article, we notice something that has not yet hit labeling, whether it's a warning on a particular adverse effect or a precaution or whatever, if there's a contact person, we can, you know, deal with at the FDA that can tell us whether this is under active review, make sure that it's already been put into the system for perhaps an accelerated look and deal with it that way, that's what we would like to

do.

But we do not have -- with the volume of literature that's out there, we do not have someone that is -- we do not have a policy of reviewing all of the medical literature, primary literature. You know, that's a situation where, yeah, it might be ideal if you had --

DR. COHEN: Well, actually some of these have been situations where I know that practitioners have contacted the company to request that this be added.

DR. RATTO: Okay. Well, clearly I'll say this. If someone has contacted us with specific information at First DataBank and said, "Such-and-such drug interaction appears to be an issue. We want it to be investigated," we will do that. We will put that through our process promptly, and we will coordinate with the drug interaction people because there is a specific group that handles drug interactions that's separate from patient education per se, but we'll, you know, communicate with them, and that information is processed when there is a specific inquiry such as that.

CHAIRMAN GROSS: I have a question out of my ignorance. Is there a person at the FDA that First

DataBank and other vendors could relate to when there is a change in licensing based on some complications so that they would have the information? Is there some kind of a communication that could be set up?

DR. TRONTELL: I think, as Nick Ratto has just described, there is the MedWatch program, which certainly publicizes and announces those formal actions that the agency has taken in terms of relabeling or "Dear Health Care Practitioner" letters that are sent out.

It's more complex in the area where there may be still yet some ongoing assessment of a particular safety signal. We can certainly do our best to establish such lines of communication, but when the agency hasn't yet completed its assessment, we may be in a difficult position to comment.

DR. RATTO: What I was specifically referring to is if there is some statement. For example, there was a consensus statement by the cardiology society, American Cardiology Society, recently related to doxazosin and hypertension use and having problems with patients developing congestive heart failure and other cardiovascular issues.

And we were in a bit of a quandary as to whether to include that per se just based on the

statement that was made, which was, you know, strong caution should be advised when using it for hypertension.

If we had someone at the agency that we could, you know, just basically contact to ascertain whether that particular statement or any other similar to that, or perhaps a literature inquiry from one of our customers is on the radar screen essentially, that is something we were planning to discuss.

CHAIRMAN GROSS: Okay. Stephanie.

DR. CRAWFORD: What consideration, if any, has your company given to making some arrangement through which this information could be put on the Internet, directly accessible by the ultimate patient consumer?

DR. RATTO: Our company, in particular, is represented on the Internet by, I believe, Medscape, and there may be other relatively smaller users as well, but that one in particular comes to mind.

CHAIRMAN GROSS: Okay. If there are no other questions, we'll let you sit down. You're obviously in a very critical position in our discussions.

Does anyone have any questions of any of the other speakers? Yes, Michael.

DR. COHEN: For Dr. Day, considering all of the information that we're trying to jam pack into these patient information leaflets, do you see a role for icons of some sort? Is there a way to use icons to benefit information provision or communication?

DR. DAY: The answer is yes and the answer is no. It depends on how you use them. Pictograms can help, and there is a library of USP pictograms that have been tested in various ways. Usually they've just been tested, given to people and say, "What does this mean?"

I don't think that's adequate. There are a bunch of other things that need to be done. So a variety of tasks, and some of the testing that we've done, we've looked at what happens when you look at the pictogram versus a pictogram in the context of the leaflet, and when the leaflet does or does not have text, that is the meaning of the pictograms, and it's nearby.

So if you fulfill all of those things, if you have a pictogram and the text nearby, that's the maximum situation or the best situation.

And pictograms are potentially helpful for people who don't read well or perhaps have not very good English and so on and so forth, but then there

are cross-cultural differences in the interpretation of pictograms.

So there is research going on elsewhere in the world where you take the USP pictogram library, and then you vary it as a function of the way your local icons would have them. For example, the way we package milk, if you're supposed to take or not take something with milk, our milk cartons look different from the way they do elsewhere in the world. So people wouldn't recognize them, and so on.

So, yes, there's a role to play, but every time you make a suggestion to add something like a pictogram, have you lost something else? So what didn't you put a pictogram on?

And so if you're not supposed to take it if you're pregnant and you use that with a really understandable pictogram, then does that mean you're going to decrease knowing something else?

So the answer is, yes, if it's done well and tested carefully.

DR. GARDNER: Ruth's comment reminded me that I wanted to ask Nick and the other vendors if any of this material is available in other languages at all.

Does anyone subscribe to the Spanish

language version of your service?

DR. RATTO: We have our product available in Spanish, and we estimate within the next four months we'll have a French version. We're in the later stages of negotiating for a full translation with that, and we've hired a translator.

So that's primarily now for our Canadian customers, but it could be for any other French speaking.

CHAIRMAN GROSS: Okay, and believe it or not, we're done a little bit early. So what we will do at this point is take a break for 15 minutes, and we will reconvene and the committee will consider the three questions that are attached to your agenda.

So 15 minutes, and we'll reconvene, and that will be at 3:00 p.m. we'll reconvene.

Thank you.

(Whereupon, the foregoing matter went off the record at 2:47 p.m. and went back on the record at 3:07 p.m.)

CHAIRMAN GROSS: Okay. I think we're going to get started. We were a little bit ahead of schedule. We don't want to fritter that time away. So if everyone could take their seats, we will get started.

The main purpose of the remaining session is to consider the three questions that are attached to the agenda. The first question is: what additional analyses of the FDA, NABP, Svarstad study do committee members suggest should be done to answer any remaining issues about the adequacy of patient information?

So I'll entertain any comments from the members at the table. Sharlea.

MS. LEATHERWOOD: I just might ask. There were several comments, and I certainly wasn't aware of this, but there were comments that there were certain criteria that maybe were not appropriate. There was no basis for putting those particular subcriteria in the evaluation form.

And so I wondered if we should make sure that all of those criteria were based on something, and if not, then drop criteria and reevaluate the data.

CHAIRMAN GROSS: Well, there are a lot of criteria there, but, Bonnie, do you want to take a stab at anyone's?

DR. SVARSTAD: I think it's certainly possible. I mean, there are always judgment calls on this in the sense that the expert panel was working with the Keystone criteria, on the one side, and the

approved labeling, on the other side, and how to interpret those is a judgment call.

And we certainly have the ability to drop items and reanalyze without certain items. So if the committee wanted that, and I think I, in fact, offered to do that to the FDA staff. That's one issue.

The second issue is that there may be items that are high or low priority, and it's possible to reanalyze the scores, eliminating low priority items.

But our mandate was to try to interpret at least the action plan as well as we could.

CHAIRMAN GROSS: Yeah. I mean, there are two purposes here. One is this was a research study that soon will be published, but the other issue is what action flows from these results.

Brian.

DR. STROM: Yeah, just in follow-up, a number of the public speaker were making comments about some specifics about the study. I would urge you not to bother to go back and readdress those specifics. I think, as you said, there are always judgment calls. There are always gray areas. One could argue about one point one way or the other.

None of that is going to change the substance of what the finding is or the findings were,

which I think is very important, and I think what we need to worry about is the substance.

This was a study. This wasn't regulation. This wasn't saying you have to have that particular statement or you have failed regulation. Part of the problem with regulation is it ends up being too rigid.

And so I wouldn't want our focus -- I wouldn't want to generate a lot of undeserved work for Bonnie, and I wouldn't want our focus to be distracted from the larger findings of the study by worrying about what amounts to small technicalities that, if changed one way or the other, wouldn't change the bottom line answers.

CHAIRMAN GROSS: I suspect general reviewers will take care of a lot of that.

Yes, Ruth.

DR. DAY: Given the analyses that have been presented, there's quite a bit here. There's a lot more that could be done, and that was my understanding of what this question is about. What additional analysis --

CHAIRMAN GROSS: Correct.

DR. DAY: -- of the current data set?

And I made a list of a whole bunch of them, and then in talking with Bonnie I found, oh, she's

already doing those, and so on.

One, in particular, I think the factor analysis of all those different criteria would be very interesting so that we can see what of all the various subcriteria cluster together and whether they do fit, and what underlying factors emerge, and if those are the same ones that are intended by the categories of the criteria, and that would do a little more to tell us about validity.

I think you've shown us a lot about reliability of the instrument, and we need to look a little bit more about validity in the sense of is it measuring what we say it's measuring. So that would be one thing.

Another thing, in the consumer data in the briefing book there was a partitioning of the first set of items and the last set of items, which made some sense. I would like to invite the researchers to reconsider that and repartition them in additional ways.

For example, putting together all of the ones that are about metacognition. So the remembering part was up in one category that you looked at and the others down somewhere else. So just relook and see if a different partitioning of those might be useful.

And then finally, just to mention one more, you mentioned that you didn't do the inter-rater reliabilities for the consumers because they varied so much, whereas you did that for the experts. I agree they vary a lot, but I think we need to document that.

Because any time there's information out, a given consumer says, "I don't like it that way. I want it this way," and somebody else says, "I don't like it that way. We need to do it that way>"

So what is that spread of reliabilities in the consumers versus the experts? And then if you could do some reliability within categories of consumers that are important, such as by age or by gender or by whatever seems useful.

I think there was a little bit more data mining there that we could get that would be useful.

CHAIRMAN GROSS: Okay. Arthur.

MR. LEVIN: I just had a cookie. I should be able to turn the light on.

I want to go back sort of a little more to the foundation question, which is the adequacy of patient information and what answer we have to that question.

I would say that the answer we have is it's not, and I would argue that the information we have

from this study if we look at Public Law 104-180 would actually trigger the last part of that, Part E, which says not later than January 1, 2001 -- we're a little behind times -- "the Secretary of the Department of Health and Human Services shall review the status of private sector initiatives designed to achieve the goals of the plan described in Subsection A. If such goals are not achieved, the limitation in Subsection D shall not apply, and the Secretary shall seek public comment on other initiatives that may be carried out to meet such goals."

Now, I think there are lots of other initiatives that can be carried out to meet those goals, but I think we need to have a proactive process because we've been going now for more than two decades, and for those of us who have been on this issue for all of that time and maybe more, we're always coming to the same place, which is we have these huge gaps of time that go by.

And then when we go back and take a look, we find that the private sector initiative has not done the job.

I mean, I think it is really appalling if they can't get font size right. That's not rocket science, when everything, the med. guide, proposed

reg. of '95, the Keystone plan, talks about, you know, how to make things readable in terms of appearance and somehow that doesn't translate to action in 2002. I think that's appalling, and it's a real failure on the part of this private sector effort.

In page 20 of the Keystone report, useful is described in the following way. "Prescription medicine information shall be useful to consumers."

"Useful" is defined as enabling the patient to use the medicine properly and appropriately, receive the maximum benefit and avoid harm. And I think what we've seen from this study is that we fail -- I mean, the effort has failed to meet the goal as set of 75 percent useful information by 2001.

By this definition of useful, by the results of the study, we're not there. It seems to me the law is clear and calls on the Secretary to take certain actions, and I think that's what our conclusions should be.

CHAIRMAN GROSS: Well, following along with Arthur's comment, I guess I would ask the committee to consider the question: should we ask the data vendors to present a joint proposal as to how they're going to comply with the Keystone criteria and then monitor that in a year or two to see if that's happening?

A number of people have brought up the issue that the system hasn't worked quite as well as it should. Should we, rather than sort of a helter-skelter approach, should we ask for a joint proposal from the people responsible for providing this information?

Bill.

DR. CAMPBELL: Let me go back to responding to the additional mining of data and also respond to that question.

Three and not momentous items, but I think the issue of experts rating readability and consumers rating readability is still a little unsettled, I guess, in my mind because the experts are, in fact, the consumers when you come to this point. I would rather know what the consumers' rating of readability is and call that the expert than the expert's professional reading of what consumer readability is.

I just think that ought to be revisited with a little different take on it, I think.

I didn't see a slide or table, I didn't think, that showed the distribution of leaflets by size. I saw them by size by product, by size by vendor, and so forth, but globally. Maybe that was there and I didn't see it, but that was some

information I'd like to see.

And lastly, I just continue to be troubled by a bit of these structural issues that impede the movement of optimum maximum information to the pharmacy level, such as a vendor updating daily or weekly, but it not getting to the pharmacy except quarterly, and issues of that sort.

And as Sharlea mentioned, cost differentials. I would like to know if there are differentials; if there's a relationship of any kind based upon the rapidity, accessibility, and frequency of updating and that sort of thing with the other measures, global measures, of compliance.

And to your question, Peter, my suggestion is we need a Keystone II. I think we really need to convene a Keystone II, not just the vendors, but it's clear to me there is a difference of opinion in many circles on the interpretation of the original Keystone. So I think we need to really revisit that report and clarify and interpret what was intended.

And then I think that group should be charged to release a Keystone II report that would take these criteria and subcriteria and validate that they are, in fact, the appropriate criteria for use in measuring.

And those criteria can then be turned over to the group you suggested, the vendors, who will then have a template for implementation, and there will not be this sort of arguing and disagreement that, well, Keystone said this, but they didn't mean it, or they didn't mean it and they said it, and so forth.

A very important issue has to do with the labeling. Is the labeling the gold standard from which it should not depart or is it intended that the Keystone include it off label in other sources of information?

So I do believe Keystone II is appropriate.

CHAIRMAN GROSS: A question about Keystone II. If we do Keystone II, you mentioned the word "validate" the criteria, and validate could take several years. Could we have some discussion on that? Is that something that you want to do or can we take the Svarstad study and update Keystone and go from there and then have that checked and validated later on?

I mean time is a question that has to be considered.

DR. CAMPBELL: I didn't mean validate with outcomes data.

CHAIRMAN GROSS: Okay.

DR. CAMPBELL: I don't think we have time to do that. I think we have to face validate from the consensus, and then I think part of the Keystone Group recommendations, I would hope, would be a 2004 evaluation that would precede 2006.

CHAIRMAN GROSS: True.

DR. CAMPBELL: So we would have a fast turnaround to see where we are with that.

CHAIRMAN GROSS: Jackie, do you want to comment on that?

DR. GARDNER: Like a broken record, I guess. I'm back to the issue of our charge is related to risk management and safety, and in particular, I've been interested both from the background materials that we were given today about what was the resistance to the first or to the patient package inserts from the professionals, and then as each group came through today we heard about how you really can't bombard consumers with too much safety information because, you know, they just can't absorb it or they don't want to and so on.

I would like to have if we're going to do a Keystone II or something in the interval to have a good deal more consumer input into this question. We clearly from Bonnie's study -- even with what we do

have, are not meeting those criteria related to safety communication, risk communication in these inserts, I mean, these leaflets.

And the question is: how are we going to do that? How are we going to meet that need?

And I think we have to find out from consumers, not from professionals and vendors, how much is too much and how do they want to see it? What way is an acceptable way to learn about these risks?

And I'd like to see more work done on that with the people who have to bear the brunt.

CHAIRMAN GROSS: Bonnie, do you have any sense of how much is too much from what you've done?

DR. SVARSTAD: Well, I think all of this is very complex, you know. Those of us that have been in patient information, Ruth and others that have been studying this, I think it's very hard to take an issue with as many complexities and end up saying because we can't agree, let's make the consumers make that decision on how much is too much.

That's not to say that we couldn't learn a lot by studies of information overload, but when I look at the bulk of these leaflets, I don't think there's a problem with information overload, quite frankly.

And I'm sorry, Bill, that I didn't have the data on the distribution of leaflet length. I have that. I just don't -- it's up in the room, you know. But the bulk of these are less than one page, certainly less than one page. And I think I did give some statistics that many of them were less than five inches.

I guess I'm also a little unsure about what a Keystone II would accomplish unless you really, really focus in on establishing priorities of the criteria, and I would agree that there might be criteria in here or subcriteria that you could in a consensus building with professionals and consumers, just as you did the first time around, saying, "Okay. Now we've gone through this," and we could give these items or these criteria or these subitems more priority than others in the interest of still staying within a reasonable length for consumer information.

But these are very difficult issues, and I think it's really hard to put it back in the consumer's lap because I think they will end up saying, "Do we want to know drug names? Yes," or if they said no, what would we then say?

I'd say you should know them because the studies show that you should know them, and you'll

make fewer errors.

Contraindications, do they want to know about that? Well, I think we heard one consumer talk about that her mother would have benefitted, and I think we can all think of people who would benefit.

So even though there might be a few consumers who say, "I am scared by this information," the other consumers will say, "Well, we want to know it."

There may not be a consensus. We act as if there's a consensus among consumers. There isn't. They're like professionals. They have difference of opinions. They have different perceived needs.

So this is a very complex thing to come to. Specific directions? We know that specific directions reduces errors. Would I want you to go back and backtrack and revisit that issue if a consumer said, "No, I don't want specific directions"?

I'd say, "Oh, gee, that's taking about ten steps backwards."

Side effects? I mean, every consumer survey you read out there by sociologist, health service researcher, psychologist will say consumers want to know about side effects. We don't need anymore studies to know that.

So, you know, I'm not sure what you would get by additional surveys unless you were to really talk about things like formatting. I think Ruth's point here about formatting is a good one.

CHAIRMAN GROSS: Ruth, any comments on what we've been talking about?

DR. DAY: Does amount of information matter? It depends on how you show it, and so asking people do you want more or less of that, until you show it to them in different ways, I don't know what the answers mean.

CHAIRMAN GROSS: Okay. Jackie.

DR. GARDNER: I guess thanks for clarifying what I was trying to say, both of you, which is I don't know. I wasn't even suggesting surveys. I mean it's clear from your data, Bonnie that whatever it is, we're not doing it right if it's amount, if it's format, if it's whatever it is. I think that's the area that we need to focus on because those are the areas that are important for us in managing risk.

So I don't know that we need more surveys then. If it sounded like that, I hadn't thought it through, but I do think that that's the area where we need more information, however we get it, and we're failing to do that.

CHAIRMAN GROSS: Yes, Ruth.

DR. DAY: Just to follow up to what Jackie is saying, I agree we need more information from consumers, but I think it's about true comprehension and, you know, problem solving and then some perhaps actual use studies. I guess we'll get into that when we talk about recommendations, but there were DOA (phonetic) to do some post market surveillance and so on with this format versus that form, et cetera.

So yes, consumers; no, not more surveys.

CHAIRMAN GROSS: Okay. Arthur.

MR. LEVIN: I would certainly argue against a Keystone II. First of all, it took a statute, an act of Congress to get Keystone I, and I don't think we're going to get Congress to stipulate a Keystone II, and there's a whole history there which I won't bore you with, why we had a Keystone in the first place and where the statute comes from.

It just seems to me that it really depends on how you view the importance of written information for consumers. I think there are those of us who see this as the ultimate safety net; that for lots of reasons unfortunately well documented in the literature, the amount of counseling by prescribers is minimal. The amount of counseling by dispensers is

minimal, and so what we're left with is a written piece of paper maybe. The only thing standing between the patient and harm, the patient optimizing the benefit of the drug or whatever.

So I mean, to continue to have this argument is just beyond me. I don't understand it. No one is suggesting, as people kept suggesting we were suggesting, that the written information is supposed to supplant physician or prescriber counseling or dispenser counseling. I think if prescribers and dispensers were doing the right thing, we might not need a written piece of paper.

But unfortunately, we know for a variety of reasons it just doesn't happen or it doesn't happen with enough certainty and frequency and adequacy to protect patients.

So I look at that piece of paper saying if you were being given a drug, what is it that you would like to know if you knew nothing else. What are the few, one, two, three bits of information that would be most important to you as a patient?

And to me answering that question says to me those are how to prevent harm and how to use the drug to optimize benefit. And if I came away with nothing else, that's what I'd want to know.

Why is this so complicated? I mean, we know how to do this, and I think the problem is we haven't had the will to make industry do what we want them to do, and every time we get close, we have opposition that pushes it further back and we're told, "Leave it to the private sector.

I think after 20-some odd years we have to say, "Why do we want to leave it to the private sector anymore? They haven't gotten it right. We have to change the way we do things."

So to me, the only responsible action in terms of the study, the survey, and the public health law and the public law is to make that Section E come to life, and that is to say the Secretary -- the January 1, 2001, which is now 2002, survey shows that we have not met the goal.

And if we haven't met the goal, the Secretary has to begin to take initiatives to meet that goal.

CHAIRMAN GROSS: Okay. I'm going to take the Chair's prerogative and ask us to move on to Question No. 2. Much of our discussion is going to be an overlap of a number of these areas, and I'd like to go through each of the questions, hear discussion, and then let's come up with some recommendations at the

end of that.

I think that will be easier than dissecting it out artificially.

Okay. Question No. 2 says: what additional research does the committee recommend to document the areas and means for improving written patient medication information handed out by pharmacists?

The committee may wish to consider the following: the action plan or Keystone criteria and its subcriteria of usefulness and ability to assure maximum impact on appropriate patient use of prescription drugs.

For example, can individual criteria be analyzed to assess their impact on patient knowledge or behavior?

Methods to determine if Keystone criteria and subcriteria should be prioritized or others added or deleted.

And finally, the influence of overall length of written materials on consumer reading and comprehension of materials.

Some of this has been discussed already. Would anyone like to comment on that question? Yes.

DR. CRAWFORD: Not the subquestions. I would like to make a comment on the overall Question

2 about additional research to consider just so we don't miss some of the things we've said before.

I have questions about what are the barriers that are preventing some of the independent retail pharmacies from being at the same level and giving out some information at least as to change.

It's been highlighted quite a bit here earlier this morning that we're missing a big part of the information. Depending upon what source you look at, it's estimated that mail order pharmacies, although they're small in number, they are filling about 13 to 15 percent of the out-patient prescriptions. Id o think we need information from that segment both on the distribution and usefulness of the information they provide, as well as what the patient consumers feel about the information they receive, its readability, et cetera.

And also so that we don't lose the point, from the consumer perspectives which are critical to make sure we get a wide spectrum of consumers, patient consumers, in that process.

CHAIRMAN GROSS: Okay, Stephanie. Thank you.

Any other comments? Questions? Yes, Ruth and then Michael.

DR. DAY: In terms of improving the pharmacy leaflets, what content areas do we need to look at? I would say risks. All of the different risks really need improvement

There are a lot of things that were found wanting. They're so easy to fix, for example, making sure that the date off the leaflet is on there. I mean procedurally out in the real world, it gets a little difficult, but that's an easy thing to know how to address.

But what's more difficult is what are the most effective ways to communicate the different types of risk in written format, and it may be that that's just more difficult information, maybe not, but by exploring different formats for doing that, I think we'll make leaps and strides.

CHAIRMAN GROSS: Michael.

DR. COHEN: Yeah. I guess throughout the consumer movement we've heard comments about consumers being in a position to prevent a lot of the adverse drug reactions, and that's what this whole thing is about obviously, adverse drug events, but one area which is dear to me is medication errors.

And I think, you know, from our experience with the error reporting program, also with FDA's

MedWatch program we have a lot of information in the database about recurring serious medication errors that I think we could communicate information to patients about and put them in a better position to prevent some of these.

A good example would be we've had a serious problem with giving drugs that are intended to be given weekly on a daily basis. Methotrexate is one. There have been several fatalities as a result of that.

To me any prescription for methotrexate for immunomodulation should be accompanied by information that would warn patients, you know, that this is to be given weekly and not on a daily basis. So that is just one example.

There are certainly others, and I'd love to see something built into your research to test. We have the information. It's just a matter of putting it together, and in fact, we've already been talking with the Office of Drug Safety about a project where we would actually go back into the database and try to pull out the most important medication errors that patients should know about or physicians should know about, pharmacists, et cetera, and develop that into a database that could be used.

So I'd like to see that.

CHAIRMAN GROSS: Yes, Bill.

DR. CAMPBELL: A lot of people have provided comments that I think were extremely valuable, and my problem is I've agreed with all of them, and you can either look at this situation as approaching 90 percent in terms of quantity and the ability from some of Dr. Svarstad's data providing a very doable leaflet that will achieve 100 percent in terms of qualitative measures.

So you can read that as saying we're, if not there, a step away or you can read it that it is highly -- it is very little increase in terms of quantitative and no increase in qualitative.

And I think the lynch (phonetic) here is what's the meaning of the criteria and subcriteria. That's really what we're missing. That's the way you close that confusion.

And it seems to me we have to -- I apologize for the term "Keystone II." I didn't mean it literally.

We have to go back, look at those criteria, and determine what they mean and validate them in terms of communicating them to others.

I used the HIPAA example earlier. No vendor

would come in today without saying, "We are HIPAA compliant in what we're providing you."

And yet we have people saying that the vendors are not even using the term "Keystone" and clearly don't recognize it. So our problem are these criteria and subcriteria that have to be revisited and either revised or accepted.

CHAIRMAN GROSS: Jackie.

DR. GARDNER: I'd like to echo and be more specific about one part of Stephanie's suggestion that in looking at the barriers with having community pharmacy access and provision of adequate material, specifically the software vendors, what work can we do there?

It doesn't matter if First DataBank creates the perfect documentation, if it gets somehow diluted out before it gets to the pharmacy level.

CHAIRMAN GROSS: Yes, Sharlea.

MS. LEATHERWOOD: I might try to respond to that a little bit. That's where I think we have a big problem because I, again, focused on the 89 percent who actually had changed their behavior from 55 percent giving it out in I believe it was 1996 to 89 percent giving something out in 2001. So there was a behavior change, and that is such a difficult thing to

achieve.

So that has been accomplished. I believe that the information that I've been giving out at my pharmacy was the correct information. It wasn't, but I believed that it was.

So I think pharmacists are in a very difficult position because we're given this monograph from our software vendor, and we give it to our consumers. We counsel them -- I do anyway, Arthur -- and we trust that that is the information we should be given.

So just to answer your question, I'm trying to think of ways to get the software vendors involved in this so that they can then carry it on to the pharmacists and, therefore, to the consumers.

One thing would be to have a discussion with them that we were going to perhaps develop a list of which pharmacy vendors have the appropriate monographs available and which do not. I think that just even the discussion of trying to put that together would incentivize them to all pretty much be compliant because it's a very competitive industry.

So, I mean, that's just one idea, but I do think we have to work with them, those of us in organization work. We've got to work with ASAP. That

is their organization, and they have to help us get there also. So somehow we have to work with them.

CHAIRMAN GROSS: Ruth.

DR. DAY: In terms of additional research needs, I strongly recommend that we be more adventuresome about considering formats for pharmacy leaflets, even one-page leaflets.

Do consider the overall look, and also whether we can use different formats for different chunks of information.

And when you do that, you then increase the visual distinctiveness of each chunk of information, which will get more attention being paid to the different parts. "Oh, what's this? Oh, what's that? Oh, that looks interesting," and so forth, and hopefully effect comprehension and behavior.

So I think a strategy for doing this is to look at the leaflets we have now and look at those content areas, generate a variety of alternative formats. Test them in the laboratory, and test them for a variety of cognitive tasks for overall ability to find and use, attention paid, amount of reading and studying, but also memory, comprehension, problem solving, and decision making.

And based on those laboratory studies, then

go out to some kind of actual use or field test, perhaps a collaboration of various stakeholders, putting some, you know, Alternative 1 versus Alternative 2 out there in the real world, given that they've met certain regulatory, legal, et cetera, criteria and try and see what happens after we get some fine tuning from the laboratory studies and we now have one or more different options for a variety of information. Test it in the real world.

And there can be all kinds of testing, whether it's follow-up surveys or even surveillance data, looking in one market versus another market, where there's a leaflet of Format Type A versus Type B, and so forth.

So I think there's a lot that we can do, but we need to be adventuresome in thinking about this issue.

CHAIRMAN GROSS: Brian.

DR. STROM: I like Ruth's suggestions a lot. I think it's very important we not see the research as an excuse to delay action, and we'll come to the Question 3 as yet, but I think it's also important that we recognize that none of this is set in stone; that there's a lot of information to be gathered; that this should evolve and improve as time goes on;

that we should operationalize, do a better job of operationalizing now whatever we know now, but should continue to learn information, and the kind of things that Ruth is suggesting would help that.

I would argue, for example, that I think for different drugs, different things probably should be included in the label, but you risk including too much and diluting out the real message if you have a very precise list that has to be the same for every drug. Depending on the risks from a different drug, you might have different information provided.

But that needs to be tested. I mean, I think we have a lot of unknown, untested information, and I think there's lots of opportunity here for experimentation, both in a more controlled setting and in a real world setting.

You know, if you take an example like a warfarin-Bactrim interaction, for example, where there's no question it's well recognized, the drug is out there. You know it should be used, or the cisapride example that Michael was talking about before where you know the interactions. You know it's being used contrary to interactions. It's very well documented it was being used contrary to interactions.

Try different labels in different areas and

use monitoring programs to look to see if people are using the drug despite that as experiments in order to evaluate it, again, not though to stop action now, but rather so that whatever is implemented now becomes a reasonable next step, and that things can continue to improve after it.

CHAIRMAN GROSS: Michael.

DR. COHEN: Yeah, someone should point out that not all of the information comes from these drug information vendors for pharmacies. A significant amount of information gets to patients through emergency rooms where they use different drug information vendors, entirely different, and I've seen some of this information, and it's not all that it should be, believe me.

Also, we have other specialty areas, like oncology, that frequently use the manufacturer provided patient information, as well as their own patient information, and there are other areas as well.

I'm not sure how to capture these, but I think that is something that we need to take into account because there are a significant number of patients that will receive that information as an alternative.

CHAIRMAN GROSS: Jackie.

DR. GARDNER: And to get it in this section of the meeting where it was mentioned before, we need to do a good deal more work with different racial, cultural, language understanding and processing than has been done to date as well.

CHAIRMAN GROSS: Okay. There is something in the performance improvement world called PDCA cycles: plan, do, check, act, and the cycle gets repeated.

And as has already been mentioned, this will be an evolving process. Because we're not going to come to the ultimate solution is no reason not to try to seek an intermediate solution and then improve on that.

So I think we're done with Questions 1 and 2. Question 3: suggested actions to achieve the 2006 goals. This does not mean that we wait until 2006 to do it, but we work on it now.

What actions do committee members suggest to improve consumer medication information to meet the 2006 goal of 95 percent of new prescriptions dispensed being accompanied by useful written information?

Please provide opinion on relative importance, low, medium or high, and time frame for

implementation, immediate, near term, or long term. Sample topics can include legibility and comprehensibility of interventions, a means to insure that technical content on warnings, precautions and adverse events are complete; means to insure that data distributors understand what is Keystone compliant; processes for implementing improvements, such as workshops or FDA guidances; and who are the critical stakeholders.

So I think this is the crux of what our day has been devoted to. We need to come up with some recommendations and consider these issues.

Brian?

DR. STROM: I'd like to propose an accreditation process. I hate to use Joint Commission as a model because I'm not crazy about the way Joint Commission works, but in this situation it may be a model that works better.

From what I heard today, my sense is it's clearly not working, and there has to be a concrete change, and whether or not it's time to go fully to regulation or not, the question is: is there any other thing short of regulation that might lead to a concrete change?

I didn't hear any from any of the testimony

we heard today, specific proposals that convinced me it would change. And so let me make a specific proposal. What if there were an independent body? Nonprofit independent is fine. That's why I used the Joint Commission model, and that in order to be accredited as a vendor to provide this kind of information, get the UL seal of approval, so to speak, you need a transparency in the process of how the labels are created.

You need a clear quality assurance process where there's a clear, ongoing, peer review, feedback, feedback to manufacturers as was suggested, so that there's an ongoing reactive process in order to continually improve it.

And then you have an expert committee, like the Joint Commission site visit, which spot checks in a random sample basis for any of the vendors the types of CMIs that are being handed out and rates them on a value rating, perhaps using something similar to what Bonnie described as the rating.

I don't think it could be done uniformly. What she did was an enormous amount of work and took obviously a huge amount of work just simply for drugs and even just creating the criteria, but in a sense what I'm saying is let's use her work not only for the

information it provides, but let's learn from the process she created and try to institutionalize that process.

And then there would be a numerical rating basically. I'm glad to hear there are at least two vendors in the market, which means they can compete, and they can compete based on their rating, and that rating information would be public and would be made available to pharmacies to be able to use, in turn, in competition that we are using a firm that has the best rating possible in terms of patient information available.

And whether that accrediting body is created by some existing external organization, the FDA or -- except then it would be regulatory -- or the CERTs or some other organization or a Keystone group of organizations or a primary pharmacy organization, whatever the group, it should be an aggregate of private organizations with major consumer input included as part of it as well.

But it would create an accrediting body to basically say this is or is not a viable, credible set of information for patients, and in a sense, it's one more chance between now and 2006, though I wouldn't wait until 2006 to evaluate it, to say in a way that

isn't quite as extreme as regulation, but is much more coercive than just leave it up to the market to do what it wants, that they will evaluate things concretely.

CHAIRMAN GROSS: Bill, did you have a comment?

DR. CAMPBELL: Well, just to weigh in and support that. Brian has provided much more articulate commentary on what I was thinking about earlier.

USP at one time made a similar sort of proposal as a non-federal and nonprofit organization that set standards. Rather than terming it accreditation via standard setting organization, you used the term UL, and that has been an idea that has floated around at various levels.

At one time National Association of Boards of Pharmacy and some Boards of Pharmacy were looking at the possibility of part of the regulation of the practice of pharmacy in the state. This was a critical issue of the information that was coming to the pharmacies and protecting the public health to set some standards on that.

So I think it's imminently doable. I think it is logically defensible, and it has the advantage of being something that could be turned around in a

short period of time, and there are organizations nationally and statewide that are very interested in moving in and doing it.

So I applaud and support the proposal.

CHAIRMAN GROSS: I agree also with Brian. I'd like to add some comments.

I think before any whatever the accrediting body, whether it's that or whether the FDA issues a guidance and then monitors whether the guidance is being followed, I think before that, we would need to have a workshop of the data vendors, the software vendors, the pharmacists wherever they may be in the community, the hospital, the emergency room, with chains, VA, wherever they may be; get together with our group, with experts on formatting and other important areas to assure effectiveness of the information.

And we can talk about other stakeholders so that it can be said that everybody who needs to know about the Keystone criteria know about it, were there, and then the FDA could issue a guidance, could set up an accrediting body however it is to make sure that these are followed.

And then if they are not followed, then some action could be taken against that particular vendor

or whoever the stakeholder is that isn't compliant.

Yes, Arthur.

MR. LEVIN: Let me talk first to your comments and then to Brian's.

I don't know how many ways I can say this, but believe me, everybody who needed to know what the Keystone process was about was at the table. It was a very inclusive process which, frankly, for some of us made it an extremely difficult and painful process, but everybody was there, and if they weren't actually at the table, they were at every meeting in the chairs around the table.

That produced a consensus document that we, I think, conclude didn't do it. So I'm not sure what continually bringing people together is going to accomplish in getting the task done unless we do have some way to make it count if you do what you're supposed to do and to make it count if you don't do what you're supposed to do.

And that's what the Keystone process sort of lacked, except it did set up two judgment days, 2001 and 2006, and I think, you know, we're letting 2001 judgment day go by without making a judgment, and I think that's unfortunate.

So we have to figure out where the authority

comes from to make a judgment any earlier than 2006 because that's what the statute sets up.

With regard to accreditation, you know, I have the same opinion of JCAHO as you do, and I don't think accreditation works. I don't know that the FDA has deeming authority anyway. I don't know whether I want to create the precedent for the FDA to behave like CMS and deem things all over the place, and when everybody goes around and follows up, whether it's the IG or CMS' own process, follows up the accreditors. They find lots of problems with the accreditation process.

So I understand the intent, but I'm not really comfortable with the notion that accreditation is the way to go.

We talked about a Good Housekeeping seal of approval in the Keystone process, and the vendor said no. And it certainly wasn't going to be USP because they were a vendor, and the other vendors weren't going to say that's the seal of approval we wanted.

There were lots of the stuff that you people are talking about that we talked about and were voted down on time and time and time again in the Keystone process. We talked about a sort of interactive, you know, real time evaluation process by an FDA-like

advisory committee. That was one of the options we presented.

We were voted down on that by all of the pharmacy groups, all of the vendors, and all of the manufacturers at the table.

So it's painful to me to hear that these are the solutions. We talked about this years ago, and these were not acceptable avenues to go down for any of the folks who are complaining about any possible move to regulation.

So it's unfortunate that you were all not at that table because we really went through a lot of these things that we're talking about today, and these things did not get anywhere because of the opposition of information purveyors, professional associations, pharmacy associations across the board to all of these suggestions.

CHAIRMAN GROSS: Remember in the spirit of democracy we're going to have to go around the table to the advisory committee members and get your individual opinions as to what you want to do.

Ruth.

DR. DAY: Here's something you didn't hear at the Keystone way back when. That is we need comprehension testing. I've already said that today,

but part of this question in our actions to meet the 2006 goals is for us to say what should we do in the immediate term, the near term and the long term, and here's what I would propose.

We need immediately looking at alternative formats for the overall leaflets and subparts within it, cognitive testing, modification, and a reiterative cycle there. That can be done very quickly.

Then the near term is to try a pilot study of actually having these formats that work out in the real world and have patients have them, and we can do follow-up testing with those patients, whether it's some kind of phone survey or actual comprehension testing.

And then the long term is to start watching changes in the surveillance data before and after such things are put into place.

So that is something that is, I think, a new suggestion relative to what went before and is now parceled out in terms of the time frame.

CHAIRMAN GROSS: Yeah, Ruth, I think what you're talking about is perfecting the form, but I think even before we get to that point we need to have all of the information from Keystone put on the forms by all of the vendors, and then we can perfect that.

I don't know that we should be doing both simultaneously.

DR. DAY: Peter, I understand what you're saying, and I accept that perspective, on the one hand.

On the other hand, this testing that I am suggesting doesn't have to have all of the real information that's going to be on all individual drugs and so on. I'm talking about formats for general types of information, like side effects.

So no matter what the drug is or how many more side effects we're going to have to have or not, and so on and so forth, what is an effective means to get people to look at it, understand it, remember it, and use it? And that can be done on a limited basis with each type of information and so on and see: do we get improvement from 40 percent comprehension to 80 percent, 90 percent? And then we can say this is a better format.

And meanwhile the other people are figuring out what the criteria are and let's massage this a little bit, and so on. But these generic forms of representation once the data are in should stand, and so I think that they're not one and then the other, but could be parallel efforts going on at the same

time and then come together.

CHAIRMAN GROSS: Sure.

Yes, Brian.

DR. STROM: Let me respond to Arthur's comments in a few ways. The straw we basically have heard is 1996 there was a process, a lot of suggestions and a lot of the suggestions were voted down as you're indicating.

We're now looking at the 2001 data and 2002, and it didn't work. We are making a judgment. It didn't work. And so what we're suggesting is let's go to some of those things that were voted down and saying it's now time to do it.

That's the response to that. I think I agree with you that I'm not crazy about the Joint Commission working, as I mentioned before, but I think there's a very key difference in what I'm suggesting versus the Joint Commission. The Joint Commission has a basically dichotomous decision rule. Either you're accredited or not, and not being accredited is so drastic that they almost never use it.

And so it still changes hospital behavior a lot, but it doesn't have the ability to drive incremental change as much as you would want.

I think the rating system that I was

describing, assuming there's at least two people in the market, is very key to driving and motivating that.

The last comment is you talked about reluctance to have FDA's convening authority. I think that makes sense. That is, I think your reluctance makes sense.

I think the answer if people buy my suggestion is either if private industry is saying we still want to do it, either they volunteer now to organize such a convening authority and accrediting organization in a way that FDA and this committee feels is comfortable and has teeth and is real, or it's time for FDA to regulate.

CHAIRMAN GROSS: Alternatively, there are ways that FDA in between regulation and no regulation at all; there are things that FDA can do in between that.

DR. STROM: Either way it's compelling as opposed to leaving it up to industry. I think the point now is industry hasn't succeeded for 20 years or hasn't succeeded at this point. It has to volunteer to take the next more coercive step that it was reluctant to take in 1996 that was voted down or else it has to be forced to

CHAIRMAN GROSS: Yes, Paul.

DR. SELIGMAN: Arthur, you started the discussion by correctly pointing out that the law does call for the Secretary to act, and I'd be interested in your thoughts as to what those actions should be based on your experience.

MR. LEVIN: I mean, I sort of favor a mandate, but aside from that, and I don't mean to -- you know, I'll come back to it.

I certainly think that the suggestion of some of us in the Steering Committee of the Keystone process -- it's in the report, by the way -- that there be a sort of locus of responsibility within FDA and an advisory committee or an advisory committee-like process because this advisory committee did not exist in 1996.

It's just a recent creation -- to be sort of in charge of sort of this sort of real time evaluation of what's going on out there and sort of fully engaged with all of the participants in the process, to sort of, you know, move the process along in the right direction on a day-to-day basis, if you will, rather than these big glumps of time where there's sort of like, "Okay. Do this and then we'll wait until five years and then we'll evaluate it and tell you whether

it's working or not," which has led us down this path of 20 some odd years of delay.

So I certainly think that there is this coincidence that here we were in Keystone suggesting something and maybe now this committee is the creature to sort of deliver on that promise.

I think if the Secretary and the Acting Commissioner recognized the failure to meet the goal and then proactively said, "This is what's going to happen. This committee is going to -- you know, an FDA advisory committee is now going to have responsibility for continual evaluation and movement of the plan forward. We're not going to wait until 2006, but this is going to be an ongoing activity, and that committee has the responsibility and the authority to bring together all of the players and to sort of figure out what a reasonable schedule of compliance will be and what the penalties will be for noncompliance along the road."

I mean, you know, as I said at the beginning, I'd like to see a mandate, but a mandate doesn't always make things happen, and I think there has to be other processes involved.

And I think having an FDA responsibility for evaluation and forward movement on the plan would be

an important step.

When I said I didn't want FDA to get in the deeming business, that was my concern. I think the responsibility belongs with FDA, and I think the responsibility -- and I still agree with what we were suggesting back in '96 -- that an advisory committee or advisory committee-like process should be responsible for evaluation and moving the process forward towards the desired goal.

And I would agree with Ruth that you can do a lot of things simultaneously. I mean, I think the first job, as I say, things were missing. Get them in there. And while we're doing that, we're going to figure out how to do things better, but we've got to get the threshold; we've got to get the floor.

And that doesn't mean the floor works perfectly. It may even work very imperfectly, but it's what was required by statute. It is what was required by the action plan.

There's also flexibility here. This is a process piece, and that process can go forward, it can change, and we can learn and do things better. Nobody is arguing with that.

But that would be my take on it.

CHAIRMAN GROSS: For the benefit of the

committee, can the FDA tell the committee what are the options that the FDA would have to deal with this? Exactly what is regulation and what is nonregulation and what are those options?

DR. TRONTELL: I'm going to try to answer that question because I think when we start talking about regulation, we have to look at, you know, where FDA, in fact, has authority to regulate a particular sector of the United States.

And in a sense, our regulatory authority is largely confined to dealing with drug manufacturers through our ability to regulate their products and to approve them and various materials associated with the approval of those.

So I think that where you get into what might be from a regulatory standpoint something potentially problematic, I think we have the power of persuasion certainly with the potential force of regulation behind us to try and exhort individuals to work cooperatively together, a guidance document without the back-up of a regulation, which would invoke the full possibilities of the public law, is something, you know, we would have to think.

Our hope is to have from the committee some suggestions as to process to pull this together.

I might take the liberty now, having tried to answer this question, to throw another question back to the committee because I see some ambiguity described here in how the criteria were interpreted in the strict subcriteria that have been described.

But I also see several principal players here, and this starts to get at the issue of regulation. Who might begin to address this? We've talked about the data vendors. We've talked about the software providers and the intermediaries and also the pharmacists who may operationally, if they have one printer that prints the label and a piece of paper, have to get something that fits into a ten inch by eight inch format and still do the job of what we're trying to accomplish.

And I'd appreciate hearing back from the committee any suggestions about how we can work with this array of players, with the moral force if not the regulatory force that the agency has to improve this information.

CHAIRMAN GROSS: Well, I guess the idea that we're stuck to one printing format in this day and age sounds inconceivable, but that's a separate issue.

Anybody else want to comment?

DR. STROM: Just to comment that in terms of

how to work with all of the various players, my suggestion about an accrediting body or however you word it would be a way of having all the players involved in naming that.

And obviously FDA would have to play a major role in that process.

CHAIRMAN GROSS: So it sounds as though -- tell me if I'm wrong -- but it sounds as though there's a consensus that the stake holders need to meet; that whether you want to call it a workshop, a conference, information so that we're reinforming everybody about the Keystone criteria, that's really only part of it, and we need to hear any problems they may have so that everybody is on the same page so that we can move forward from there.

And so all of the players, all of the stakeholders need to be involved, and they need to be defined.

So starting from that point of view, is that -- do people agree that we need to get a group together?

Steph.

DR. CRAWFORD: Yes, i strongly agree with that. That was one of the suggestions I was going to make with the action plan, but a little different from

how it was done before, from what we've heard today and what we've been reading, I have questions as to how well the information, the very important information from the Keystone criteria has been filtered down from the critical stakeholders, from the professions, the vendors, consumers, the agency, other users.

So a part of this workshop consensus conference if it were to come about, I think the critical stakeholders should also come with suggested or action plans of how they would sensitize, update the issues, the problems, the challenges to the practitioners and other players because I'm not sure if it went down from the high organized levels of the pharmacy, of the vendors, to the independent pharmacies, the community pharmacies, the mail service, and other institutionalized base out-patient pharmacies.

So I'm concerned it's being considered at the top without getting input or information to the people throughout at the lower levels organizationally.

DR. CRAWFORD: I'd like to just comment that while I would favor getting all of the stakeholders together, I'm not sure I would call it a consensus

conference. I would think of it more as a state of the art in science or lack thereof conference, and I would invite, not just have it as a public offering; but I would specifically invite the various stakeholders to come, and there would be presentations, say, of Dr. Svarstad's study and where we are and the history from Tom McGinnis, whatever, something like a little mini what we did today.

And then an a priori set of problems. Here are the problems. How do they happen? How do we solve them? And what are suggestions?

And then get input in all of that. That might be very useful.

CHAIRMAN GROSS: Okay. Yes, John.

DR. SULLIVAN: I would certainly endorse your suggestions, Peter. We certainly have to do better, and getting all of the stakeholders together would be a start, whether it's a workshop or whatever format you would prefer. I think that's clear that we have to do that.

And then you can either take the carrot or the stick approach and you can move from there.

There clearly has been progress, but it's in no way optimal. I guess I would also like to just comment because I didn't get a chance to jump in

before.

We can give an absolutely perfect -- something to the patients in written form that is absolutely perfect, but then we have no idea whether it just goes in the trash like 90 percent of the rest of the mail that we get every day. Certainly people that are intellectually curious will have already checked it out on the Internet, which lots of people do these days. There are multiple methods of getting information.

So we clearly have to do more research, but I think your suggestion, Peter, as a first step of getting the stakeholders together, and then if they can't come up with something to regulate themselves, then we can recommend to the agency that other steps be taken.

CHAIRMAN GROSS: Just to elaborate, the purpose of getting together would be to get everybody on the same page, and then that's why I wasn't clear exactly what form it would take as far as the FDA was concerned, was to have some type of oversight group, whether it's called a guidance or whether it's called a Joint Commission type accrediting agency. I'm not sure what that form should be. I'm not sure that we can solve that today.

And then whatever that group is, there would have to be some sense of what happens if one of the stakeholders doesn't comply. I mean, they're a carrot and stick. There has to be some sense that there would be some penalties if a stakeholder didn't comply. Otherwise we're going to be right back where we are.

Brian.

DR. STROM: I think you addressed a lot of my concern. I want to be clear that I certainly agree with the idea of having a meeting of all the stakeholders. I don't think it should be informational. I think the information is out there. I don't think that's the issue.

I think there needs to be a meeting of the stakeholders to decide what is the new structure that will be put in place that will have carrot and stick both as part of it, short of FDA having to impose something.

So it would be an action meeting. It would not be an informational meeting.

DR. DAY: But perhaps I was too gentle in the way I said that. It would start with educational. Here are the problems. How do we solve them? And, by the way, here's some options and, you know, some

pretty strong ones.

And then get the objections up front before it's mandated or, you know, put out there. Get feedback and then go forward with something at the end of the meeting.

CHAIRMAN GROSS: In fairness to the stakeholders, we do need to hear if they have any particular problems with what we're talking about as far as putting it into action. You know, we need to make a decision on that.

Bill and then Arthur.

DR. CAMPBELL: Thank you.

Well, I do believe we have come a long way in five years, and I believe the world is really substantially different in terms of recognizing drug risk in this country. This committee is one example.

The FDA organization, the funding and concentration on post marketing use of drugs and so forth, and so I'm, frankly, much more optimistic, I suppose, than Arthur on this particular topic.

One of the major things that has happened has been the formation and coming together of the practitioner organizations, AMA, APhA, SHP, and so forth, around the white paper on the professional's role in developing effective risk management in drugs.

I think FDA was a party to that paper as well.

So it seems to me we have already formed the nucleus of the constituency group, the stakeholder group that needs to come through that, and pardon the plug, but I also think the formation of the Centers for Education, Research, and Therapeutics, which is funded jointly under FDA and ARC to assure safe and effective use of drugs and to partner with public and private organizations to do that, and has a history now in developing workshops on drug safety, drug risk, drug communications and so forth, makes it a very natural next step.

CHAIRMAN GROSS: Arthur.

MR. LEVIN: Just, you know, Bill, I'm a big fan of CERT.

Here's my problem. I don't think people understand that what 104-180 did is tie the stick up. The stick that the Secretary had was tied by this piece of legislation.

Why? Because there was a proposed rule to mandate what was then called medication guides. Folks didn't want that, and so they got an act in Congress that for all practical purposes tied the hands of the Secretary, prohibiting the Secretary from enacting a mandate.

That's what this statute says, except that there would be two occasions on which a judgment could be made as to whether to untie the Secretary's hands or not. The one is the overdue judgment we're now letting pass, I think, from what I'm hearing in many ways, and the stick is still tied, my friends, until 2006 by statute.

That's what you have to understand. Where is the stick going to come from? Now, it may be a Good Housekeeping seal of approval and a competitive business with two vendors, and we'll probably end up with one vendor if that industry goes like every other, you know. There goes competition.

There is no stick if this opportunity goes by and we have to wait until 2006. The stick is not around until 2006. That's what this statute did.

Now, in my mind, when I responded to Paul -- and the FDA can correct me if I'm wrong on my understanding of what the statute does -- is that we have to give the stick back. That doesn't mean the Secretary has to use it. It simply unties the Secretary's hands as the Secretary's hands were untied before the enactment of this law.

This law was very specific in heading off the medical guide proposed rule of '95. This is

nothing that goes back to 1938, to 1962 in the history of FDA regulation. This is a very specifically enacted law by those folks who did not want a mandate for medication.

Get rid of it, I say. Untie the Secretary's hands. That doesn't mean the Secretary has to do anything that he doesn't want to do or she doesn't want to do, but it begins the process of saying: hands are untied, folks. You haven't done it yet. We're going to work with you to get it done, but there's no longer this prohibition.

Otherwise we have to wait until 2006 to put any teeth behind this.

CHAIRMAN GROSS: Arthur, I'm not sure the committee is saying anything different from what you're saying. It's probably semantics, but what we seem to be saying is that there will be a stakeholders meeting. Call it whatever we're going to call that meeting where everybody reviews what was presented here, what's known, what has to be done. That's number one.

Number two, an oversight group gets set up. The form of that I don't think we can commit ourselves to today, although we'll see what everyone else thinks.

And then that oversight group has to have whether you call it a stick, enforcement measures or some action that they're going to take. In order for the oversight group to be effective, there needs to be -- it needs to be understood that there's some action they can take if compliance isn't achieved.

So those three areas, I think, address what we've been hearing today.

DR. STROM: Peter, can I formally move that we take a specific vote, whatever the wording specifically is, but that will untie the stick?

The point is based on the data we heard today, it is not yet successful in the way we want it to be. I think the next step from a process point of view is exactly what you describe, but I think it is important that it be done in the context of the stick being available, both because it will make that next step more effective and it will allow for a step to follow if the next step isn't effective.

DR. DAY: Could I please hear some words on what --

CHAIRMAN GROSS: Wait. We have a motion. We have a motion on the floor. Is there a second?

PARTICIPANT: Second.

DR. DAY: I want clarification of the

motion, please. Would you put it in -- instead of a stick removal, okay?

(Laughter.)

DR. STROM: I agree with you. My wording was far from -- I guess maybe Arthur can help because I'm not sure exactly what the letter of the law is. We should word it in the context of that original law.

MR. LEVIN: A draftsperson and I may be able to do this.

"The Secretary Review." This is Part E of the title. "Not later than January 1, 2001" -- and understand that we're behind. That's what is going on now -- the Secretary of the Department of Health and Human Services shall review the status of private sector initiatives designed to achieve the goals of the plan described in Subsection A, and if such goals are not achieved -- that's 75 percent written useful information -- and if such goals are not achieved, the limitation in Subsection D shall not apply, and the Secretary shall seek public comment on other initiatives that may be carried out to meet such goals.

D is limitation on the authority of the Secretary. The Secretary of the Department of Health and Human Services shall have no authority to

implement the proposed rule described in Subsection A or to develop any similar regulation, policy statement or other guideline specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs.

DR. GARDNER: So, Brian, might you say that having reviewed the evidence presented before us, this committee judges, has determined that the --

DR. STROM: The 2000 goals have not been --

DR. GARDNER: Have not been met.

DR. STROM: Or 75 percent availability of useful information --

DR. GARDNER: Of useful information.

DR. STROM: -- have not been met.

DR. GARDNER: And, therefore, we recommend that Subsection D be not --

DR. DAY: That the Secretary invite public comment on --

DR. GARDNER: Right, exactly, exactly.

DR. DAY: -- the other options.

DR. GARDNER: As afforded, as specified in Public Law.

DR. DAY: Right.

DR. STROM: Yes.

(Laughter.)

CHAIRMAN GROSS: Let's go around the room and see if everybody agrees. Ruth?

This is agreement that 75 percent compliance has not been achieved.

DR. DAY: I agree that the 75 percent complies with useful information has not been met, and that we should invite public comment for other options according to all of the law, regulations, yes.

CHAIRMAN GROSS: Okay, and, Jackie, your opinion?

DR. GARDNER: I agree with Ruth that 75 percent of useful information has not been met, and that we should invite public comment according to the provisions of Public Law 104.

CHAIRMAN GROSS: Bill?

DR. CAMPBELL: It's close. I agree that the goal of 75 percent of information distributed that can be classified as useful, and by the Keystone criteria of allowing the consumer to receive maximum benefit of the drug has not been met. I agree with that.

And I further agree that we should not simply invite comment, but we should provide guidance and advice on how that goal can be met.

DR. DAY: And I amend my comment accordingly now.

DR. STROM: And I would like to amend the original motion accordingly.

(Laughter.)

CHAIRMAN GROSS: Forget the motion.

Steph?

DR. CRAWFORD: I agree with everything that's been said, but I'd also like to acknowledge that I do think substantial progress has been made, though we need to do a lot more.

CHAIRMAN GROSS: Okay. John, your comment?

DR. SULLIVAN: I would certainly endorse Bill's and Stephanie's comments that technically it hasn't been met, but there has been progress made.

CHAIRMAN GROSS: Michael?

DR. COHEN: Yeah, I will so endorse it. I think, you know, we only looked at four drugs, and in each case there was significant problems with the information missing in our particular area, risk management and drug safety.

So I couldn't see it any other way but not extending this until 2006 or voting as you have.

CHAIRMAN GROSS: Brian?

DR. STROM: I agree.

CHAIRMAN GROSS: I agree also.

Okay. The next is make a recommendation or

make some suggestions to the FDA, some options. The first thing we talked about was a workshop, getting all of the stakeholders together. Why don't we go around the group and comment on that?

DR. GARDNER: May I ask a question, Peter?

CHAIRMAN GROSS: Yes.

DR. GARDNER: Given that this committee was convened for the purpose of looking at this question, can the committee invite -- convene such a meeting to gather further information? Because there seems to be a venue issue.

And although I agree about the Secretary, maybe that is the best place for it. It seems to me to yet introduce another organizational element.

CHAIRMAN GROSS: Yeah. I think this is up to the FDA. We're just making some suggestions and they'll make the final decision.

So this time I'll start at the other side of the table. John.

DR. SULLIVAN: Could you --

CHAIRMAN GROSS: As far as do you want to discuss what options you think are worthwhile as far as gathering a group together or workshop of the stakeholders?

DR. SULLIVAN: I would concur with your

previous suggestions that probably a workshop would be the first step.

CHAIRMAN GROSS: Okay.

DR. SULLIVAN: And go from there.

CHAIRMAN GROSS: Michael?

DR. COHEN: Are you talking about a public workshop, an FDA public workshop? Is that what you're talking about?

CHAIRMAN GROSS: Yes.

DR. COHEN: And would that allow us to give recommendations or provide information?

CHAIRMAN GROSS: I think you can make that as a suggestion that that should be done there.

DR. COHEN: Well, I think there are some specific recommendations that we could make that have come out of this committee meeting today. So I would like to see that as part of this workshop.

CHAIRMAN GROSS: Okay.

DR. COHEN: That we would be involved with it, that is.

CHAIRMAN GROSS: Good. Okay.

Brian.

DR. STROM: I agree with the idea of having a workshop as a logical next step. I think it's important that it be clear that the workshop is not

informational. It is a workshop in order to decide on what the next logical activities would be that have, again, both carrot and stick as part of it, how the organization of the current system should be changed, not just informational, and if, in fact, there isn't anything concrete that emerges from the workshop that changes the system, the existing private system, then it would be considered a failure, and it would be up to the Secretary then to be more proactive and to follow it.

That should be understood going into the workshop.

CHAIRMAN GROSS: Steph?

DR. CRAWFORD: I agree with the outcome being a useful action plan.

CHAIRMAN GROSS: Bill?

DR. CAMPBELL: I agree. I would make it a practitioner organized and driven effort, and I think the major change that has occurred in seven or five years --

CHAIRMAN GROSS: What do you mean by practitioners?

DR. CAMPBELL: Is that the practitioner organizations, and I specifically refer to AMA, APhA, ASHP and the white paper group on safety and risk

management, have committed themselves as professionals in a way that did not exist five or six years ago, and while all stakeholders may be present, I think the onus needs to be on the practitioner groups.

CHAIRMAN GROSS: Okay. Jackie?

DR. GARDNER: That sounds like an unfunded mandate to me, and I'm not sure that it works, although it would certainly be nice. I think I would go back to what Brian's suggestion was, that a meeting be convened with an understanding that an action plan needs to come out of it or it gets kicked back to the Secretary.

CHAIRMAN GROSS: Okay. Yes?

DR. CAMPBELL: I didn't mean anything different. I mean, you know, the conveners, I think -- the same sort of thing, an action plan agenda for education and training. All of that has to be there. I'm just thinking that it is best handled at this point for the practitioners to have ownership of this because that's where implementation will have to occur, not the vendor level.

DR. GARDNER: How would you effect that out of this group? I mean if we recommend that and go away today, you would expect them to pick it up or you

would expect the FDA to? Tell me.

DR. CAMPBELL: It will fall in the FDA's agenda to do it. I'm just saying that the mechanism for convening and implementing should be through them. It's simply a recommendation.

CHAIRMAN GROSS: Okay. Ruth?

DR. DAY: I support a workshop which has an educational component directed towards an action plan outcome, and I think it should be sponsored by the FDA with participation of the professional organizations in developing it.

CHAIRMAN GROSS: Good. I agree with all that's been said.

Would any of our guests and presenters like to say anything?

MR. LEVIN: I was out of the room for half of this. So apologies.

I just want to understand why, Bill, you think the professional groups should have ownership of this issue.

DR. CAMPBELL: I think the professional group needs to implement it, and if they're going to implement it, they really need to own it at the very beginning. I don't mean own it, taking it out of FDA, not at all, but they really have to be driving it from

the very beginning.

MR. LEVIN: I'm still puzzled. How do professionals drive the information vendor process? Explain that to me. How do they? I don't understand.

DR. CAMPBELL: I think that's the challenge for professionals to develop, whether it's professional practice standards through their regulatory boards, through whatever. I don't think the professional groups at this point have owned this process.

MR. LEVIN: I remain confused. There are two participants in the information business as I understand it, although there are far fewer than I used to understand. I think a remaining professional organization is the Association of -- what are they now? They used to be Hospital Pharmacists.

PARTICIPANT: Health System Pharmacists.

MR. LEVIN: Health System Pharmacists that are information vendors and providers, and the rest, I believe, with USP out of the business are proprietary.

So, again, I don't get the connection with professionals and the vending of information, which is what this process is about.

I mean, the origin, unless we talk about the

scientific origin, but the origin of the material, the product is with the vendor. The vendor is either an organization, a not for profit organization, or it's a for profit organization.

DR. CAMPBELL: And who's the customer?

CHAIRMAN GROSS: I think at this point --

MR. LEVIN: The customer is the patient.

CHAIRMAN GROSS: At this point we're really just giving our opinions.

DR. COHEN: Peter, could I just ask one thing?

CHAIRMAN GROSS: Yeah.

DR. COHEN: The time frame.

CHAIRMAN GROSS: Staff first and then Michael.

DR. COHEN: Oh, I'm sorry.

DR. CRAWFORD: For Arthur I can just give two examples of how the profession could help in the process, one through educational programming, articles, et cetera, but also in the absence of regulation or guidances, what people look for but they want are professional standards, and the pharmacy organizations do provide professional standards on the use of information technologies and other things because I still think part of the problem is that the

end professional users are not necessarily aware of all of these criteria.

So I think it's very critical that we involve the profession.

CHAIRMAN GROSS: Paul?

DR. SELIGMAN: I'd be interested in Bonnie's thoughts on this, but clearly the pharmacies are purchasers. I mean they're buying the information, and to that degree, I think they have clearly a stake, you know, in terms of what it is they're buy and why they're buying it and in some cases why they're not buying it, from whom they're buying it from, and the quality that they demand from that purchase.

CHAIRMAN GROSS: Why don't we go on to the last part of this? And that is that following that meeting or maybe during the meeting, at some point an oversight group will be appointed. Exactly what it will be called I'm not sure, but they will have some -- they will develop some enforcement measures to try to assure that the Keystone criteria are met.

Arthur.

MR. LEVIN: I would like to speak in favor of this committee being the group. I don't think this committee as constituted can do it, but I think there are models in other advisory committees for handling

where one committee ends up with a very complicated and not overlapping issues.

And the example that comes to mind is the Food Advisory Committee of the FDA, which is now in six subcommittees, dealing with things like natural toxicants and contaminants and infant formula, two very different issues, and biotechnology, a very different issue, but with the subcommittees all reporting back to the full committee.

It seems to me we were what we had in mind, those of us who talked about this in the Keystone Steering Committee process, to have an FDA advisory committee as sort of the umbrella. I think there are ways to operationalize it, given that we're small. We have a lot of other things on our plate.

But I think there's a lot to be said to vesting the responsibility in an advisory committee process. Since we're the ones making these recommendations, I think we're responsible for making sure they go forward.

CHAIRMAN GROSS: Okay. Let's go around the room. Remember we don't have to all agree on exactly what the oversight group should be and what the enforcement measures and methods would be. We just need to come to see if we have a sense that that's a

direction we would like to suggest to the FDA that be pursued.

Ruth.

DR. DAY: I would like to hear the language of what we are all agreeing to before I make a comment.

In a way it's good. It changes as we go, but if someone could make an initial stab, we agree there should be an oversight committee to --

CHAIRMAN GROSS: That's basically what I said.

DR. DAY: But to -- does that mean to periodically review the materials and do sanctions and so on? I just want to know how much of a task is being recommended.

CHAIRMAN GROSS: Yeah, the concepts were there be an oversight group and that there be some measures and methods of enforcing without being any more specific.

DR. DAY: In a nonspecific way I agree.

(Laughter.)

CHAIRMAN GROSS: That's all we need.

DR. GARDNER: I could agree with that concept as proposed.

DR. CAMPBELL: Yes, agree.

DR. CRAWFORD: I agree, although I'm a little confused. Is this an oversight group that would be separate from the FDA? I'm a little confused.

CHAIRMAN GROSS: It would be part of the FDA.

DR. CRAWFORD: It would be part. Thank you. Then yes.

DR. STROM: I agree.

DR. COHEN: I agree, and if you think about it, we do have most of the components that would be necessary. The way the committee is constituted right now, the individuals who are on it have various backgrounds that would fit just perfectly if you were going to design a committee. I think most of us would fit in.

CHAIRMAN GROSS: Okay. John?

DR. SULLIVAN: I would also agree, but I think we have to remember that we're purely an advisory committee, aren't we?

CHAIRMAN GROSS: Exactly. Okay. Are there any other burning issues or comments before this group?

If not, the meeting --

DR. COHEN: Peter?

CHAIRMAN GROSS: Michael.

DR. COHEN: We need a time frame for that meeting.

CHAIRMAN GROSS: You've got to be serious.

DR. COHEN: Not have it a year from now. I'd like to see it happen pretty quick.

CHAIRMAN GROSS: Okay. Makes sense.

Okay. The meeting is adjourned. Thank you all.

(Whereupon, at 4:42 p.m., the Advisory Committee meeting was adjourned.)