Now, on the next section of findings, we're going to talk about this variability, and we're going to say, well, now, why the variability. Could it be due to the consumer background characteristics, age, education? And could it be due to pharmacy characteristics? Do they vary from chain independents?

And third and most importantly, do they vary by the leaflet characteristic? And I'll focus in that set of results on length, font size, and vendor, and version of leaflet within that.

So I'll stop there. Thank you.

CHAIRMAN GROSS: Bonnie, thank you very much.

At this particular point we'll take a break, and we will reconvene in 15 minutes.

Thank you.

(Whereupon, the foregoing matter went off the record at 10:32 a.m. and went back on the record at 10:51 a.m.)

CHAIRMAN GROSS: If I could get everybody's attention, I think it's time to reconvene the meeting. So we're ready for Men in Black, Part II. I mean the report of evaluation of written patient information penetration, and usefulness, Part 2.

Dr. Svarstad will begin.

DR. SVARSTAD: Thank you, everyone, who donated Hall's lozenges, Life Savers. I hope my voice -- I think it will hold out, but thank you for putting up with the coughs.

Okay. The second set of results. Let's start with leaflet ratings by consumer characteristics, and first off, what we basically tried to do here was determine whether gender, age, education, race, ethnicity, current drug use was in any way associated with high or low ratings. So we did a variety of statistical tests, and the first, easy conclusion was that ratings, consumer ratings, that is, were unrelated to gender, age, education, and current drug use.

One of four ratings for one of four drugs was related to race not in a strong way, but I report it nevertheless. White rates gave somewhat higher ratings than non-white raters for nitroglycerine leaflets, but race was unrelated to other ratings for the other drugs.

And for those of you that do statistics every day, you know that when you do a large number of comparisons, you're expecting that at least occasionally you will get a significant. So this one

finding may simply reflect that we're doing many tests here. So I would not attach a great deal of significance to it.

So I think we conclude at least given the population of raters, that we didn't see that consumer ratings were correlated significantly with their background demographic characteristics.

Now, let's look at pharmacy type, and here I have a graphic showing leaflet distribution and overall ratings by experts and consumers by pharmacy type. This again pertains to over 1,300 leaflets, and the pharmacies are simply categorized independent versus chain, and these terms are debated within research circles. So knowing that it's kind of hard to make these categorizations, and this perhaps is multi-unit organization, but in any case for the sake of simplification here, I've put them in two categories.

And what we see is that the percentage of patients, shoppers who are given any kind of information, you know, a very partial, small piece of information or a full leaflet, did vary significantly by pharmacy type with the percentage of shoppers receiving information was 79 percent in the independent or smaller pharmacies and 98 percent in

the chains. And that's significant at the .001 level or greater.

When you look at the overall mean ratings of the experts that this rates now from zero to 100 percent, you see that the mean rating for the professional of leaflets obtained from independents was 43, and the mean for the chain was 55. Again, it was significant, a significant difference.

Interestingly enough, the consumers also rated them significantly differently in the same direction. The mean consumer rating was 49 for these pharmacies and 65 for these pharmacies.

So we do see differences by pharmacy type, and I think that I have some slides a little bit later to comment about that further, but I should say that I think that this is not as simple as it seems, but it would appear that pharmacy versus chain are either using different systems or they're implementing them in different ways.

But I have some samples. I brought quite a few samples for you today so that you can kind of see some of this.

Okay. Now, let's go to length. We categorized the leaflets by length, by those that were under 5.6 inches in length, this size, you know, half

of a standard sheet of paper, or 5.6 to 11 inches, this size paper or somewhere in between or over 11 inches, which would be a second page.

We did not find any three-page leaflets, and I unfortunately did not bring a slide on the actual percentage, but I can get that to you by this afternoon because I brought my computer, and I'll dig out the data, but I think the distribution is more towards the low end, and it was pretty rare for us to see two-page leaflets.

So what we have done is categorize the results for what these short leaflets, these middle range leaflets, and the longer leaflets, and we have the mean expert rating for each leaflet length controlling for drug here.

Now, what this shows is that the mean expert rating for these very short pieces of information I should call them is 44. For the ones at this level it's 56 and 57 for those that are at this level.

So I'm sure if you did a statistical test to compare these two, you would not find it significantly different, but it is between here and here. Okay.

See pretty much the same trend for each of the drugs. Higher expert ratings for the ones that are at this length here and quite low ratings for the

shorter ones, and I've brought examples of leaflets in this range, as well as in this range. So I'll show you those later.

Let's look at the consumer ratings. The same approach. We're asking what the mean overall rating for the consumer is on a scale of zero to 100 percent for leaflets that varied by length.

Lower ratings for those that are shorter, and a little bit higher or significantly higher for those in the 5.6 or half page to a page and a half, or less rather.

We see similar trends here, but they're probably more marked than you saw for the expert, that is, the mean rating for the consumer is 50 percent here and 70 percent up here. That is, there is some tendency to give leaflets that were over here a higher rating.

Is that associated with length? Not necessarily because it could very well be that a leaflet that is somewhat longer has a different format and different font, and I'll get into that a little later.

In other words, a leaflet that's a full page long as opposed to a half page long may use bullets, may use different spacing, different font, which the

consumers are reacting to. So it's important not to be misled that consumers are necessarily asking for or expecting long leaflets. That's not what these findings show at all.

Now, let's look at the issue of font size. We had staff do this. After asking staff to measure font size, we got these notes back saying, "Isn't there somebody else that could do a better job of this?"

So we did have staff do this and trying to do it in a consistent and standard way. So the results here, we're categorizing leaflets at smaller than ten point or ten point and greater in font size.

And you see that, first off, for atenolol the smaller font size leaflets did get lower ratings. Now, remember that this is an aggregate rating. So if you look at readability or print size, you're going to see much stronger results, but we're looking at overall aggregate rating right here.

Pretty much the same trend for all four drugs. In other words, consumers are giving lower ratings to those shorter leaflets.

Now, let's look at the rating of readability. If you remember, at the end of the consumer forum, we asked them overall how easy or hard

was it to read on a scale of one to five in this particular case.

Here you see the one to five with five being the best and one being the poorest. Let's look at atenolol. You see a pretty marked difference in readability by this somewhat crude classification, and the same trend for the other drugs.

That is, on leaflets with small font size measured by staff independently, consumer ratings tend to be or are significantly lower, meaning there is a link here between the objective measurements and the consumer rating on those rating forms. And these are all significant at the .001 level or better.

Now, the next question was: does it vary by vendor? And Sharlea Leatherwood noted before, and I think as John Coster noted before, there's been merging and much activity in who is actually providing the information. It wasn't our role, and we didn't have the resources to really investigate this except to say that the data are consistent with the idea that there now are very few vendors evident.

One of the difficulties that we had in studying this was that the pharmacy did not always include the publisher information and the publication date, making it difficult to identify where the

information came from.

So that was evident in only probably 55 percent of the leaflets. So what we actually did was we did obtain copies from one vendor, the main vendor, of their leaflets, and we went back and reanalyzed the data so that we could try to determine what percentage of the leaflets actually used data from that vendor and get a better estimate perhaps of how this vendor frequency or distribution looks in the pharmacies that we visited.

So we've classified them here into three categories, and I'll mention a fourth category. The first, the vendor was -- now we're looking at atenolol leaflets because we couldn't go back to 1,300 of them, and so I picked the drug class and focused on that one.

Vendor could not be ascertained at all in 46 cases or 13.5 percent. The Vendor 1, could be identified by comparing what we saw on the sheet to information we got from Vendor 1. I say partial message because in that particular case the pharmacy was printing off either the patient counseling message or the warning label message.

The vendor has shorter messages that are available that I think are certainly not intended to

be the full monograph. They're called patient counseling message or warning message. They're very short, and I'll show you some examples.

We found those being used in five percent of the cases or 17 cases. In the remaining cases are 81.5 percent of the cases, 277 atenolol leaflets. We found that Vendor 1 was the vendor, data vendor.

Now, that reflects this state of affairs in the year that we collected it.

Now, because we kind of anticipated that there would not be that much variability, and we did have some interest in what kinds of information are provided in hospitals and institutions, we added information from a second vendor to the ratings by experts and consumers, but we are not including those data in the main report because they're not from community pharmacies. It's what I would call comparison leaflets.

And we put institutional here because these leaflets are, as I understand it, primarily distributed in hospitals, out-patient pharmacies, out-patient situations or in-patient.

But in the tables then, you'll see Vendor 1, partial; Vendor 1, full; or Vendor 2 with this little asterisk, meaning that's a comparison leaflet, and

I'll show you examples later.

Okay. Now, the first thing that we've found that's pretty obvious to the data vendors, I'm sure, and to everyone here perhaps, and that is that maybe it's not so obvious, but making that kind of split-out by Vendor 1, partial message; Vendor 1, full message, does account somewhat for these leaflets that are extremely short.

For the leaflets where we could not identify the vendor, 83 percent of them were under five inches. Think about that for a moment. For the leaflets where we could not identify the vendor, 83 percent were under 5.6 inches. They fit within this piece of paper.

The partial messages, overwhelmingly 94 percent were of the short variety. When you got to the full message, you had about 27 percent still being at this level of shortness, and I think that these -- and I'll give you an example here -- I think those are primarily the ones where you've got a full leaflet compressed into a half page using a font size that even I can't -- you know, that's hard to read, but I'll show you those examples. So you have several things happening here.

The Vendor 2 leaflet takes up a full page

and about this much of the next page, and it compares with Vendor 1, full message leaflets that are slightly more than one page. Okay. So we do have variability on length.

Now, let's look at the variability by date of vendor in terms of ratings by experts and consumers. First off, we know that there is substantial variability by date of vendor with the highest being Vendor 1 and this comparison Vendor 2, and the lowest being those partial messages and unidentified vendors.

This is the vendor not identifiable. This is the Vendor 1 where it's partial. That is, the pharmacy has only printed out the patient counseling message, not the full monograph.

And this is Vendor 1 with a full monograph, and this is the comparison two, comparison leaflet called Vendor 2. I should have put motion on here so you could just see one drug at a time because this is kind of information overload here, but let's stick with our first one so that we don't get too overloaded.

These are the mean expert ratings for each vendor type. You see the mean rating for the experts was 32 for this unidentified vendors and 28 for these

partial messages, and then it jumps up to 56 percent for the full leaflet from Vendor 1 as printed out by the pharmacy, I should always say, because the pharmacy can influence how it's printed out.

And then the comparison leaflet is this bar here. So it reached the 75 percent for that one.

Pretty much the same here, although it's not quite the same trend, which is why I give both drugs.

And the third one is pretty similar to this, and you see, again, that the full leaflets, whether they're from Vendor 1 or 2, are rated much more highly by experts than these unidentified leaflets or these partial leaflets.

So vendor certainly has more influence than consumer characteristics and even pharmacy type.

Now, let's look at by criterion. Here's Criterion 1, name or indication, and you see here that these short, unidentified vendor and short messages are weighted quite low, a mean of 32 and 28.

It jumps up to 56 and 75 for Vendor 1 and 2. You see a similar pattern here and this is contraindications. Now, this is why it's very important to look at vendor, because this is much different than if you lumped all of these together.

It suggests that if these pharmacies here

that are using Vendor 1 system and have full access to the full monograph, the decision to use only partial is the one that's kind of influencing the rating there. Do you see that?

Now, when you get to directions, they're very low here and somewhat moderate. Precautions are very low here and neither one of them is meeting criteria on cautions as fully as the criteria would require.

When you look at adverse drug reactions and what to do, you see low ratings, again, for these shorter, partial messages, and you see somewhat better for the full leaflet, and you see very high rating for the Vendor 2.

General information, low here and kind of low-moderate for both of these.

Accuracy, it's interesting that accuracy is pretty high overall, which was reflected in the earlier findings, but it is kind of interesting. I don't recall the statistical findings to know whether these -- you know, why that dips down a little bit, but the overall message is that accuracy is not the issue there. It's completeness of the information, specificity of the information, and those other characteristics of the content.

Now, if you look, this is, I think, somewhat interesting. According to the experts and the expert criteria, the unidentified vendor, the vendor partial, and the vendor full, all had about the same ratings on legibility and comprehensibility. Vendor 2 had much higher ratings on legibility and comprehensibility and had a mean score of 83, and you'll see why this is when I show you the example.

So to conclude here, the ratings by vendor are, I think, quite interesting, and they show that there are significant differences between vendor and within vendor as to how it's implemented.

And finally, I think it suggests that it is possible to get much higher ratings if you look at these leaflets that are being distributed in the institution because they do, in fact, get higher ratings on these criteria, but not all criteria. So it's not as simple.

Now, let's look at the consumer. Consumers also rated the unidentified leaflets and the partial leaflets at lower levels, and they rated Vendor 1, full monograph, is higher than Vendor 1, partial message, and they gave higher ratings to the Vendor 2 on atenolol, glyburide, atorvastatin, and nitroglycerine.

So you see somewhat the same patterns across all four drugs with lower ratings being given for the first two, moderate to variable ratings for Vendor 1, full message, and higher ratings for the Vendor 2 comparison leaflets.

Now, this is by these three items that are at the end of the consumer form: easy to read, easy to understand, and useful, with one being poor and five being the best, and this is where I think the form kind of comes through as being pretty sensitive in the sense that you see that the short messages and the full message -- this here, they seem somewhat hard to read on these partial messages for some reason, but overall the unidentified Vendor 1 receive moderate scores on this readability issues.

And of course, that readability, the print size, print quality, and spacing. It's somewhat a function of the vendor because the vendor can influence that, but it's also influenced, as I aid before, by the pharmacy.

And much higher on easy to read. The 4.7, almost a five. Similar over here and similar over here.

So we conclude that both in terms of the overall aggregate rating, as well as individual

ratings by item the consumers are giving lower ratings to the unidentified vendors and lower ratings to pharmacies that use only partial messages from Vendor 1.

Now, data vendor by pharmacy. You see something kind of interesting here. I just did this a few days ago, but you see that the use of vendor does vary by pharmacy type.

With Vendor 1, full leaflet being more likely to be used in chain pharmacies and somewhat lower in independent pharmacies, the unidentified vendors are more likely to occur in the independent pharmacies than they are in the chain pharmacies, as is this partial implementation of Vendor 1.

Now, let's take a look at the Vendor 1 leaflets to see if there are differences in versions and also to determine whether or not the pharmacy organization or the software company that does that information, whether there are changes to the database, either additions or deletions.

To do this we did a subanalysis. We analyzed full leaflets used by 16 pharmacy organizations. We actually analyzed 155 leaflets from those organizations.

It's just kind of interesting to see that

five of the organizations used what we call version one. Five organizations used version two, and six organizations used version three.

Now, you may say, "Well, why are there these three versions?"

Well, remember, as previous speakers noted, there were several database vendors prior to this study and those during the period of study were identified by one data vendor.

So you've got several databases here that are being maintained by a single vendor, and I'm not the person to ask how that will be working or how that works or where it's going in the future. I suspect that we've got people in the audience and around the table that can comment on that better than I, except to say that there were, we found, three basically different versions, and with the help of vendor one who sent us prototypes.

We then compared the actual leaflet against the prototype, which would then tell us whether or not sections had been eliminated by the pharmacy organization or their software vendor. That was what we were trying to ask.

The results are as follows. The overall ratings do vary somewhat by leaflet version, just that

basic question, as they're implemented in practice. No prototype fully met the criteria, and some organizations did, in fact, add or delete information from the prototype, but not to a great deal.

There are small sections that are omitted or small sections that are added, but we did not find wholesale editing, at least for the material from these 16 organizations.

Whether the unidentified vendors obtain information from Vendor 1 and make alterations, we cannot necessarily say because we couldn't identify what their sources was.

Now I've probably totally confused you, but I hope that's clear.

Expert ratings by leaflet version. So we have Version 1, Version 2, Version 3. One of these versions has five sections to it. Another has eight sections to it usually.

And without getting into it in great detail, if you look at the prototype, they do vary when you look at them a little bit. So what we're now looking at is, well, what do the expert ratings show for these different versions, all maintained by the same vendor?

What you see is kind of what I just said. When you look at name and indication for use, these

two versions meet the criteria quite well because their mean rating was 83 and 85 percent of the points on this criteria. But this version, leaflet Version 3, does not.

On the other hand, when you get to contraindications, Versions 1 and 2 fall down. That's loose language. One and two have lower ratings. Version 3 has a relatively high rating.

There is not much difference when you look at directions or criterion 3. All versions are pretty close, although Version 2 and 3 are somewhat higher.

Precautions. There's not a great deal of variability here, but it is significant, but when you look at the figures you say, well, these two are a little bit higher than this one and this one specifically, but you don't see the kind of variability that you see here.

If we look at the side effects information, you see that leaflet one has a much lower rating, 36 percent of the criteria met versus 53 percent for Version 3. In other words, this leaflet does not meet criteria as well as this one does.

And you see quite a bit of difference here on general information. This version included much of the required information on this criteria, whereas

these two versions did not.

You see that they all, again, are pretty good or very good -- excuse me -- on accuracy and legitimacy -- legibility and comprehensibility are pretty comparable here.

Okay. Now, in other words, leaflet version did tell you something, and you need to look at the individual criteria, and it's kind of interesting because what happens then is that since one version meets some criteria and not the other, they kind of come together with similar scores, but they don't have similar scores when you look at individual criteria.

Okay. Now we looked at additions and deletions from the prototypes. This is Version 1. This is Version 2. This is Version 3. I had a pharmacist graduate student go through and compare the leaflets for each of these organizations against the prototype and tell me exactly how they differed, and then I did the same only for a smaller number, but to verify this.

And what we found was kind of interesting. On Version 1 we found no editing of -- well, I should tell you what we did find. One out of five organizations using this version deleted the publisher and disclaimer information, and those were the only

deletions that we found for that version.

And two gave out the full monograph, plus the label, which doesn't really have anything to do with additions/deletions. It just tells you how the pharmacy is implementing that version.

You assume then or you can conclude then that four out of the five organizations made no changes in the leaflet and that none of them changed the content of the section within it. That is, they didn't start tinkering with the side effects or the contraindications or whatever.

Version 2, one organization deleted the additional information section and added label. In other words, this was the only change in Version 2.

For Version 3, this was a little bit more complex because I suppose that this particular version may or may not -- I think it potentially is more changeable because lines and sections are marked with text markers so that you could take sections out, but as several individuals have noted, licensing agreements are supposed to cover some of this, and that's not my area. All I can say is what happened from our sample.

Version 3, five organizations deleted the

warning box, which I'm not sure if this is really required or whether it's an optional, but they deleted the atenolol warning box or warning section at the very beginning of the leaflet. That's not to say that they eliminated any warning about atenolol. It's just that whatever warning was there was somewhere else. It may or may not have been the full warning required, but it certainly wasn't highlighted for the patient by separating it out in some way even though the prototype did separate it out.

Version 3, five organizations also eliminated the overdose section completely, just eliminated. And four deleted the drug names and notes. Now, that might vary somewhat by drug, but five organizations added the disclaimer about this information doesn't include all uses, side effects, drug interactions, et cetera. So they added some information.

So what do you conclude from this? Largely or generally, there is not an editing within a section. In some cases for some versions there is a removal of sections.

Ratings of the distributed versus the prototype leaflets, the example of atenolol. We've got the distributed leaflets that we collected versus

the prototype that we obtained from Vendor 1, and what you see generally is pretty close ratings here, except when you get to here and to some extent here. You can kind of see that.

On number two, contraindications. Number four is precautions. That's where the atenolol thing might come in so that this might reflect some variability between the distributed and the prototype because there may be some -- let's see now here. Just a minute. Let me look at this.

This one is pretty much the same, and we can't do statistical tests because there's only one prototype. Nothing makes sense.

Overall it's pretty close here that even though a few organizations eliminated a warning box, it reflects the fact that somewhere else in the document the warning was included. Okay? That's what I conclude form this, and that's just Version 1.

And actually Version 1 did not have a warning box. So I'm kind of talking out loud here.

Version 2, you see they are also quite similar, but there are some discrepancies. You see that, for example, the prototype is a little bit better here and here than the actual distributed. And if I went back and I compared which organizations I

could pinpoint for you -- and we kind of did this, but I don't want to identify pharmacy organizations here. Nothing is served as I see it by that.

But what was interesting is that we could pretty much identify where the low ratings were likely to occur based on what we knew about changes in the prototype.

A little bit more here now on Version 2. Remember I said earlier that this is the version that has the text markers. So it may be easier for these corporations or software vendors to remove certain sections, and this is where there were more changes.

And you see more differences between the prototype and the actual. For example, here, here, here. Five is side effects, and this would be the outcome of a number of organizations eliminating the overdose section, for example.

So what do you conclude? There's more changing with some versions than others, and when the changes do occur, they do seem to reflect the ratings for certain criteria in predictable ways.

I think we've reached now the conclusions, and I'm going to give these conclusions and then I would appreciate switching over to the examples, and then that will be concluding this second set.

The conclusions then are that, first, highest ratings have been for scientific accuracy and being nonprofessional without a doubt. The lowest ratings are for information about contraindications and precautions.

Third, the lowest ratings are for leaflets that are extremely short, less than five pages long or have a font size that's extremely small.

The lowest ratings are also for leaflets from independent pharmacies and unidentified vendors.

Finally, there is no prototype that fully met all eight criteria, and under that, experts and consumers were both critical of legibility.

What is the conclusion here? It is that pharmacy organizations can influence the ratings by first selecting the vendor and the leaflet version from that vendor, however that plays itself out.

Secondly, they can influence it by modifying the leaflets themselves, at least those versions that are modifiable. Now, licensing agreements, I can't really speak to that.

The third bullet that I should have had here is that pharmacy organizations can influence legibility by influencing print size, print quality, and readability, the font size.

So I think that there are some areas that could be improved.

Now, let me now shift to the final step here, which is to show some examples and with each example, I will give you what the mean expert rating was for that sample.

Some of those have been distributed to the committee, I believe, and I am not going to go through all of those. I'm just going to go through a few of them. So would you help me?

Thank you.

Partly a function of the font. This is the case from Pharmacy 313, and that was all the information that the patient got. "Do not stop med. abruptly," and then it was repeated. "Do not stop med. abruptly."

This is not the auxiliary label on the bottle. This is the information that was on a piece of paper that the patient was able to take.

The expert rating on that was 16. Curiously enough, the consumer rating was also 16. So I think they agreed.

Here's another one that would be either a partial message or certainly an unidentified vendor. This is take with/after food or milk. Do not stop

med. abruptly.

One wonders whether this is coming from the same vendor since the same -- or it could be coming from a pharmacy that's somehow -- well, I don't know. It's not identified.

Please remember some doctor offices require 24 hours' notice on refills.

The mean on that was 16.

(Pause in proceedings.)

DR. SVARSTAD: I should note that the patient names on here are fake names. They are fake names, and this was done for a number of reasons. And I hope that there aren't any physician names, but these are physician consultants that did this, and we've certainly tried to remove any other names. But I will try to pay some attention here to make sure.

Yeah, I just want you to know that the patient names are not real.

Okay. Thank you for reminding me.

I'm going to cover up even the fake names, if I can. Here is from Vendor 1, and I'm sorry you can't read the details of this, but you see that this is, I think, as I recall, this is from Version 1, and you see a number of sections there.

You don't see publisher, but you do see

other information about how to refill, go to the Internet, et cetera.

The mean on that was a 51.

This is another example. The mean rating on this one was a 41. You see kind of a question-answer -- boy, I wish I could get that better. Why am I taking this drug? To treat heart and/or blood pressure problems. How should I take it? Are there any side effects? How do I store this? If I should miss a dose? What about generics?

The how should I take it: follow M.D. directions. Do not miss doses, and do not suddenly stop taking this without M.D. okay. Tell M.D. of other drugs you use/illnesses you have/allergies/if pregnant.

The slashes are a little hard to follow.

Are there any side effects? Very unlikely, but report cold hands/feet, swollen hands/feet, mental changes, bruising, bleeding, weakness, trouble breathing.

This is an example of a patient counseling message that was printed off of Vendor 1. It's exactly word to word from Vendor 1 rather than the full monograph from Vendor 1.

Follow directions, period. Do not stop

without doctor approval. May cause drowsiness/dizziness. Drive with caution. Notify your doctor if you intend to become pregnant. Check with doctor before taking other medicine. Promptly report unusual symptoms, effects to doctor. Inform doctor/dentist prior to any surgery.

This received a 27, which would put it in Level 2.

I can't get this to work as well as I would like, but I wanted to show this one as an illustration of the font size. This is the leaflet, and I would estimate that the content is maybe three to four inches, and I don't have the data file with me, but the font size is extremely small.

So this would be an example and is an example of Vendor 1 material that's been compressed down to a very small font size, but it's colorful. But the content would receive about the same score as the other content would through that version, except on legibility.

Here is another one. You can see the difference on font, but the similarity in information. You see the familiar structure, common uses, how to use this medicine, cautions, possible side effects, before using this medicine, and overdose. This is

Version 3.

Yes, that's Version 3, but you see in the caution section there, if you could read it, which you probably can't, it starts out by saying, "Do not stop taking this medicine without checking with your doctor."

That would be considered partially adherent because it talks about do not stop suddenly, but it doesn't talk about the potential need for gradual dose reduction and it does not take that material and put it up front at the top.

And actually this version from the vendor, it was up at the top, but that was removed.

Okay. You also see something characteristic about the information from this vendor or these pharmacies that I'll note here. Notice how the cautions -- that long paragraph. There are no bullets. The material kind of runs together.

Now, from a consumer perspective, that's hard to read, and even the experts, they would send me back this note, "I can't find the information." And I suppose they were trying to find it quickly, but sometimes they had to read through a leaflet two or three times to make sure they found the information or gave the leaflet a chance.

But I'll show you a little bit differently how that kind of information could be reorganized or at least presented in a way that meets the Keystone criteria because the Keystone criteria would say there should be bullets. The Keystone criteria would say there should be more spacing between the lines. The Keystone criteria would -- font size in this case is okay probably. I'm guessing.

Now, this is one where -- here's the black box warning up at the top, and that was in the original prototype from the vendor. This particular pharmacy organization kept it in. The others had taken it out.

And you also see that this one includes the overdose section, and a number of the other organizations had eliminated that. This was in the prototype.

This leaflet actually was one of the highest rated leaflets, but still only got a 61 percent probably because a little bit more legible, but it was, I think, Version 1. No, actually it's Version 3.

You see that while it doesn't have the warning box up there, it does have the overdose information. It does have additional information, and it includes the vendor publication date, et cetera.

So if you wanted to trace it, you could.

Now, I've just got a couple more and then I'm going to finish. Here is one of the few leaflets that we saw that were two pages. I'm not sure. This document camera doesn't like it for some reason.

The point, I guess is that -- I can't seem to get it to work properly.

This is the first page, and the first page shows -- and this is from Vendor 1, common uses, how to use this medication, cautions, and then the second page shows possible side effects, the publisher or the vendor -- excuse me -- the vendor date, publication date, and the disclaimer. But it's still only rated a 57 probably because print quality was poor.

Now, I'm afraid that the bottom line here is that we did not see a lot of two-page leaflets. They're all rather short here, and if anything, the experts pointed out that there was for some organizations more information presented on the backs of the sheet, et cetera. And you won't be able to see this very well, but for this organization, you have the side -- it's a fold-out, and on one page you see your natural vitamin center, your thoughts please, quick tips to relieve small stresses. I use "stressed out." Some nutrition information and I think kind of

interesting, health hotlines, and this is the drug information, prescription information. That one received a 45.

And here is an example and the final example. This is from the Vendor 2 comparison sheet, which we did not edit this or change it in any way. We just printed it off the Web at our institution.

And you see here this had a mean rating of 75 percent from the professionals, and the consumers gave it a mean of 97 percent.

Often in the open ended, the consumers would say this is great or this is the best, but I think that what they were probably responding to was the very different format here.

You see that there is quite a bit of white space. You see that headings are on separate lines as the Keystone criteria had recommended. You see that bullets are used to separate information as the Keystone criteria had suggested, and you see a font size that's consistent with what the Keystone criteria suggested.

So I think it's rather interesting that both the experts and the consumers rated this more highly. Now, a practical question is: could this information be reduced to one page? And you know, those

questions, I think we have not tried to bring it down to one page, but I do think it would be possible. I put it up there as a comparison, not something that's actually being given.

Okay. So that ends my presentation of the second part of results, and I hope it has been clear. Thank you.

CHAIRMAN GROSS: Thank you very much, Bonnie. It's a fascinating study and a tremendous amount of useful information.

Are there any questions? Yes, Arthur.

MR. LEVIN: Yeah, I sort of have a problem in understanding where the eight criteria are derived from because one of them, which happens to be one that gets high marks when a lot of other things don't, is a criterion in the Keystone report, and the others are components of what is useful information, and they're sort of different. I mean, they're a little bit of apples and oranges.

And the reason I'm concerned is because the sort of high marks of scientifically accurate, nonbiased, non-promotional sort of may give people hope that we're actually making progress when I think the results of this study tell us that we're not making any progress and things are pretty dismal 34

years later.

And the reason I'm concerned is I don't know how something is scientifically accurate if it doesn't follow the definition in the Keystone report, which is information consistent with or derived from FDA approved labeling, and if it fails to meet some of these component requirements, it's not following the label.

In other words, if you leave out a contraindication that's in the label, then how is this scientifically accurate?

So I have a problem, a disconnect between the raters giving, you know, an average 90 percent compliance ratings to that particular criteria, and then low marks to its constituent parts. I don't know how you get from that low mark of constituent parts to a 90 percent.

And to me it's very important to sort of tease this out because if we didn't have that 90 percent, I think we'd all say this is just totally dismal, and the 90 percent sort of says, "Well, there's some progress. And I don't think it's real. I think it's illusory, and I think it comes about by confusing what was called a criteria in the Keystone report, making that one of eight criteria when the

other seven are sort of components, as described in that report.

CHAIRMAN GROSS: Bonnie, do you want to comment?

DR. SVARSTAD: My reading of the Keystone report, but I wasn't on the Keystone Committee, but my reading of the Keystone report was that the Keystone -- that as a committee you were trying to identify the criteria that would be included in useful, and that scientific accuracy was one component of useful. And that's why they're separated out as they were.

We all had somewhat difficulty interpreting the Keystone criteria on accuracy, nonpromotional, et cetera, and I think that what the panel was trying to do here was to separate the concepts or the constructs of completeness or specificity or legibility and accuracy.

You can be accurate in what you say, but incomplete. But if you define useful as accurate and accurate by some other criteria, then you would, of course, get confused. But I think I don't have my copy of the Keystone Committee report here, but it did, it seem to me, separate out these different criteria, and that's what the panel was trying to get

at.

I think when you look, for example, at these "do not stop medication abruptly," you know, that's an extreme. Now, is that accurate? Well, that statement is accurate, but is it complete? No. Is it specific? No. Is it legible? You'd have to look at the thing to see if it's legible. Is it comprehensible? Probably.

You can have something short and incomplete, but still be quite readable and still quite understandable and, according to the panel, still accurate for that statement. That's, I think, how the panel proceeded.

CHAIRMAN GROSS: Okay. Ruth.

DR. DAY: I'd like to thank Dr. Svarstad and all of her collaborators on this project. It is most useful and very thorough, and I'd like to just note there have been a tremendous number of changes since the interim study.

The inclusion of vendor analyses and the consumer panel and changes in a lot of the methodology has really been terrific.

There's one part that still bothers me. It's not easy to solve, but I would like clarification about how some of the data were then collected.

Sometimes there are multiple idea units in a given line item, which is a subcriterion. For example, for glyburide on Criterion 5.5, which is adverse events, it says allergic reaction.

Under the allergic reaction it says fevers, chills, rash, and trouble breathing. So if I were one of your expert raters on the panel and only one of those was present, I suppose I'd give it a partial. If two were present, I'd give it a partial, and so on and so forth.

So every time that a given criterion only gets one point as opposed to two, there could be different reasons for that. One out of two is missing or three out of four is missing and so on.

And furthermore, there might be different criteria that the raters use to decide on partial credit. So could you tell us a little bit about what the instructions were to the raters? Because that gets to the guts of what the data are that you get to begin with.

DR. SVARSTAD: Right. Certainly, the side effects section or Criterion 5 is the hardest one with regard to that. Why is that hard? You mentioned a number of side effects. Well, the other problem is that there are many different ways to word that,a nd

if we think we're trying to arrive only at one wording, we'd never reach full adherence.

So I directed the panel to help in clarifying this, and in most cases -- and I'm not sure whether you have got the version that the panelists actually used, but it spelled out that you have to list two of these four to be considered fully adherent. You have to list one of these three to be considered fully adherent.

So this was spelled out quite carefully, yeah.

DR. DAY: All right, and just one other question. You didn't get a chance today to tell about the readability analyses that were done by objective methods using the Gunning Fog Index.

DR. SVARSTAD: Yeah.

DR. DAY: And it's one of many. And I did note in the full report that you said that you did that analysis on the section we started out about how to use or take the medication.

DR. SVARSTAD: Right.

DR. DAY: And you had to choose something. Why did you choose that, in particular?

DR. SVARSTAD: We chose that one -- I think that's a very good question, Ruth -- because where --

and the experts will tell you this, too -- where you start and should you sample and so forth. We started there because generally that was the first section that the consumer was confronted with when reading these that had full sentences and that really would be considered helpful or useful to the use of the medication.

Now, the logic would go a little bit like this. If it starts by being unreadable or overly complex or overly long words, long sentences, et cetera, that you lose the consumer there because most people start at the beginning. They don't start at the end.

Now, with that said, if you went to the side effects section and you started doing a readability assessment, you may find a different result, and I think further analysis certainly would be possible.

I think that as you know, Ruth, there's a lot of difference of opinion among experts about using any of these readability scales for medical material because, you know, you in a sense have difficulty translating certain side effects into common language without losing the information. So that's why we started there.

DR. DAY: Well, I think that's good

rationale, and it's a good first start at all of this. We've been doing readability analyses on TV ads and Internet and pharmacy leaflets and the PI, the approved labeling, and we get systematic differences in readability as a function of the content areas.

DR. SVARSTAD: Yes.

DR. DAY: It's kind of interesting.

CHAIRMAN GROSS: Yes, Jackie.

DR. GARDNER: Bonnie, since our function is risk management and communicating risk, I'm interested in what the consumers had input into in your study, and it feels as if we consistently get poor results in the areas of high concern to us, which would be precautions, contraindications, adverse effects, and so on.

And yet it isn't clear to me that the consumers were asked specifically about how important they thought this was or how well -- readability? Maybe it was in there. I don't know.

And my question, I guess, related to that is: did you have information about the consumers, about whether they were taking any of these drugs they were evaluating, and could there be a sub-analysis according to whether usefulness was different between people who had some experience with the drug and knew

what they thought was important versus people who were just trying to read a document to evaluate it?

DR. SVARSTAD: That's a good question, Jackie. We went around and around about how to handle the folks that you would anticipate had used the medication.

The facilitators were requested to go through and ask anyone to identify -- on the background information sheet they had to list the drugs that they had used before. They were actually asked whether they had used any of the four drugs and if so, which ones.

If they had used it, they were not generally asked to evaluate it. Why? Because these are new users. We were trying to generalize to new users, not former users or current users, et cetera.

It's still an interesting question, and I'm sure we probably, if we looked very carefully, we probably have some that slipped in there, you know, that have already used it, but it an interesting other kind of study that one could easily do with the leaflets.

DR. GARDNER: Then I guess my question would be in a more global --

DR. SVARSTAD: But these were quite

experienced consumers because 77 percent of them were taking one or more med. on a chronic basis.

DR. GARDNER: Yeah. My bigger question then would be in your opinion, knowing what you know then about your study, do you feel that consumers have had any input into the results related to issues of safety and risk.

DR. SVARSTAD: Yes. We did ask them about completeness, and you might say, well, we didn't go in and ask them why do you think it's incomplete, but we did this primarily based on a pilot study where we did go in and ask them, you know, please rate the amount of information on each of these topics, and we listed out the topics.

We did that in the 1999 pilot study. My impression was that this global assessment of completeness, helpfulness, usefulness was tapping into the issue of whether there's enough information.

Now, can we say precisely which aspects of communication are missing? No. We were kind of, I think, based with the question of how you do that with a large sample like this.

But I do not want people to take away from this that consumers were only concerned about readability because the data actually show that they

were quite critical of these other components. I just haven't presented them here today.

CHAIRMAN GROSS: Dr. Brian Strom.

DR. STROM: Bonnie, this is very impressive and a very important body of work. One of the things that's clear is the dramatic disconnect between the proportion of patients who get material and the quality of the material they're getting, and yet your Vendor 2 data indicate it is possible to do it right.

Can you explore with us again where the Vendor 2 data came from? Who was generating those?

DR. SVARSTAD: It came from one of the -- well, without identifying the vendor -- do you want me to identify the vendor? Are you asking me to do that?

I'm not sure. This is a well known vendor.

DR. STROM: So it is one of the commercial vendors?

DR. SVARSTAD: Yes, it's a very well known vendor, and it was mentioned by a previous speaker.

(Laughter.)

DR. GARDNER: But predominantly it came from an institution. Didn't you say it came from an institutional --

DR. SVARSTAD: Well, this vendor -- we did not see any sheets from this vendor in the community

pharmacies. You know, an offhanded comment on my part is that my impression is that Vendor 1 has the predominant provider of community pharmacies and that Vendor 2 may be focused largely on institutional.

And it's not exact. When I say it's possible, I think it's possible to adhere to the Keystone criteria in an efficient way. I don't think it's simple to simply say, "Oh, well, go to Vendor 2 and buy their database," because we're still trying to integrate databases here.

I think what's happened in the U.S. is very interesting, and that is that you've got information now being distributed out there. It's computerized, and having it linked to the dispensing system is critical to its implementation.

If you go to Australia, it's not integrated. There are separate databases, and adherence is very low. Distribution rate is very low.

CHAIRMAN GROSS: A general question for my information. Has anyone asked Vendor 1 and 2 if they're aware of the Keystone criteria and if they are, why they chose -- why the ones who didn't use it chose not to?

Is that known?

DR. SVARSTAD: I would not want to speak for

Vendor 1 or Vendor 2. I haven't really asked them.

I'm sure that there are -- well, I think that if you can see these different versions here, the complexity of this particular study was that several vendors were -- material from several vendors were maintained by a single vendor this time around, and that's part of it.

How Vendor 1 feels about different criteria and what would be needed to implement all of the criteria, I think, is something that you'd have to ask them about, but you know, there are a lot of products. So I think that if you were to, for example, implement the criteria about legibility, it would mean reformatting the information so that it's not all lumped together, et cetera.

CHAIRMAN GROSS: I guess my concern is if this is a voluntary system and we're relying on goodwill, it would be interesting to find out what the attitudes of the data vendors are about the Keystone criteria.

Arthur?

MR. LEVIN: Just a point of information. Several data vendors were part of the Keystone process, and certainly one of them that has been mentioned by other speakers today as a major player

was at the table.

So for them not to be aware of, you know, what that process was and what the conclusions and summary, I have to believe that they know exactly what the criteria are.

CHAIRMAN GROSS: Okay. Stephanie.

DR. CRAWFORD: Thank you.

Bonnie, I wish to echo the compliments expressed to you and your collaborators previously with respect to the insightfulness and comprehension of this report or comprehensiveness.

I especially applaud the efforts to include the consumer ratings, but as my students know, some always is going to fall on my "but."

With the consumer panel being 89 percent white and 54 percent education behind high school, I did question the representativeness of it with respect to medication users in consideration of the very high prevalence of heart disease, high blood pressure, high cholesterol, diabetes among African American and Latino populations.

You did try to address it in looking at and said that the race of consumers was largely unrelated to their ratings, at least when they were dichotomized. That's why there's non-white, but as we

know, there are problems with the sample size and lumping all of the groups together.

So for this report I only ask that that be kept in mind when considering and interpreting the results, and certainly if there is future research to continue these good efforts you've started, we should try to get a much more diverse panel, perhaps even some more qualitative data analysis as well.

CHAIRMAN GROSS: John.

DR. COSTER: I just want to go back to the comment before Stephanie's, and again, this is an issue that I think you should address to the database companies that speak later, but there was, in fact, mergers and acquisitions going on in the marketplace. I don't know to what extent the leaflets that were collected reflected all of that happening in 2001.

There used to be a short form, as I said before which was discontinued in April of 2000. Whether the systems were still using the short form is another issue.

I didn't know there were three versions of this particular vendor's information, but I think that that is an issue that is worth exploring, whether or not those things happening in the market, in fact, affected the information that was collected.

DR. SVARSTAD: I think, if I may --

CHAIRMAN GROSS: Please.

DR. SVARSTAD: -- I think that the abbreviated monograph, we did not see that. However, we did see, as I noted, about 17 cases where they were just printing out the patient counseling message and rather than the full monograph, just to answer your question.

DR. COSTER: I think though, and this is something that you should address to the database companies, there may have been a patient counseling message. There may have been a short form, and there may have been a long form.

And I don't know if the database companies produce the counseling messages as well or if they are produced by, you know, other entities.

DR. SVARSTAD: Vendor 1 and the versions under Vendor 1 include both the patient counseling message, which is short, and the full monograph. They're called somewhat different things, as I understand it.

CHAIRMAN GROSS: Okay. Thank you all very much.

It has been an excellent session this morning. We will now adjourn for lunch and reconvene

shortly after one.

(Whereupon, at 12:15 p.m., the meeting was recessed for lunch, to reconvene at 1:00 p.m., the same day.)

AFTERNOON SESSION

(1:11 p.m.)

CHAIRMAN GROSS: Good afternoon, everybody. Thank you for all coming back.

We're going to proceed now with the open public hearing, and I'd like to ask Dr. Ratto, Dr. McEvoy, Donna Storey, Thomas Menighan, Ray Bullman, and Dr. Sasich to please come up to the front.

I guess most of you are already here, and Tish Pahl.

Now, with respect to all of the other participants, we ask in the interest of fairness that the people how are about to speak address any current or previous financial involvement with any firm whose product they may wish to comment on.

The first speaker is Dr. Nicholas Ratto, manager of Consumer Drug Information Group with First DataBank, the knowledge inside in San Bruno, California, and he has up to seven minutes.

DR. RATTO: Thank you.

I wanted to give a couple of quick highlights on my background. It's very similar to the clinical pharmacists at First DataBank.

Earlier in my career I practiced in a number of health care settings, including acute and

ambulatory care. My responsibilities included direct patient care in pharmacist operated triage, diabetes and anti-coagulation clinics during my 11 years in the VA system, as well as direct participation on medical and infectious disease teams.

Consequently I've personally counseled many hundreds of patients, as have my colleagues.

The written patient education survey that Bonnie reviewed earlier utilizes a scoring document which we consider to be valid, though we do take issue with a few of the criteria on each individual drug surveyed.

We also suggest that in future surveys selected authoritative, secondary references, such as the HSF drug information reference source, be utilized in conjunction with the professional labeling.

As an example, we discovered a labeling reference to, quote, unquote, reaction to allergy shots for atenolol that did not have any literature information backing it up, as per a Medline search.

The conclusion regarding the survey is that we -- and that includes all that are involved in written patient education, including the meg. guide system through FDA, have work to do regarding overall quality improvement. I think that's clear.

First DataBank has, in fact, developed a clinically well substantiated and field tested, thorough editorial policy and procedure for patient education. We will compare that to the scoring guidelines that came through the recent survey as well for any additional updates.

We are in the process of reviewing the 2000 monographs for full compliance with this particular policy that we have in place at this time, given that that policy has evolved over time as requirements for patient education have evolved over the last ten to 12 years, and also the number of monographs involved.

There are those inside and outside of FDA that would tout the FDA approved med. guides as the best solution to this quality issue that we face. However, I do want to point out that even the med. guides are not fully action plan compliant.

For example, I performed a cursory review of Ziagen, which is abacavir, med. guide, and found that while it contained a considerable amount of useful risk information, it did lack any advice related to to other medications being taken, and did not give advice regarding suspected overdoses or storage information, along with a couple other areas, and only partially met criteria for missed dose advice, as well as

information about keeping it away from children, et cetera.

Now, my point here, please do not misunderstand. My point here is not to criticize FDA or deflect the discussion away from First DataBank or any other provider, but merely to demonstrate that as was stated earlier, no written document is idea at this time.

Those that tout the FDA approved med. guides and the routine distribution of the professional FDA approved labeling to patients -- and I emphasize the word "routine distribution" -- are highly skewed towards the risks of drug therapy.

Again, don't misunderstand me. Provision of risk information is entirely appropriate and necessary.

Distribution of the professional labeling to selected patients at the discretion of the pharmacist or physician is appropriate, however, not at the expense of quality of life and benefit information.

And I'm not really speaking about the benefit noted in the survey criterion which deals with maximizing drug effectiveness. I'm basically discussing quality of life.

A majority of patients in my experience and

informally corroborated by conversations with colleagues that may include David Blair, who is a past NCPIE Communicator of the Year honoree; most patients do not have either the formal education or the medical knowledge to put risk information into proper perspective without direct assistance from a health care professional.

For example, these patients, upon reading of the risk of death due to rhabdomyalysis (phonetic) from the cholesterol lowering statin drugs may frequently refuse to take the medication. This could result, of course, in a negative impact on quality of life. The patient, for example, may suffer a premature or preventable major cardiovascular event, such as a myocardial infarction.

This insidious problem of noncompliance is frequently not adequately addressed given the difficulty of characterizing or tracking it. Studies already show that medication compliance rates are in the 50 percent range, which is an unacceptably low number in our opinion.

The risk information does need to be communicated. There's no question about that, but along with benefit information. For example, in our monographs, we explicitly state that statins help

prevent heart attacks and strokes. When the indication is made of a possible fatal outcome for a drug, we note the incidence of that potential fatality by saying that it's either rare or infrequent, depending on what the literature supports.

This gives the patient a more balanced picture of risk and benefit. Non-clinicians or ex clinicians may tend to lose sight of these critical issues in the zeal to fully inform a patient.

First DataBank's clinical pharmacist staff is solely interested in assisting health care customers in improving patient care. Furthermore, we believe that no written document can ever fully substitute for a personal interaction with a professional. Every patient is unique, and each has their own knowledge base, misconceptions, biases or barriers to communication.

The health care professional lends crucial perspective and individualized advice to the patient which cannot be capsulized in any leaflet. The written patient education material is an essential component of this process, but inherently never can stand alone if your goal is a fully educated patient.

Efforts must be made to utilize the proven methods of freeing up pharmacists' time to counsel

patients, such as automation aids and use of certified pharmacy technicians.

In conclusion, I reiterate our proposal to FDA for ongoing periodic dialogue and feedback related to our written patient education information. The purpose would be to address quality issues, and I suggest this would best be accomplished in cooperation with some of the clinician members of Dr. Svarstad's group whereby constructive interchange would occur regarding content and format of monographs.

Perhaps as appropriate, the action plan or scoring guideline sheet criteria may be revisited in the future, which was actually mentioned earlier as well by a previous speaker.

Other drug information providers and various stakeholders would be welcome in the discussion as well.

CHAIRMAN GROSS: Thank you very much.

The next speaker is Dr. Gerald McEvoy, Assistant Vice President for Drug Information of the American Society of Health System Pharmacists.

DR. McEVOY: Good afternoon. The American Society of Health System Pharmacists appreciates the opportunity to provide comments to this committee.

My presentation has not been paid for by any

organization or pharmaceutical company. ASHP does receive monies from external organizations through their purchase of advertising in our journal, leasing of exhibit space at our annual conventions, and through corporate sponsorship, which is wholly disclosed to participants of selected continuing education related publications.

ASHP is a 30,000 member national pharmacy association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems.

ASHP has a long history of medication error prevention efforts, and we believe that the mission of pharmacist is to help people make the best use of their medicines. Assisting pharmacists in fulfilling this mission is ASHP's primary objective.

The society has extensive publishing and educational programs designed to help members improve their professional practice, and it is the national accrediting organization for pharmacy residency and pharmacy technician training programs.

ASHP believes that private sector publishers, including professional associations like us, must play an important role in the creation and

dissemination of useful medication information. ASHP has long been an advocate of the role of pharmacists in providing useful written and oral counseling to patient about their medications, and we have a 25-year history of publishing medication information intended to educating patients about their drug therapy.

ASHP was a member of the Keystone Group, and was one of the first private sector publishers to incorporate the guidelines of their 1996 action plan for criteria, goals, layout, and language on useful prescription information in its patient resources.

I might mention that that effort took us about two years to complete. We began it in 1997 and completed it in 1998.

ASHP applauds the progress made by community pharmacies in voluntarily providing written information on prescription drugs. The results of the study clearly indicate that gains have been made in that regard in terms of the numbers of patients who are receiving such written information. Almost 90 percent of them in this study did, and that compares with figures of around 55 to 64 percent in surveys that were conducted in the mid-1990s.

While this certainly is a laudable achievement, we also recognize that continued

attention to improving the usefulness of this information remains important, as reflected in widely variable scoring of the information quality, particularly regarding the risks of treatment.

However, as acknowledged in the 1996 action plan, it is expected that as the plan is implemented, additional information will be gained regarding what constitutes useful, and that any associated guidelines should be subject to periodic review, evaluation and refinement.

Therefore, ASHP believes that the current study should be viewed principally as a further refinement of the definition of useful rather than as an indictment of the current voluntary efforts. In fact, careful inspection of the criteria used in the current report indicates that usefulness was defined in many cases by criteria that were not specifically enumerated in the 1996 action plan.

For example, the plan does not specify the inclusion of pharmacologic therapeutic class information as a component of what is considered sufficiently specific and comprehensive. Yet this weighs heavily in the current report findings where three out of eight subcriteria used to measure this component in the glyburide information are about the

provision of pharmacologic therapeutic information.

Another example is the specific inclusion of a statement that atorvastatin is an HMG-CoA reductase inhibitor, a very cumbersome class designation that probably has very little meaning to patients relative to the more commonly used term, "statins."

The source and rationale for some criteria also are unclear. for example, the origins of a precaution about kidney disease and atorvastatin; the eight-hour missed dose window specified for atenolol, atorvastatin and glyburide.

The reason that I bring up these examples is that we as publishers need to be part of the process. We need to understand the basis of these statements because they are going to be applied as yardsticks for our information.

In the spirit of the action plan regarding the evolving nature of the definition of usefulness, what seems most important is that criteria that will be used in judging the usefulness of written consumer information should be widely agreed upon and circulated to both public and private publishers so that they will be fully aware of the yardsticks against which their information will be measured.

In doing so, however, it is important that

FDA also not lose sight of the goal of the action plan that some flexibility in content be allowed.

Missing from the current report are recommendations on how to further improve the usefulness of this information. Therefore, ASHP recommends that FDA solicit advice in the form of an advisory panel of experts and public and private sector stakeholders regarding further refinement of the definition of usefulness and the associated specific criteria that will be used in evaluating adherence to this definition.

The panel also should recommend mechanisms for insuring that publishers and providers of consumer medication information are fully advised about such ongoing developments to that appropriate changes can be implemented in their data.

Likewise attention should be given to possible implementation of other recommendations included in the action plan. As part of this strategy, the advisory panel should be charged with identifying priority areas and interventions for improving the usefulness of this information and should provide advice on possible interventions in the development and distribution of the information.

ASHP strongly believes that the proper

course for FDA is to defer regulatory action at this time while pharmacy organizations and private sector medication information publishers and providers maintain their commitment to improve the usefulness of information that is provided to 95 percent of patients by 2006.

As part of ASHP's commitment to the mission of pharmacists for helping patients make the best use of their medications, the society will continue to follow the findings of and make recommendations to FDA and other groups, as well as make appropriate enhancements to its patient medication information aimed at improving usefulness.

In addition, ASHP remains ready to assist the FDA in further implementing the recommendations of the 1996 action plan both as a professional pharmacy association and publisher, and in serving any formal advisory capacity the agency pursues in this regard.

Thank you.

CHAIRMAN GROSS: Thank you very much.

Donna Storey is next, and she has a personal story to relate to us.

DR. STOREY: Thank you for the opportunity to speak here today.

My mother, Monica George, died of Rezulin

induced liver failure in September 1998. She is one of the 66 Rezulin fatalities officially acknowledged by the FDA.

I understand that this committee was created, in part, as a result of an FDA report on lessons learned from the handling of the Rezulin fiasco. However, I was very concerned to discover that one member of this committee recently appeared as an expert witness for Warner-Lambert in a Rezulin trial here in Rockville involving my mother's case.

In his testimony, he described Rezulin as a success story and a model case. He also stated that from the public health point of view, there was no reason to recommend monitoring liver functions the first year the drug was on the market because that could lead to warning fatigue.

Rezulin may, indeed, be the model for how things do work, but should this be your model for future drugs?

The Rezulin story begins with the very troubling circumstances under which the drug was approved. For further information, this has been well documented by David Willman in his series of articles on Rezulin in the L.A. Times.

However, in keeping with today's topic, I'll

focus on what happened after the drug was on the market.

As reports of serious liver events began to come in only months after approval, the FDA and the drug's maker, Warner-Lambert, responded by sending "Dear Doctor" letters calling for increased liver monitoring. It took almost two years for a black box warning to reach the PDR.

The question is: how much of this information reached the patients already taking Rezulin?

I believe that the answer is very little, indeed. In fact, it reached few doctors. Some of the country's most prominent hepatologists who treated my mother were woefully ignorant of the mounting evidence of Rezulin's toxicity to the liver.

Most troubling was the FDA's reaction to the death of Audrey Jones and Rosa Delia Valenzuela, two patients involved in clinical trials of Rezulin. Both women suffered liver failure in spite of strict monitoring, their liver enzymes rising precipitously only weeks after normal results.

Although this was a clear indication that liver monitoring was not effective, the FDA never made any public comment on these cases.

My mother began taking Rezulin in November 1997 based on information her doctor received months before from a company salesman. The doctor stated under oath that he did not read "Dear Doctor" letters.

Would my mother, a registered nurse, have stopped taking Rezulin if she had known of the growing number of reported liver problems?

Although I'm confident the answer is yes, the real point today is that she was never given the choice. The current system penalizes patients who begin a new drug early on, in essence putting them in the position of unwitting participants in a poorly controlled clinical trial.

As a consumer, I have a few suggestions for improving this situation. When the safety profile of any drug changes, this information should immediately be made available in plain language a part of the patient information leaflet we're talking about here when the prescription is refilled.

These changes should be highlighted prominently, in red, for example, at the top of the page and dated. And I'd also recommend a consultation with the pharmacist should be required.

I also suggest that a newly approved drug, especially one approved on the fast track, be

identified as such on the label, including a caution that the complete safety profile is not yet known.

And it's also vital to make the reporting of adverse events not voluntary, but really mandatory for health care professionals so that we can build an accurate safety profile in the first place.

I know that some argue this kind of disclosure would only frighten patients, but we really should consider who is being protected when this information is withheld.

Doctors are spared phone calls from worried patients, but any physician or pharmacist who truly values patient welfare should at least be willing to answer a few questions about medication and reevaluate the risk-benefit tradeoff for an individual patient.

Drug companies have also fiercely resisted changes of this sort.

I'd like to return to the Rezulin example for a moment. Three weeks before my mother died in indescribable agony Warner-Lambert held a party. This is the flyer for it. "Celebrate Rezulin at the Billion Dollar Bash. It's Become a Blockbuster Drug."

This demonstrates the enormous benefits to drug companies if concerns about warning fatigue override concerns about safety. Rezulin would never

have earned a total of $2.1 billion if it had only been prescribed to the relatively small population of insulin dependent Type II diabetics who did not respond well to other therapies. For these patients, the benefit was clearly worth the risk.

It was never worth the risk for a mild diabetic like my mother, who was in good health and had a hemoglobin A1c of seven before she began taking this so-called miracle drug.

Yes, all drugs have risks, but unfortunately, in the current environment where efficacy is misleadingly determined by surrogate endpoints, adverse side effects are consistently downplayed and profit is valued over human life to the point that some drug companies offer to indemnify doctors who are sued for prescribing their drug, as Warner-Lambert did with Rezulin.

All of the risk falls on the patient, all the more so if we are denied access to crucial information.

As I've done more research about drug safety in the aftermath of my mother's death, I've been horrified to learn that the Rezulin model has, in fact, been repeated over and over again in the past ten years. No one seems to be learning anything.

As members of the Drug Safety and Risk Management Advisory Committee, you are in a unique position of power. You can keep using Rezulin as a model of how things should be done. You can keep information from patients and provide political cover for FDA missteps.

You can use your appointment to this committee to make extra income serving as an expert witness for pharmaceutical companies or you can see Rezulin as a cautionary tale. You can advise the FDA to enact changes that will inform and thereby protect consumers.

I urge you to use your influence to address the serious systemic problems with the safety of prescription drugs so that American consumers who take an FDA approved drug need no longer wonder if they take their lives in their hands.

I would also like to submit for the record the transcript of Dr. Brian Strom's testimony from January 28th, 2002 in the case Andrea Shaw, et al, v. Warner-Lambert, Parke Davis.

Thank you.

CHAIRMAN GROSS: Thank you, Dr. Storey.

Next is Thomas Menighan, immediate past President of the American Pharmaceutical Association.

MR. MENIGHAN: Good afternoon. Thank you for the opportunity to present the views of the nation's pharmacists.

I'm Tom Menighan, a long time community pharmacist and home infusion practitioner. For the last two years, I've been involved in the provision of health information and communication capabilities to consumers and pharmacists via the Internet.

I am immediate past President of APhA and today am appearing on behalf of more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians.

We frequently partner with groups to develop educational materials for pharmacists and consumers. However, we did not receive any funding today to participate,a nd I am representing solely our members and our association.

We applaud the FDA for stimulating and our pharmacist members for providing written materials to consumer. Yet as evidenced in the evaluation of written information provided, the December 2001 report, many challenges remain.

The biggest challenge, however, is not in making written information useful. Rather, it's getting written information actually used by

consumers.

For those of you who sat in the restaurant next door at lunchtime, an alarm went off. I looked around the room, and I noticed nobody responded. Nobody got up. Nobody changed what they were doing. They went about their business.

I tell you; I submit to you alarms go off all day long every day in our lives, and we've learned to ignore them. There's to much noise out there. Absent someone saying directly to you as an individual, "This is important. Pay attention," most people won't.

To insure the safe and effective use, pharmacists help patients manage their medications with oral consultation, written information, and increasingly other services. Written CMI, the subject of today's meeting, is one method to provide patients with information on proper use.

We support the provision of better information, including written CMI, about drug therapy. Our profession has made great strides in this area, as suggested by other speakers and recent reports.

However, the results of the study also show that the quality of information distributed varies and

did not meet the criteria for usefulness 100 percent of the time. While we agree that CMI can be improved, determination of specific inefficiencies and the outcomes of change will require continued research.

One very concrete way of gaining improvements would be, as suggested previously, to more broadly publish the criteria used in the study and then to challenge vendors and publishers to meet or exceed the criteria.

Yet no matter how well patient information is written, it's useless unless patients use it. Written information is an adjunct for communicating to patients. The primary mechanism continues to be one-on-one encounters between health care professionals and patients so that new information can be factored together with their routine.

This is especially true for older patients with multiple chronic medicines and confusing therapeutic regimens. Written information can support and enhance medication therapy management services, but written information alone without accompanying oral consultation is insufficient to meet the needs of consumers and will do little to improve patient comprehension and compliance.

Without the pharmacist emphasizing the

importance of written information to individuals, we risk patients throwing it away just like junk mail.

Customization, not standardization, is part of the answer. It's important to note that CMI developers should be encouraged to improve the quality of patient information, and that criteria for evaluation should be publicized. APHA will not support government regulations that would specify the content, precise language or the specific design of CMI.

Patient information must be tailored to each patient and used to supplement information provided by the pharmacist and other health professionals. Attempts to standardize the content would reduce our ability to provide information specific to the particular drug and the particular patient.

We should, instead, foster innovation that takes full advantage of technology, pharmacists' knowledge of their patients to create better educational experiences for consumers.

Regulation may unintentionally hamper our ability to provide customized information to individual patients. If encouraged, consumers will ask questions that bring the written information into their consciousness and lead to improved care. The

ability to customize that information is key.

Vendors who have written information should be encouraged to keep that information contemporary. Information and relative weights of various components that should be communicated to patients will vary for each product.

For example, proper storage instructions are more important for products subject to degradation, such as antibiotics that are reconstituted at the pharmacy.

For other products, such as solids, storage conditions may be less important. A patient with asthma on multiple drugs will be more interested in information on interactions and dosage adjustments to maintain proper care.

We understand the agency recognizes progress made in distributing patient information and is not moving to regulate CMI at this time. We strongly support the FDA's efforts to improve appropriate use of medications through patient education activities, and we are committed to providing and improving educational efforts of pharmacists with their patients.

In summary, the nation's pharmacists urge FDA to, one, continue promoting the voluntary

distribution of written CMI as an adjunct to oral counseling.

Two, publish criteria to help vendors shape CMI for pharmacy management systems while allowing for innovation to customize and meet individual patient needs.

Three, encourage increased use as well as the usefulness of written information through support of medication therapy management services.

Thank you for your consideration of our views.

CHAIRMAN GROSS: Thank you, Mr. Menighan.

Next is Ray Bullman, Executive Vice President of the National Council on Patient Information and Education.

MR. BULLMAN: Thank you.

My name is Ray Bullman. I'm the Executive Vice President of the National Council on Patient Information and Education, a nonprofit coalition of 135 organizations whose mission is to stimulate and improve communication of information on appropriate use of medicines.

As such, NCPIE served on the Keystone Committee in 1996 to develop the action plan for the provision of useful prescription medicine information.

My presentation today is not supported by any external organization or pharmaceutical company. NCPIE does accept unrestricted educational grant support from pharmaceutical manufacturers and foundations.

Also, please note that the following comments do not necessarily represent the opinion of all members of our coalition.

A review of initiatives to improve consumer medicine information is important to appreciate the historical perspective in which the advisory committee will make its recommendations. Many of these were mentioned by Tom McGinnis this morning. I would like to add to his comprehensive presentation the following.

One, the Omnibus Budget Reconciliation Act of 1990, or OBRA '90, which mandated that pharmacists extend an offer to counsel Medicaid recipients about their prescription medicine, subsequent to implementation of this federal provision in 1992, nearly all states amended their Pharmacy Practice Acts to extend the offer to counsel to non-Medicaid customers as well.

Two, Health People 2000 and Healthy People 2010, both address prescriber and pharmacist

counseling, communication about medicine's appropriate use and potential risks, and quality of written medicine information.

Three, "To Err Is Human," released by the Institute of Medicine November 1999, which focused national attention on the magnitude and impact of medication errors, especially in hospitals. The report has stimulated an unprecedented level of programming, collaboration, and research to understand and eliminate avoidable medication errors.

Additionally, ongoing national outreach campaigns, such as FDA's own Take Time to Care initiative, and NCPIE's talk about Prescriptions Month, National Brown Bag Medicine Review Program, and most recently Be MedWise, launched in January of this year continue to stimulate and reinforce the need for quality medicine communication between consumers and health care providers.

A key element of each of these campaigns is that CMI is most effective when it features high quality oral counseling with supplemental written information that is mediated by the health care provider.

It is only with the full commitment of all health care professionals to actually talk with

patients about prescriptions in a meaningful way that patients will understand the possible risks and realize their medicine's full benefits through enhanced CMI.

I recommend a CMI research agenda that includes the following issues:

Number one, how much information is too much? For those prescription medicines that require medication guides, do we know their effect on patient understanding of possible risks?

Do we know the extent to which the medication guides contribute to appropriate use?

Do we know how medication guides have affected patient adherence and health outcomes?

Number two, what effect does a simplified format for CMI have on safe medication practices? For example, what post marketing research is being done or considered on the new drug facts label now required on most nonprescription medicines?

Number three, focusing, for example, on the five or six prescription medicines most commonly prescribed and used by persons age 65 and older and considering different formats for and quantity of information conveyed on pharmacy generated leaflets; different types of follow-up contact from physicians,

pharmacists, nurse prescribers, and physician assistants with various time frames of starting a new prescription.

Number four, advice to use one pharmacy for all your medicines and complete the patient profile form are common suggestions to promote safe medicine use. What percent of patients age 65 and older have such forms on file at their local pharmacy? Are these patients asked each time they come in for a new prescription to fill out and/or update their form? Are patients routinely asked about OTCs and dietary supplements they may be using so that this information can be added to the profile?

Number five, much attention has been focused on adoption of computerized physician order entry systems primarily in hospitals as a way to reduce medication errors. While the advent of PDA technology has made this an option for ambulatory care settings as well, implementation to date is extremely limited.

In the year 2000, Dr. Susanna Bedell cited discrepancies of up to 75 percent in reported versus recorded medications. Dr. Bedell's research was conducted in physicians' offices.

What if community pharmacies sent a copy of high risk patient's profile forms to each of the

prescribing physicians? To what degree could such technologically enhanced pharmacy prescriber communication improve CMI overall?

Finally, the research findings reported by Dr. Svarstad today serve as an important baseline from which subsequent improvements in CMI can be measured. I suggest that FDA reevaluate CMI in conjunction with the mid-course review of Health People 2010.

I would also suggest that further assessments include CMI offered via the Internet. There are far more drug information purveyors offering CMI on line directly to consumers than there are those that provide CMI databases to retail community based pharmacy.

Such a schedule would place the reevaluation in 2005 to then be repeated at the end of the decade. This is a logical approach and time frame to support FDA's role as the lead federal agency for monitoring progress to meet the Health People 2010 drug safety objectives, two of which are to increase the proportion of patients receiving information that meets guidelines for usefulness when their prescriptions are dispensed, and secondly, to increase the proportion of patients who receive verbal counseling from prescribers and pharmacists on

appropriate use and potential risks of medications.

NCPIE remains committed to working to insure that consumers receive useful information about their prescription medicines.

Thank you very much.

CHAIRMAN GROSS: Thank you, Mr. Bullman.

Next is Dr. Larry Sasich, who represents the Public Citizens Health Research Group.

DR. SASICH: Thank you very much for this opportunity.

My name is Larry Sasich. I'm with Public Citizens Health Research Group in Washington, D.C., and neither the organization nor myself have any conflicts of interest that would bear on today's meeting.

The Food and Drug Administration's characterization of the results presented here today in the 2001 evaluation as showing a private sector making progress and meeting the goals of providing the public with useful written prescription information is disgraceful.

Likewise, the finding that the overwhelming majority of pharmacy generated leaflets adhered fully to the criteria of being scientifically accurate is appalling and is apparently a failure of the studies'

authors in the FDA to understand the definition of scientifically accurate, as defined in the 1996 action plan.

The action plan is the basis for the evaluation of the quality of written information being distributed to consumers by pharmacists and was agreed to by commercial information vendors, trade lobbies representing pharmacy and medicine and consumer groups. There was nothing unknown to the people who are now producing unregulated commercial information vendors. They were all at the table. They knew what the rules were years ago.

If the Food and Drug Administration and the study's authors had adhered to the action plan, their conclusion would have been simple. No prescription drug consumer that gets one of these patient information leaflets is receiving written drug information that meets minimum acceptable quality standards of the action plan.

The action plan criteria are minimum. They're a floor.

Public Citizen was a member of the Steering Committee that negotiated the action plan in December of 1996, and the plan is very clear as to what constitutes acceptable information that will count

towards the quantitative goal of 75 percent of consumers receiving useful drug information.

Page 16 of the action plan states only written information that is useful will count towards the quantitative goals of the plan, and to go back a little bit, Public Law 104-180 was enacted in 1995 and led to the action plan. This law required the action plan to achieve goals consistent with the goals of the FDA's 1995 proposed medication guide rule.

The agency's stated standard for the termination of information usefulness was each sample of patient information leaflet will be scored on each criterion using acceptable and not acceptable cutoff points. FDA believes that for a particular information sheet to be judged as acceptable overall, it must receive an acceptable rating on each of the individual components.

During the highly contentious debate that resulted in the action plan, partial credit was not envisioned, discussed or agreed to by the Steering Committee for patient information leaflets distributed by pharmacists. It is impossible to comprehend any usefulness for patient safety information that on average contains only 50 percent of the minimum required information as documented in the FDA's 2001

evaluation.

In fact, safety information that is incomplete is misleading and potentially danger and some information is not better than none at all. Please read the short vignette at the beginning of our written comments about seven year old Cory Christian (phonetic) and what happens when parents rely on information that is incomplete handed to them by a health care provider.

Since the FDA's resurrection of the 1995 medication guide rule of the 1979 proposed rule to require patient package inserts, or PPIs, based primarily on a drug's approved product labeling, this has been a theme that goes back to 1979. Consumers and the agency have been looking for the information that's contained in professional product labeling.

There have been at least five surveys or systematic examinations of the quality of patient information leaflets distributed by pharmacists. In 1995, the agency examined the adequacy of written drug information produced by eight commercial information vendors.

For example, none of the vendors mentioned the contraindication for the use of enalapril when allergic reactions or angioedema occurred during

previous treatment with similar drugs. This is potentially life saving information for patients.

A study published in April 1996 assessed whether 50 Washington, D.C. area pharmacies would simultaneously dispense prescriptions for the potentially life threatening combination of urethramycin (phonetic) and the antihistamine terfenadine, which has since come off the market.

In May 1993, patient labeling was added to terfenadine's professional product labeling. This information specifically warned in upper case, bold letters not to use terfenadine with urethramycin. Patients were also warned that this interaction could cause death.

The FDA's and the manufacturer's expectations were that this information would be provided to patients by pharmacists. Some commercial information vendors voluntarily chose not to include this information in their leaflets, and pharmacists voluntarily chose to dispense unregulated patient information leaflets that omitted life saving information rather than distributing FDA approved patient labeling for terfenadine that warned of the urethramycin drug interaction.

Public Citizen obtained patient information

leaflets for 15 different nonsteroidal anti-inflammatory drugs in April 1997 distributed by community pharmacists. A total of 59 leaflets produced by four commercial information vendors were evaluated using four criteria based on the 1995 proposed medication guide rule. None of the private sector leaflets met the criteria.

In a study conducted by Private Citizen conducted in April 1998, 15 licensed pharmacists evaluated the PILs for five fluoroquinolone antibiotics produced by four unregulated commercial information vendors according to the scientific accuracy criteria of the action plan. The information content of these patient information leaflets was not satisfactory to meet the scientific accuracy criteria of the action plan.

Public Citizen commented on the methodologic inadequacy of the FDA's 2000 survey. Despite the shortcomings of this FDA funded survey, only 12.5 percent of pills distributed with the drug ibuprofen informed consumers of the drug's contraindications and only 5.3 percent included the specific precautions, their significance and how consumers could avoid harm.

Rather than demonstrating progress, as the FDA seems to believe, the private sector has shown a

consistent inability over the years to produce useful drug information according to agreed upon guidelines.

The authors of the 2001 evaluation, as they did in their 2000 survey, failed to comprehend the action plan's simple definition of scientifically accurate: information consistent with or derived from FDA approved labeling.

The private sector leaflet for nitroglycerine is one example of a lack of accuracy found in these leaflets. There are others that are in our written testimony.

The professional product labeling for nitroglycerine clearly indicates the use of this drug with sildenafil together as contraindicated. These leaflets were evaluated for containing the subcriteria about the use of nitroglycerine in combination with sildenafil.

Only 32.7 percent of these leaflets were fully compliant. Unbelievably, 99.1 percent of the leaflets were found to be scientifically accurate.

The private sector leaflets omitted the majority of important safety information for consumers that is available in these drugs' professional product labeling. The FDA and the authors of the 2001 evaluation are negligent in portraying to the public

that the majority of these leaflets are scientifically accurate.

We are now 22 years past the private sector's promise to develop a variety of systems that would meet the goals of the FDA's 1979 proposed rule that have required patient package inserts, or PPIs, for ten classes of prescription drugs.

Spearheaded by trade groups representing pharmacy in medicine, a lobbying effort was undertaken that caused the PPI regulation to be amongst the most controversial issued in the last months of the Carter administration. Needless to say, consumers favor the proposed PPI program.

The day after President Reagan's inauguration in 1998, the White House called the FDA to make it clear that the PPI regulation was not to be enforced. This would not be the last time that an elected representative of the people would attempt to prevent the public access to high quality written drug information.

On two occasions in the recent past, Michael Crapo of Idaho penned legislative language to prohibit the FDA form implementing the medication guide rule.

In 1982, the FDA officially rescinded the regulation in favor of a voluntary plan. Private

sector initiative commenced with the formation of the National Council on Patient Information and Education and the consistent failure of the private sector to deliver what was promised, culminating in the 2001 evaluation.

The failure of the private sector to meet the quality goals established in the action plan and thus, the failure to achieve the distribution goal of 75 percent of patients getting scientifically accurate information leaves only one option under Public Law 104-180, and I quote. "The Secretary," meaning the Secretary of Health and Human Services, "shall seek public comment on other initiatives that may be carried out to meet such goals."

We urge the Drug Safety and Risk Management Advisory Committee make a single recommendation to the FDA. The FDA should follow the process as defined in Public Law 104-180 and go forward as rapidly as possible with implementing the action plan by regulation. Giving the private sector a free ride until 2006 to meet the goals of the action plan would be irresponsible.

Thank you very much.

CHAIRMAN GROSS: Thank you, Dr. Sasich.

The last speaker for the public hearing

segment is Tish Pahl of Health Resources Publishing Company.

MS. PAHL: Good afternoon. My name is Tish Pahl of the law firm of Olsson, Frank and Weeda here in Washington, D.C.

I'm speaking today on behalf of Health Resource Publishing Company of St. Louis, Missouri.

It is likely that leaflets Health Resource publishes in retail pharmacies were reviewed in Dr. Svarstad's study.

Health Resource thanks the committee for the opportunity to present its views. Health Resource has already submitted its written comments to the committee. Today we wish to elaborate briefly upon that written comment.

Health Resource commends Drs. Svarstad and her colleagues for the enormous effort evident in the 2001 evaluation. Measuring something as nebulous and subjective as usefulness is a daunting task.

Health Resource provides prescription drug information to consumers as the retail pharmacy level. Health Resource publishes customized educational newsletters at the pharmacy that are given to the customer with his or her prescription. One section of the newsletter provides prescription drug information

that is intended to satisfy the useful information standards of Public Law 104-180 and the Keystone criteria set out in the action plan for the provision of useful prescription medicine information.

The Health Resource consumer medication information, or CMI, strives to be scientifically accurate, neutral, useful, and to be presented in a format that is easily understandable to consumers.

Qualified experts prepare the CMI. It is derived from authoritative references, such as FDA approved labeling. It is reviewed for completeness, accuracy, consumer comprehension, and is updated regularly.

Health Resource tries to get CMIs to a sixth grade reading level.

I will now turn to our brief substantive comments on the 2001 evaluation. First, the 2001 evaluation measures the usefulness of CMIs collected according to over 60 separate subcriteria for each drug. Many may not have anticipated that a CMI would be expected to contain this much information at this level of detail.

Health Resource repeats the call made earlier for greater, more open public discussion of the standards for setting the subcriteria that will

measure usefulness.

Second, in Health Resource's view, more information in a CMI must be balanced against the need for that information to be legible and comprehensible to consumers. Health Resource believes it would have been very difficult for a CMI to include all of the information that was expected in the evaluation on a single sheet of paper without also compromising comprehension and legibility.

The information is so extensive, it would have had to have spilled onto additional pages in order to be readable. Health Resource's experience is very consistent with that observed in the study. Pharmacies have been very resistant to expanding a CMI beyond a single page.

We believe there are several reasons for this resistance. The single biggest concern is work load and work flow. An additional page multiplied by hundreds or thousands of prescriptions is an enormous increase in cost and work for a typically short staffed pharmacy. With more pages floating around a busy pharmacy, errors may also be more likely.

Health Resource understands that pharmacies are already under pressure from vendors to increase the amount of information in a CMI. Even before the

2001 evaluation, Health Resource has seen CMIs in as small as five point type as pharmacies struggle to include the information, but still keep a CMI to a single page.

CMIs must include the level of detail expected in the 2001 evaluation. The issue of limited space and legibility within that space must also be addressed.

Finally, Health Resource is concerned that consumers will not read detailed risk information. Consumer fatigue with long winded risk information is evident in the consumer reaction to the brief summary requirement that must accompany most prescription drug promotion.

According to FDA's recently released data, 70 percent of consumer survey respondents read little or none of the brief summary. Fewer people are reading the brief summary now than they did three years ago. In Health Resource's view, written information no matter how useful is not going to be a substitute for the advice of a consumer's health care professional.

To this end, Health Resource believes that a CMI should concisely focus upon those side effects, warnings, contraindications and precautions that are

the most common and the most serious. The CMI should plainly state that it is not complete and that a consumer can obtain more information from his or her health care professional.

Thank you.

CHAIRMAN GROSS: Okay. Thank you very much.

That's the end of the public comment. The next speaker is Dr. Ruth Day from Duke University, who will give us a framework. The title of her talk is "Consumer Comprehension of Educational Material, Key Cognitive Principles."

DR. DAY: So the question is: how do consumers comprehend educational materials?

In order to answer this question, we need to consider a variety of key cognitive principles. Underlying those principles is the idea of cognitive accessibility.

Cognitive accessibility is the ease with which people, both consumers and professionals, can find, understand, remember, and use drug information and, of course, do so in a safe, effective, and efficient way.

So what are some of these cognitive principles? Well, there are too many to talk about today. I'm only going to focus on a few, but I would

like to mention that they have been studied in carefully controlled laboratory studies for many years, all of them at least a decade and some of them as long as 50 years. So there's considerable empirical support for these principles.

Information load. Obviously too much is not good. How much is too much? We'll come back to that in just a moment.

We can manage information load better by using other cognitive principles, such as chunking. Chunking involves putting together what goes together and separating it out from surrounding information.

We can further enhance people's ability to understand a chunk by helping out with coding, how they're going to code that information into their minds. An obvious way is to put a title or a subtitle in front of it. That enables people to then understand the information better and also remember it better later.

Representation deals with different types of formats that can be used for chunks of information. Some formats help and some hinder comprehension, and we need to pay attention to that.

Location is important as well. If, for example, we have a long list of items within a chunk,

such as side effects, it's very well documented that people will do better in processing the information at the beginning and the ends of the list, and they're going to miss the information in the middle.

So what can we do to enhance their processing of information throughout a list and other aspects of the leaflet?

Much has been said today about readability. There are objective measures, formulas for readability. There are many of them. However, they only do two things. They look at the length of sentences and they look at the familiarity of the works that are used. That's all they do, and that's where those measures of sixth grade level, eighth grade level, and so on come from.

There are many more things involved than comprehensibility. We need to take into account syntactic and semantic factors. For example, for syntactic, how complex is the grammar? So I can make up a sentence which is relatively short and it will do well in readability measures, but it could be so complex that it's hard to understand the information it contains.

Another measure in comprehensibility has to do with the number of idea units that are present.

These are what are called propositions. So how many propositions are there in some information and how densely is it packed?

Obviously attention is a very important principle, and there are many different types of attentional processes. How do we get people's attention? How do we get them to be able to direct it to some information when they need that and separate it out from other information, and so forth?

We want people to do a variety of cognitive tasks with these leaflets, not just read it over when they get them, but to do a variety of other tasks which I'll talk more about in a moment.

And metacognition is another concept that I will come back to.

So load. How much is too much? This is on a lot of people's minds. Typically when we think about load, we look at information load. So how many pages, how many words, how many inches, and so on?

But it isn't so much information load that's important as cognitive load. How much mental work has to be done in order to understand the information?

So we can look at the number of mental steps, their complexity, and so on, and in some cases we can even find that something that's a little bit

longer is easier to understand than something that's a little bit shorter, or vice versa.

So here's an example. This is an excerpt from a pharmacy leaflet. The source is at the bottom there, and it starts out, "Tell your doctor, nurse, and pharmacists if you," and then there's a whole bunch of contraindications, and so on.

So in the laboratory what we do is we show this type of information to people, and then we ask them questions about it either with the leaflet present or with it absent in order to test straight comprehension and memory.

The simplest question that you can ask as in any comprehension test, but a really simple warm-up question is: how many different things do you need to tell your health care provider before you use this information?

So you just saw that last display. How many different things were there, approximately?

Eight. Thank you, Tom.

Most people say seven or eight because of the bullet structure. Bullets are good, but a bullet is not a bullet is not a bullet. They can be used well or poorly.

This display shows that these bullets are

not being used very well, and if I add this red line here, you can see there's a tendency to chunk all of the text together in a box, and those little bullet dots are floating off to the side.

There are other ways to use bullets. Let's take this same example and show it in a revised format. Even if you can't see the details here, you can see very quickly that there has been chunking, put together what goes together; separate it from other things around it; give it titles; give it some coding.

And when you look at this, and bullets have been used in a different way as well, but when you look at this, you can see there's far more than the seven or eight bullets that there appear to be to begin with. As a matter of fact, there are 18.

So people can better process the information in some formats than in others. So let's talk now about cognitive tasks.

What do people do with these leaflets? What can we test in the lab? And what do we want them to do and do they do out in the real world?

First of all, do they read it? So in the lab we can find out with different kinds of leaflets do they read it; how much time they spend. Do they read the whole thing? What do they skip, and so