UNITED STATES OF AMERICA

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

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DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE

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MEETING

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WEDNESDAY,

JULY 17, 2002

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Original

The Advisory Committee met at 8:00 a.m in the Ballroom of the Holiday Inn Gaithersburg, Two Montgomery Village Avenue, Gaithersburg, Maryland, Dr. Peter A. Gross, Chairman, presiding.

PRESENT:

PETER A. GROSS, M.D.	Chairman
WILLIAM H. CAMPBELL, Ph.D.	Member
MICHAEL R. COHEN, R.Ph., MS, D.Sc.	Member
JOHN M. COSTER, Ph.D., R.Ph.	Guest Speaker
STEPHANIE Y. CRAWFORD, Ph.D.	Member
RUTH S. DAY, Ph.D.	Member
JACQUELINE S. GARDNER, Ph.D., M.P.H.,	Member

PRESENT (Continued):

SHARLEA M. LEATHERWOOD, R.Ph.	Guest Speaker
ARTHUR LEVIN, M.P.H.	Consumer Consultant
KAREN OSTER	Guest Speaker
BRIAN LESLIE STROM, M.D., M.P.H.	Member
JOHN T. SULLIVAN, Ph.D.	Industry Representative
BONNIE L. SVARSTAD, Ph.D.	Guest Speaker
THOMAS H. PEREZ, M.P.H., R.Ph.	Acting Executive Secretary

FDA REPRESENTATIVES:

THOMAS McGINNIS, R.Ph.

PAUL SELIGMAN, M.D.

ANNE TRONTELL, M.D., M.P.H.

PUBLIC SPEAKERS:

WM. RAY BULLMAN, M.A.M.

GERALD K. McEVOY, Pharm.D.

THOMAS MENIGHAN

TISH PAHL, J.D.

NICHOLAS RATTO, Pharm.D.

LARRY D. SASICH, Pharm.D., M.P.H

DONNA STOREY, Ph.D.

C O N T E N T S

P R O C E E D I N G S

(8:11 a.m.)

CHAIRMAN GROSS: Good morning. I'd like to call the meeting to order if everyone would please have a seat.

I'm Dr. Peter Gross. I'm Chair of the Drug Safety and Risk Management Advisory Committee.

And today we're going to address the issue of the components of the consumer medication information sheets. This is a discussion about it, not a regulatory affair.

So I'd like to turn the meeting over now to Tom Perez.

MR. PEREZ: Good morning. The following announcement addresses the issue of conflict of interest with respect to this meeting and is made part of the record to preclude even the appearance of such at this meeting.

The Food and Drug Administration has prepared a general matters waiver for Dr. Brian Strom, special government employee, which permits him to participate in today's discussion. A copy of this waiver statement may be obtained by submitting a written request to the agency's Freedom of Information Office, Room 12A30 of the Parklawn building.

The topic of today's meeting is an issue of broad applicability. Unlike issues before a committee in which a particular product is discussed, issues of broader applicability involve many industrial sponsors and academic institutions.

The committee members and invited guests have been screened for their financial interests as they may apply to the general topic at hand. Because the general topic impacts so many institutions, it is not prudent to recite all potential conflicts of interest as they apply to each participant.

FDA acknowledges that there may be potential conflicts of interest, but because of the general nature of the discussion before the committee, these potential conflicts are mitigated.

In addition, we would like to disclose that Dr. John Sullivan is the nonvoting guess industry representative on the committee. He is not a government employee, and hence, we do not screen him for conflicts of interest and can make no comments on his actual or perceived conflicts of interest.

In the event that the discussions involve any other products or firms not already on the agenda for which FDA participants have a financial interest, the participants' involvement and their exclusion will

be noted for the record.

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

Thank you.

CHAIRMAN GROSS: At this particular point, I'd like to introduce everyone to you. So we're going to start off at the table on the left here. If you would please introduce yourself.

MS. LEATHERWOOD: I'm Sharlea Leatherwood. I'm a pharmacist and owner of pharmacies in Kansas City, Missouri. I'm Chairman of the Executive Committee of the National Community Pharmacists Association.

MS. OSTER: I'm Karen Oster. I'm the Assistant to the Executive Director at the National Association of Boards of Pharmacy.

DR. COSTER: John Coster, Vice President of Federal and State Programs with the National Association of Chain Drug Stores.

DR. SVARSTAD: Bonnie Svarstad, professor of social pharmacy and sociology, University of Wisconsin, Madison.

DR. SULLIVAN: John Sullivan. I'm a

physician. I'm currently head of clinical pharmacology at Amgen, and I represent the Pharmaceutical Research and Manufacturers Association.

DR. COHEN: I'm Mike Cohen. I'm President of the Institute for Safe Medication Practices, and I'm a pharmacist.

DR. STROM: I'm Brian Strom. I'm a pharmacoepidemiologist at the University of Pennsylvania.

MR. PEREZ: Tom Perez, Acting Executive Secretary to this meeting.

CHAIRMAN GROSS: Peter Gross. I'm Chair of the Department of Internal Medicine at Hackensack University Medical Center in Northern New Jersey.

DR. CRAWFORD: Stephanie Crawford, University of Illinois at Chicago, College of Pharmacy. I'm a member of the Drug Safety and Risk Management Advisory Committee.

DR. CAMPBELL: Bill Campbell, Dean of the School of Pharmacy at the University of North Carolina, Chapel Hill.

DR. GARDNER: Jacqueline Gardner, Associate Professor, Department of Pharmacy, University of Washington in Seattle.

DR. DAY: Ruth Day, I'm at Duke University

and direct the Cognition Laboratory.

MR. LEVIN: Art Levin, Director of the Center for Medical Consumers. I'm the consumer representative on the Advisory Committee, and I was a member of the Keystone Steering Committee.

MR. McGINNIS: Tom McGinnis, Office of Policy, Food and Drug Administration.

DR. TRONTELL: Anne Trontell, Director of the Division of Surveillance, Research and Communications Support in the FDA Office of Drug Safety.

DR. SELIGMAN: Paul Seligman, Director of the Office of Pharmacoepidemiology and Statistical Science and Acting Director of the Office of Drug Safety, FDA.

CHAIRMAN GROSS: At this point I'd like to reintroduce you to Dr. Paul Seligman, Director of the Office of Pharmacoepidemiology and Statistical Science, who will give us a welcome and charge to the committee.

DR. SELIGMAN: Good morning. Welcome and charge.

(Laughter.)

DR. SELIGMAN: First of all, let me thank all of the members of the Advisory Committee this

morning for giving their time, effort, and expertise to address this important issue as well as our guest speakers and all of you in the audience who will be participating in today's meeting.

This is the first full, independent meeting of this Drug Safety and Risk Management Advisory Committee, and I can't think of a more interesting, appropriate, and timely topic for this committee to engage in.

I also wanted to take a brief moment to thank the members of the FDA staff who worked so hard to set up and develop this meeting and agenda, including Anne Trontell, Jeanine Best, Ellen Tabak, Kathleen Bongiovanni, Melodi McNeil, Tom McGinnis, Kimberly Topper, as well as others.

As mentioned, the focus of today's meeting is the information that consumer receive with prescription medications. FDA has long held that to achieve the greatest benefit and to maximize the safe use of prescription medications that the consumer needs accurate, clear, comprehensive information, and that communication of this information is vital.

To this end, the FDA regulates and reviews certain communication products, including the medication guide and the patient package insert, which

is required to be included in certain hormonal therapies, such as over-the-counter or -- excuse me -- such as oral contraceptives as well as other hormonal preparations that contain estrogens and hormonal replacement therapy.

In addition, the FDA regulates and reviews information produced by manufacturers and sponsors that are used for direct-to-consumer advertising.

By way of background today, we have four presentations. The first presentation will trace the history of the consumer drug information issue which has a long, interesting and stored history, and will trace us to where we are today.

Second, we will hear from representatives from the National Association of Chain Drug Stores, as well as the National Community Pharmacists Association, who will describe how the information that is contained in the FDA approved label is conveyed to consumers and how this information is developed and the flow of the information from the developer to the consumer.

Next we will hear about a study that was done that will review the progress in meeting both the year 2000 and 2006 goals, which are stated on the slide, that by the year 2000, 75 percent of all

consumers who received prescriptions receive useful information, and that this number increased to 95 percent by the year 2006.

And finally, to insure that communication with consumers is based on good evidence and scientific principles, we will hear about the sort of key cognitive principles and some of the research done on consumer comprehension of educational materials.

The scope of this meeting then is to focus on how to improve consumer information and how best to achieve the goals set for the year 2006 by Congress. We hope to engage in a discussion this afternoon on next steps that both the FDA and in collaboration with pharmacies and consumers can work to achieve these 2006 goals.

We have posed three classes of questions for the committee to consider. These include what additional analyses of the current data should be conducted. That would be most useful in addressing this question of how to make useful consumer information available patients.

Second, we will ask the committee to look at what additional research needs to be conducted to insure that the best evidence is used to improve patient medication information.

And finally, we will be asking our committee to provide us advice on what actions would improve consumer medication information to meet the 2006 goal.

As you will hear today, substantial progress has been made in many areas towards achieving the 2006 goals, but that there are still some areas where we need, I think, considerable amount of work.

The FDA believes that continues collaboration with consumers and the pharmacy profession and close monitoring of this process should lead to full compliance by 2006 with the goals identified by Congress.

With that, Mr. Chairman, I'd like to turn the meeting over to you and wish us all a successful meeting today.

Thank you very much.

CHAIRMAN GROSS: Thank you very much, Paul.

Next I'd like to introduce Tom McGinnis, who will present some background and the history of patient information efforts.

MR. McGINNIS: thank you, Mr. Chairman.

Over the next ten minutes, I'd like to go through 34 years of history of patient information at the Food and Drug Administration.

FDA started in the area of patient

information back in 1968, when the agency believed that consumers needed information on how to use isoproterenol inhalation products properly. Back at this time the only one conveying information to patients was the prescriber. It was unethical for a pharmacist to talk to patients about their medication.

It wasn't until 1969 that the American Pharmaceutical Association changed the code of ethics allowing pharmacists for the first time to communicate to patients about their prescription medications.

In 1970, FDA required for the first time patient package inserts for estrogen containing products. This was because the data and information on estrogens and oral contraceptives was changing very rapidly, and the agency believed consumers, women, needed this information and needed to be assured that this information was getting to women about these products.

This was done by notice and comment rulemaking, a formal procedure that is quite arduous in many cases.

In 1979, FDA embarked on a project with ten classes of drugs where the agency wanted to develop, have the industry develop and the agency approve, patient package inserts. There was a lot of

controversy on this project, particularly from medicine and pharmacy. The physician groups, again, wanted to be the only ones conveying information to the patient. There was concern that patients seeing adverse events on these products may actually develop these adverse events. Typical textbook type medicine reactions, and that they may even be concerned enough not to take the medication after seeing what possible side effects could occur.

The pharmacy profession had a problem with the paper that would be generated and pushed through the distribution system in the United States. Many pharmacy departments were very small and compact. It might require putting a file cabinet back there, which was not going to be doable in many pharmacies, and as that patient information changed, which it tends to do fairly rapidly, the pharmacists have to take the new information, get the old information out of that file cabinet to make sure that the patient did get timely and up-to-date information with their prescription drugs.

With that controversy, FDA withdrew that patient package insert proposal rule in 1982. At the same time, FDA set up an internal working group on patient information, and the private sector formed the

National Council on Patient Information and Education to foster this private sector initiative, and I believe you'll be hearing more about that later.

In 1991, FDA revisited this issue. We had done telephone surveys of patients beginning in 1982 when we wrote the proposed rule, and we found in 1991 that only 32 percent of patients were telling us that they were getting any type of written information when they picked up a prescription drug.

We took a look at some of these pieces of information that were being picked up at this time, and we found the information to be very variable. In some cases there were only a few bullets of information being given to patients. In other cases, there was a paragraph or information and no more, and yet in other cases, there was a full page or two full pages of information being given to patients that looked very comprehensive and useful.

FDA continued to encourage the voluntary efforts to provide patient information through the private sector initiatives, through articles and speeches by senior FDA officials.

On August 24th of 1995, FDA published the medication guide proposed rule mainly for drugs with serious and significant side effects. As I mentioned,

for FDA to mandate consumer information with a prescription drug, we had to go through formal notice and comment rule making, which was a tedious process. This essentially would eliminate that process when the agency believed a drug posed serious and significant side effects and consumers needed that information to possibly avoid those.

The proposed rule also allowed the private sector to continue with their efforts. However, the agency was getting concerned that the progress was not up to par. So the agency set some performance standards for the private sector, those being 75 percent of patients should be getting useful information with their prescription drugs by the year 2000, and that virtually everybody, 95 percent, should be getting this information by the year 2006.

FDA also proposed broad criteria what these things should look like in this proposed rule.

In 1996, FDA convened a public meeting like this one to discuss the private sector initiatives of the proposed rule and to clarify information on what would be required of the drug industry in the formal medication guide process.

There's still some controversy on whether the agency should embark on this process, and on

August 29th, Congress passed the law and the President signed it into effect, and that was Public Law 104-180. That public law directed the Secretary of Health and Human Services to facilitate development of a long-range action plan that meets the goals and objectives through private sector initiatives.

It gave the private sector an opportunity to meet distribution and quality standards of the plan that was to be developed, and it codified FDA's distribution and quality goals of 75 percent of patients receiving useful information by the year 2000 and 95 percent, virtually everybody, by 2006.

The secretary, in not wanting to have to review multiple plans and pick one plan that was submitted, immediately contracted with the Keystone Center. The Keystone Center was a nonprofit, consensus building alternative dispute resolution organization that was successful in the past in bringing together stakeholders with varying interests in coming to a consensus process. The statute only allowed 120 days to facilitate development of the action plan by interested stakeholders.

The Keystone Center selected 34 private sector organizations to develop this action plan. The government was not part of this process.

The action plan was collaboratively developed and accepted by the Secretary in January of 1997. The criteria to develop usefulness endorsed the broad criteria in the public law, and described eight specific criteria that should be met. It was consistent with the public law, and the plan called for periodic assessment of the quality of written information.

The eight criteria that were developed by this consensus building process were, first, the consumer should have the drug name and its indications for uses.

The consumer should see the contraindications and what to do if they experience one of those or have that particular condition and are accidentally prescribed this medication.

How to use the drug to get the most benefits out of the medication.

And precautions, how to avoid harmful side effects.

The fifth criteria was serious or frequent adverse reactions to expect and what to do about them.

The sixth was general information, encouragement of the consumer to ask questions of their physician and pharmacist.

The seventh was scientifically accurate and not promotional and up-to-date information should be conveyed to the consumer. This information was not to be promotional in any way.

And finally, the information needed to be comprehensible to the consumer. It needed to be legible and readable to those consumers with a sixth to eighth grade reading comprehension level.

In 1998, FDA contracted with the National Association of Board of Pharmacy to do a pilot study to see where we were, how we were and how were doing at the time. The State Boards of Pharmacy arranged with eight Boards of Pharmacy to collect this information and to provide the materials for review.

The contract called for development of a scoring instrument based on the eight Keystone criteria to assess the usefulness of this information.

In February we held a public meeting, again, like this one to discuss the results of the interim assessment. At that time deficiencies were still noted in the distribution and usefulness of information. Stakeholders were given feedback to the agency on the draft scoring instrument. Changes were made in that instrument to be used in the end of the year 2000 study, and we announced our plans to start

that study at the end of the year 2000.

In June, FDA renewed its contract with the National Association of the Boards of Pharmacy and the University of Wisconsin School of Pharmacy for the evaluation phase. The study was implemented in January of 2001, and throughout the year 2000 a professional shopping service was used to present four prescription drugs to over 300 pharmacies in the United States in order to make a national projection on how we were doing, and the results of that study will be presented to you shortly.

Thank you.

I'll take any questions that you might have.

CHAIRMAN GROSS: Thank you, Tom. That was a very nice review.

Does anyone have any questions, in particular, on the Keystone criteria or how we got to where we are today?

Michael?

DR. COHEN: Let me try to understand something because I'm just a little bit confused about some of the background material that I read. To meet the 2000 goal, was it just the written information that had to reach the 75 percent or the individual criteria had to meet the 75 percent level when

assessed or what?

And if it was the individual criteria, which ones had to meet the 75 percent?

(No response.)

MR. McGINNIS: All information picked up by the agency was scored against a scoring instrument that we'll hear a little bit about in the next presentation. That information then was evaluated and we'll see extensively how it was evaluated.

And then the final distribution levels -- and I hate to take Dr. Svarstad's thunder away in announcing those numbers right now -- were evaluated and presented to the agency in the final report that you're going to hear soon. So I want to defer that, Mike, until we hear Dr. Svarstad's presentation.

CHAIRMAN GROSS: Any other questions?

(No response.)

CHAIRMAN GROSS: If not, we're staying ahead of schedule here. Nothing wrong with that.

Thank you very much, Tom.

Next we're going to hear about the information development and flow from the developer to the consumer. Dr. John Coster and Sharlea Leatherwood will present.

Yes, Anne?

DR. TRONTELL: We might offer some clarification to the previous question about the criteria. The law itself describes numbers for what is termed "useful information," and that useful information was subsequently specified in the criteria that are going to be discussed and presented.

So the overall description and requirement was for what was termed useful and then operationalized, as we'll hear.

CHAIRMAN GROSS: Okay. Thank you, Anne.

Dr. Coster.

DR. COSTER: Thank you.

Mr. Chairman, members of the committee, we appreciate the opportunity to be here. I understand my role and that of Sharlea is to describe as best we know it the process by which information ultimately reaches the consumer, the written information that you will be discussing here today.

Just as background, NACDS represents approximately 33,000 community retail pharmacies. We have about 200 chain member companies. We fill about 70 percent of all out-patient retail prescriptions, and like Art, I was a member of the original Keystone committee that met what seems like decades ago, but back in 1997 to put together the action plan.

So my goal today is to give you our perspectives, our research on what we know happens in terms of the process by which consumers receive this written information.

First, let me start by saying that NACDS is strongly committed to working with FDA, consumers, and our member pharmacies to continue to make strides. I think we've made significant strides since 1997. FDA's own data indicates that the percent of consumers receiving written information has increased significantly over the last ten years, but we're equally concerned that the so-called quality goals are falling short, and we ourselves want to know why that is happening as well.

I may not have all the answers today for you, but I can tell you that we are working with our members and trying to provide as much quality written information to consumers as possible.

The provision of written information by pharmacies to consumers really began as a value added service. As you know, over '90, the Omnibus Budget Reconciliation Act of 1990 required that pharmacists offer to counsel Medicaid recipients on their prescriptions, and as a result of that, almost every state changed its practice laws to require that

pharmacists offer to counsel all recipients or all patients, for that matter, on their prescriptions.

The written information leaflets, I think, really started to generate after that as a leave behind for patients to help reinforce for them the oral counseling that they receive from their physician and their pharmacist.

We all know as consumers ourselves it's often difficult at times to remember everything we're told about a prescription either by our physician or by our pharmacist, and these leaflets really act as references for patients to refer back to something about the particular prescription medication.

We don't believe, however, that these information sheets cannot and should not be viewed as a substitute for the professional advice and counseling of health professionals.

In terms of how the process flows, the nuts and bolts of how information ultimately gets down to consumers, retail pharmacies do not produce this information on their own. We purchase it or, more accurately, we license it from the major database companies that produce it.

And due to recent consolidations in the marketplace, there are really only a few producers of

this information left in the marketplace. Our understanding, for example, is that First DataBank and Medi-Span provide the written information to the overwhelming majority of the retail pharmacy marketplace, but there are other providers of written prescription information.

For example, there's a company called Gold Standard, Micromedex, USP of course, and Facts and Comparisons. I can't tell you exactly what percent of the market these other companies have or which particular market they serve, but there are multiple providers, but there are only really a few left that provide written information to the retail marketplace.

They can talk, and I'm sure they will later, in greater detail about how they actually produce the information, but our understanding is that they rely on the FDA approved labeling, peer reviewed literature and other sources.

In talking to some of our members about this, on occasion a pharmacist will note that something is incorrect in the information that's provided and will notify the database company and ask that it be corrected.

So the database companies produce the written information. Then what happens to it?

Almost every pharmacy has an underlying software processing system, a prescription processing system or a software vendor, and that software system helps to manage prescription records, helps to check for adverse reactions, produces labels, and interacts with what's known as a switch to help adjudicate and process claims.

These systems have greatly enhanced the efficiency of the prescription delivery process and have helped to improve the quality of care provided to patients by providing real time information to pharmacies.

So the database companies produce the information. Then it flows down to intermediaries' software vendors, and these software vendors then take this written information and incorporate it into the pharmacy's underlying prescription processing system.

We understand there are probably about 75-plus pharmacy software database vendors. These are companies such as TechRx, QS1, PDX, and there are others. Some of these are very small vendors, and they only serve a limited number of pharmacies. Others are larger.

But our research indicates that pharmacies do not necessarily know whether the information

they're receiving from their software vendor, in fact, meets the Keystone criteria, and in some cases the information may have to be updated or modified to fit within the processing system that the pharmacy uses.

Some of our large chains do not utilize software vendors. They have their own database systems that they develop and operate, and in talking to a few of them over the last couple of weeks, they have told us that they make no changes to the information they receive from the database companies.

In fact, I understand that part of the new and renewal licensing agreements, at least two of the major providers are requiring that no changes be made to the information.

I did an unscientific survey of the information being provided by eight of our chains over the last couple of weeks, and whether or not this is a big revelation to anybody, it looks like most of that information is coming from First DataBank as the source of the information.

The information presentation appears pretty consistent. There is some variability in the type face, in the size of the printing font. We understand that there is variability in terms of how often the information is updated in the systems as well.

For those that obtain information directly from the company, like some of our members, the information might be updated more frequently. In other cases, it's only updated quarterly.

Now, whether this has any impact on the usefulness of the information, you know, is a question.

Again, many of our members are probably unaware of the Keystone criteria for written information and probably don't perform their own assessment. I think you'll find that most pharmacies obtain independence, and Sharlea will address this further, rely on what they receive from the companies. We trust that this information is factually correct and, you know, are relying on the database companies to provide the information to us.

We believe that any information presented to patients must not only be useful, but must compel them to read the information. Written information that is two or even three pages long may not be read by patients because of its length, and clearly that's not a desired outcome.

We understand that already about 80 percent of the information produced is greater than two pages in length, the average being about a page and a half.

Therefore, any additional mandates on information that's required would obviously spill over into two or three pages.

Alternatively, information that is too short or not specific enough may not be useful. So, for example, information that simply says report any side effects to your doctor clearly doesn't help patients understand what to look for.

Thus, I think the point there is balance is what's necessary.

Let me also describe some logistical information, logistical issues for pharmacies that provide this information. I already said that in terms of the flow of information it comes from the database companies through the software vendor in many cases, and sometimes directly to the chain, and then the information has to be incorporated into the software system and then has to be printed out in some way.

Those of you who have never been behind a pharmacy counter, most pharmacy software systems utilize one printer. There's one printer behind the counter. The printer is printing out in many cases one sheet, and on that sheet is included, for example, the prescription label, refill information, maybe

auxiliary labels, as well as the written information that pharmacies are providing.

So there's generally not two systems in the pharmacy, one printing out the labeling information and auxiliary labels and one printing out the written information. It's usually all coming on the same information sheet.

So, you know, just logistically it would obviously slow down the prescription filling process when two and three additional pages of written information is being printed off.

In terms of the marketplace again, up until April 2000, we understand that First DataBank was producing both a short form and a long form of written information. We understand that the short form was discontinued, again, back in April of 2000, but some pharmacies may have continued to use the short form because it remained in their prescription processing system.

Dr. Svarstad might have some additional insight into that.

We're not sure why that was being done, but if those forms were, in fact, collected as part of the 2001 review, that might explain why some of the results fall short.

We also understand that mergers and acquisitions in the database companies, which I referred to before, may have created some issues related to updating written information to meet the usefulness standards.

Having said all of that, I just want to give you a few suggestions on where we think we might go from here in continuing to make improvements in the quality and quantity of written information.

First, without stating the obvious, I think that the database companies producing the information should be providing Keystone compliant information to their customers. There's only a few of them. So it doesn't seem like, you know, a huge task to interact with them.

And for the most part, I think they are producing that information.

Second, in terms of the software vendors, this is where perhaps we need to focus a little bit more of our attention. It's clear that many pharmacies don't really know whether the information being produces is Keystone compliant. They rely on their software vendor to assume it meets the usefulness criteria.

How can pharmacies know that this

information is, in fact, compliant? It may be in the interest of the agency to convene a workshop for companies to help educate them about the criteria and what it means to be Keystone compliance.

And we suggest that you might work with the group representing the software vendors, the American Society for Automation and Pharmacy, also known as ASAP. There's a group representing everybody, as you know.

We continue to emphasize to our members the importance of distributing information that is not edited. I am reasonably comfortable that many of our members are not editing the materials, but, you know, again, I think it's incumbent upon us to insure that for our smaller members in particular that they are not editing information provided to them by the database companies.

We at NACDS continue to support discretion to health professionals in developing information, communications to patients as a function and responsibility of physicians, pharmacists, and other health professionals. Every patient is different. So we would have concerns with any additional mandates or prescriptions or prescriptive criteria on what we should distribute.

We suggest that you also look at other out-patient dispensers of information. The study, as I understand it, only looks at independent and chain pharmacies. Clearly there are other entities that distribute out-patient information. Mail order is about 13 percent of the market. Hospitals have out-patient departments. Clinics, and there are even federal facilities that distribute out-patient information.

These patients should get no less useful material than other patients, and I think the term "useful" also needs to be assessed. "Useful" is a subjective term. What's useful to me may not be useful to you, and while there clearly needs to be some minimum standards for usefulness, to my knowledge, the Keystone criteria have never been validated for usefulness.

So we would urge that the committee consider further research into what truly constitutes useful information to consumers, whether those criteria in Keystone are, in fact, the most useful to patients.

So, again, let me reiterate that we are very interested in working with the FDA, consumer groups, this committee in moving forward to improving the usefulness of the information. We look forward to

working with you over the course of the discussion about this issue, and we hope you would consider us partners in trying to improve the usefulness of the information.

And we'd be happy to answer any questions about my comments.

CHAIRMAN GROSS: Are there any questions for Dr. Coster?

DR. CAMPBELL: Yes, I have one.

CHAIRMAN GROSS: Yes.

DR. CAMPBELL: Thank you, John. That was very helpful, at least for this member of the committee, to understand there is a significant element of the black box here operating and some of your thoughts about peeling back layers to see what's inside the box I think would be very helpful.

I did want to follow up on your comment about maintaining an approach of not editing the data. It does seem to me that the suppliers of the data are not aware of the specific user of the data in the pharmacy, and when it comes to that point, the pharmacy, the pharmacist is aware that the recipient of that articular information piece may not need to know that it may result in an enlarged prostate because that recipient may not have a prostate.

And there may be cultural differences that require communication via a different language, and gender specific information, and so on and so forth.

So I wonder why you wouldn't want to allow the endpoint provider of information to edit what is very generic information in order to make it more specific to the individual who will be using it.

DR. COSTER: Well, first of all, I agree with your characterization of information that may not be helpful, useful or even relevant to particular patients. We understand that it's the database companies that are going to start requiring as a condition of licensing the information that the pharmacy not change the information.

Now, I don't know what that means in terms of changing it. Is it you can't change it, you know, any word, or can you modify it somewhat?

So that may be a question better to ask the companies in terms of what their new licensing agreement will say.

I agree with you. I think pharmacists, physicians should have the flexibility to tailor information specific to particular patients. Information may not be relevant to an individual patient. On the other hand, you may be taking out

information that may not meet these so-called criteria.

So I think this is where you have to try to strike the balance here. What are the minimum criteria for useful information to patients, but at what point do you allow the health professional to modify to make it useful or more useful to the individual patient? Should there be any flexibility in modification?

This was one of the issues back when FDA issued their regulation back in 1996, the concern by the pharmacy and medical profession that it would lead to prescriptive standards that would not allow for flexibility for health professionals to tailor information specific to patients or allow for innovation in the future as new, different ways of delivering ways of delivering information became available.

So I think that's the balance. You have to ask yourself: at what point does the government say, "This is enough in terms of standards," but allow the health professions flexibility to alter the information?

And, again, in terms of what the database companies are going to require, I don't know. I

haven't seen the licensing agreements to know how far you can go to edit the information.

CHAIRMAN GROSS: I have a question. How do these medication sheets address, let's say, a compromised renal function in a patient? Do they address it at all?

If the kidney function is not normal and lower doses, let's say, of the medication should be used, are they address at all on these information sheets?

MS. LEATHERWOOD: Would you like for me to?

DR. COSTER: Yeah, please. And, please, maybe you also want to respond to Bill's question.

MS. LEATHERWOOD: On some monographs it would say if you have an issue with a renal problem, then to contact your doctor or your pharmacist. Basically that's what the step is. So there is a line that says if you have a kidney problem and it's actually in the terms that is understood by many people, then you address that with your physician

CHAIRMAN GROSS: Thank you, Sharlea.

Michael?

DR. COHEN: Yeah, I can certainly understand why portions of the information might need to be modified to tailor it for a patient. I guess I would

worry if we got into the area of risk management. You know, what side effects would be left off? What adverse reactions or potential for adverse reactions might be left off would be a concern.

Also, even tailoring it for individual patient, I would worry at least at this point that in many cases we don't know in the community pharmacies and in some of the other settings exactly what's wrong with the patient so that we could tailor it. We know what the patient tells us if we speak to them. That's not always done obviously, and that would be a concern as well.

And I worry at least at this point, you know, in thinking this thing out would people modify it to make it shorter or to make it compatible with their computer systems up front rather than tailor it for the individual patient's needs?

It's just a concern that we have to consider.

CHAIRMAN GROSS: Okay. One more question from Stephanie Crawford, and then I think we'll move on.

DR. CRAWFORD: Thank you.

One very quick one, and one comment. John, you had mentioned that most of the information that's

distributed, I think you said about a page and a half, and I wondered if that's a standard in an eight and a half inch times 11 inch or smaller page.

The other one is the comment about sometimes the pharmacist noticing errors and contacting the vendors, but at the same time perhaps not timely update.

What happens is the pharmacist on a practical basis still distributes the information even if there are errors in it?

DR. COSTER: The first issue of the length of the information, the length of the information clearly depends upon the font size that the printer is using, and just some examples that I collected from chains over the last couple of weeks, it's clear that the font size varies. There are some that are bigger, which is easier to read, and some that are smaller to fit within.

So when I say page and a half, I guess page and a half based on the normal font size that, you know, you would read from -- not some of the ones that I've seen here.

In terms of your second question, when I was discussing this with some of our members, they did say that oftentimes they will identify something in the

information that's either not correct and they will notify the companies. I can't answer for you like if they continue to distribute the information.

They might and they might, you know, either take that particular sentence or whatever out of that information or highlight for the patient that in this particular case this is not relevant to you, but I don't know exactly how they treat that.

DR. CRAWFORD: Peter, may I follow up with a brief comment?

About customization, we've only talked about individualizing material for specific patients. There's another way to go on this. The old USP leaflet is no longer available. That form called MedCoach had a customization procedure whereby you could print out the same information, but customize by gender and perhaps age would be another thing that I would add.

But they definitely had the age -- excuse me -- the gender. So you didn't put in the prostate for females and so forth.

And so if there are a few broad classes of individuals where the information would be different, that could be pre-set and provided by the data providers, and that would be a very useful way to go.

But once you get down to the level of individuation, things do fall off, and we actually looked at these customized leaflets and did find out that even when they were being customized for gender, things tended to fall off, and people would update one but not update the other, and so on.

So your point about being very careful not to lose information along the way is well taken. Do you know if anyone is providing information with customized subsets at present?

DR. COSTER: I do not. I think that's a better question directed to the database companies, but I would say that I think I don't get the sense that our pharmacies are today eager to necessarily customize the information to individual patients. I mean, that may be a feature that develops as the technology develops, but I don't get the sense that our pharmacies are like anxious to make this information customized for patients yet.

I mean, they want to provide them the best information they can, and there's a difference between customizing information and editing information out to fit onto. I think that's the concern. Are some software vendors or pharmacies, in fact, just editing out sections of information to fit within certain

areas?

That's more of a concern to me right now than is customization. I think that will develop over time.

CHAIRMAN GROSS: Yes, Arthur Levine.

MR. LEVIN: One quick comment. I just want us to be cautious about how much we burden written patient information in terms of exquisite detail. I mean, I think at least for myself and other advocates we think of this as sort of the safety net issue, and not to look to this piece of written information to convey every single big of individualized patient information for every patient.

If you burden it with that, it will be impossible to produce this information.

CHAIRMAN GROSS: Well, I don't want to steal any more of Sharlea's thunder. So Sharlea Leatherwood of the National Community of Pharmacists Association, would you like to present and then we'll go on with the questions after?

MS. LEATHERWOOD: Thank you, Peter.

I hope there won't be a lot of duplicate information and I'll add to instead of duplicating what's been said.

Again, I'll just reiterate. I am a

pharmacist, and I am a small business owner in Kansas City, Missouri, and I'm currently chairman of the NCPA Executive Committee.

The National Community Pharmacists Association is a 104 year old organization representing the proprietary and professional interest of independent pharmacies. There are more than 24,000 independent pharmacies in the United States, and they dispense nearly half of the nation's retail prescriptions.

NCPA would like to thank the Advisory Committee for the invitation to provide background and feedback regarding the evaluation of written information provided in community pharmacy. NCPA is pleased with the study's report that nearly 90 percent of patients are receiving patient information when they go to a community pharmacy nearly five years ahead of the benchmark established in 1996 at the Keystone conference.

However, we share the committee's eagerness to insure the quality of written information, and I am on the panel that reviewed the usefulness of the information collected in the survey. After evaluating dozens of patient leaflets, and though nearly all of them provided useful information to the patient, I did

find variability in the topics that were covered and the depth in which they were covered.

In describing the pipeline of information flow, I'll try to begin by a description going upstream. With the filling of each prescription, a patient's drug monograph is generated, and as John mentioned, it is generally being generated as part of the label. So it all comes out of the same printer.

In my pharmacy the monograph is attached to the patient's bag after receiving verbal counseling from me or one of the pharmacists that work for me. My pharmacy and nearly all independent pharmacies receive patient information through their computer software vendor, as John has stated.

Nearly all independent pharmacies are computerized and they lease or purchase software support from one of numerous pharmacy dispensing system vendors in the marketplace.

My pharmacy receives updates about twice a month from the software vendor, and these updates are usually done after store hours since the updates are sometimes very time consuming.

The cost of these updates is added to the software support charge from the computer vendor. Changes to monographs or new drug monographs are added

during these updates. The pharmacy does not have the ability to alter the patient monographs.

In fact, their agreement with the software vendor usually forbids the modification of the information.

The size of the patient leaflet may vary because the limited space in the pharmacy department limits the number of printers in the pharmacy. The same printer that is generating the two inch by two and three-quarter inch prescription labels may also print the computer monographs on the remainder of the page.

The kinds of printers used in pharmacies also vary widely. Some pharmacies use laser printers, while others may use dot matrix printers, and the type and availability of the printer and the dispensing software that is used, all influence the size of the patient monograph.

Continuing up the information pipeline, our understanding is that the majority of software vendors supporting independent pharmacy computer systems buy their information from First DataBank or Medi-span, and again, our understanding is that the computer vendors are also forbidden from changing any of the information they purchase from First DataBank, Medi-

span or other suppliers.

We understand that First DataBank and Medi-span receive their information from primary sources, most prominently from the pharmaceutical manufacturer. Our understanding is that First DataBank and Medi-span take the information given to them from the manufacturer's professional package insert and incorporate it into the patient monograph information sold to computer vendors.

That is our understanding. However, representatives from this organization, as John stated, can better describe the flow of information into their companies and into the software vendors.

During the study period, it was my understanding there was only one provider of monograph information with no other major competitor. There was only one source of this information, and this lack of competition may have negatively impacted the quality of information delivered to the software vendors and then to the pharmacies.

In my pharmacy, we've been giving written information on all prescriptions since 1988. I use them as I counsel my patients about their therapy. We give the monograph to the patient while they are waiting for the prescription to be counted and

labeled, and then I point out the various ways to avoid the possible problems and what to do about them if they occur.

My customers have always appreciated this. However, I have to say that the marketplace has driven my patients to other high volume settings, and the quality service that we provide has not necessarily been rewarded.

However, it's only through this verbal interchange that I detect possible probabilities of problems. Some patients do respond that their doctors told them everything, but as I continue to hit the highlights in the monograph, they realize that there's more that they really need to know.

Some physicians have been upset over the years about my interventions, but the benefits certainly outweigh the problems. Undoubtedly quality information is essential in providing care to patients, but I can't stress enough how the addition of oral information from a pharmacist makes the written information come to life for the patient.

In many cases, the written information will prompt the patient to ask me questions while I am counseling them. It's not uncommon for the patient to express relief that the side effect that he or she

read about is rare or unlikely. I'm able to assure them and provide guidance on what to do should a side effect occur.

And I mention this just to reinforce that no matter how much effort is placed in trying to perfect the written information, it only augments the pharmacist's verbal information.

I also just wanted to comment since after looking at Dr. Svarstad's report, we did note that independent community pharmacies did not provide as much written information meeting the criteria. And at NCPA we are looking at that.

We believe that verbal communication and personal relationships have been the cornerstone of our business. So the verbal and personal relationship has been the real crux of our interaction with our patients.

And also the other factor is that the technology needs to be upgraded and continually upgraded in independent community pharmacies. Again, as John mentioned, I think that that awareness by the pharmacist of what criteria needs to be used to measure their monographs needs to be given to the pharmacist so they know what they're looking at.

And in fact, I recently just purchased a new

computer, and since I was involved in the group that looked at the monographs, I knew what I wanted. So I asked all of the computer vendors to give me a copy of their monograph, and I analyzed it.

But I don't know any other pharmacist that would have been able to do that. So I think that's a real breakdown in what's going on here. The pharmacists need to know what criteria to use in evaluating the systems they have now and getting those upgraded or looking for new systems and making sure they meet the criteria.

Thank you for inviting me to share this information and the perspective from the independent community pharmacy, and I'd be happy to answer any questions.

CHAIRMAN GROSS: Michael, you had a question before? Dr. Cohen.

DR. COHEN: Not so much a question as a comment or actually a follow-up to Dr. Crawford before, but you mentioned it as well.

The information that the vendors supply comes from the package insert or from the official labeling of the product, and there often is quite a delay, and I guess I need to know is it the same database that provides the patient information, that

provides information that we use in the pharmacies to detect drug interactions or duplications, et cetera.

Because I can tell you that we've received reports over the years where there's been such a delay that patients have actually been seriously injured or even killed with drug interactions that have been missed, when there's been a known problem that never reached it to the drug information stage.

And I'm thinking of cisapride, for example. It took over a year before we got the drug information into the computer system in a way that it was interactive.

So if that's the kind of delay that we would see with the patient information, you can see the problem there, and that's something that would have to be addressed as well.

CHAIRMAN GROSS: Any comment, John or Sharlea, about delays in getting new information?

MS. LEATHERWOOD: I think that we are going to have to ask those that are the players in that because on our end we really don't know.

We get clinical updates. I do in my pharmacy twice monthly, but I have to pay extra to get it twice monthly, and I'm not sure that all pharmacies do that. So that's one issue.

And the other issue is when do our vendors get it so that we can get it updated.

DR. COHEN: Yeah, if they're waiting only until it gets into the package insert, that could be a tremendous delay before FDA and the company agree to have a black box warning or whatever the situation is, long after reports have appeared in the literature.

CHAIRMAN GROSS: Yes, Arthur.

MR. LEVIN: Just one comment. I think in thinking about written prescription information we do have to think about it as stand alone because there's considerable evidence that oral counseling by pharmacists doesn't occur, and there's a GAO report and other literature that demonstrates unfortunately that over 90 is not being honored in practice.

So I think given that reality, one of the things that I'd like us to keep in mind is that we can't count on everyone, every pharmacy, every pharmacist living up to over 90 and their professional responsibilities to provide counseling to patients, and that many patients may leave the pharmacy without that and with only the written piece of paper.

So we have to make sure that that written piece of paper does what we want it to do, as if nothing else will be done. That's not to say there

isn't tremendous value added to oral counseling both by the prescriber and by the dispenser, but we can't count on it.

CHAIRMAN GROSS: Stephanie.

DR. CRAWFORD: Both of the last speakers mentioned or acknowledged that probably most practicing pharmacists -- I'm not practicing, but including me -- were not as familiar with the Keystone criteria. I wanted to ask if NCPA, ACS, or other professional or trade associations representing pharmacists, pharmaceutical spectra are providing educational efforts to provide more information and education for the practitioners.

DR. COSTER: Well, I'll just say for NACDS, I mean, we continually remind our members to look for information that Keystone compliant and print the information that's given to them by the database companies, assuming that it is Keystone compliant.

I don't think we have reached down to the level of educating practicing pharmacists in chains about the Keystone Group or Keystone criteria. Maybe that's something that we need to revisit. You know, we'd be happy to look at ways to do that.

Maybe it's something the colleges ought to be doing as well, you know, in educating pharmacists

coming out from school about, you know, what quality written information looks like.

But I mean, I can speak for NACDS and say we have over the past five years tried to consistently remind our membership that, you know, they should be producing information that is of the appropriate length, the appropriate content, the appropriate type size.

Sometimes it's hard to break through to them, and hopefully some of the pharmacists practicing would put some pressure upwards and say, you know, this information really isn't helpful to consumers.

MS. LEATHERWOOD: And I am kind of winging it a little bit here. We did do some articles, especially when the med. guide discussions were initially starting, and so we've had articles in our journal, and we have had at least one or two, I believe, sessions at our annual meeting.

So that information though is dependent then though on who attended the meeting and who read the article. The other source of information would be local and state pharmacy associations. You know, we need to involve them also in the information.

CHAIRMAN GROSS: Bill, any comments about educating pharmacy students about being Keystone

compliant?

DR. CAMPBELL: We're not the problem. We do everything well.

(Laughter.)

DR. CAMPBELL: I think a point well taken. It certainly is a challenge. I think the modern pharmacy curriculum is very attentive to training, developing practitioners who are capable of providing effective counseling. I think it's a good question though whether we use this specific terminology and criteria developed by the Keystone Group that would allow the transference of that into practice.

I wanted to make an analogy, I guess. In today's world, if we would not have satisfied the term "Keystone" and substitute HIPAA, one does not talk to a vendor in this world without the vendor giving assurance that the product they're providing is HIPAA compliant or is intended to be HIPAA compliant or is moving toward that.

And yet it sounds as if the vendors in your world, John and Sharlea, are not giving you that assurance. Is that correct?

Sharlea, you've gone through the process of reviewing a number of different products. In any of that conversation, did anyone make the representation

that Keystone compliance was part of the commitment they were making to you?

MS. LEATHERWOOD: No, they did not. In fact, I evaluated over two years about almost ten computer software systems at least, and not one of them made any comments about the quality of their monograph. I asked for it, and of course, I was working with the sales force, and they were interested to know that there should be some criteria, but they were not aware of it.

DR. COSTER: May I just follow up on that?

CHAIRMAN GROSS: Yes, go ahead, John.

DR. COSTER: My professional opinion is that I think it's -- and you know, the point of this is to not point fingers -- but I think it's somewhere in the middle something is happening, and it may be at the software level, the software vendor level where most of the focus should be because, frankly, I've worked independent, and I've worked in chain pharmacy. I don't think -- you know, without disparaging pharmacists, many pharmacists do the analysis that Sharlea did to determine the type of information she's being sold.

So you know, it might be useful to focus on how do we make sure that the software vendors are

providing information to pharmacists that meet whatever quality criteria we agree are what's necessary for patients. You know, there's probably some editing going on by pharmacies. There may be information that's not totally compliant being produced by the database companies, but it seems to me like that should be where the focus should be, in trying to figure out what happens in the middle between the pharmacy and the database companies.

CHAIRMAN GROSS: Bill, I wonder if you could comment on what aspects of HIPAA you think compliance should be sought just for the audience.

DR. CAMPBELL: Would you clarify? What aspect of HIPAA?

CHAIRMAN GROSS: Yeah, as far as HIPAA is concerned, it's a rather broad statement. What you felt that HIPAA compliance -- you asked if their information or how they relate to patients was HIPAA compliant. What aspects were you referring to?

DR. CAMPBELL: Oh, I'm sorry. The point was just to make the comparison. If we're talking to a vendor today or we're looking at our health care system, the interface, the person at the interface that Dr. Coster was just describing, the person who's generating and managing that data is very sure to tell

us that the HIPAA requirements with regard to security, with regard to confidentiality, with regard to the specific details of the Health Information Portability Act are being met in the product they're providing, it isn't that we would use those criteria.

The point I was trying to make is that the Keystone criteria exists in this other interface, and it would be very useful if those vendors would do the same sort of things with the Keystone criteria that are HIPAA vendors are doing with the HIPAA criteria. I wasn't suggesting we'd use the HIPAA criteria for this problem.

CHAIRMAN GROSS: Yes, sure. Okay. Thank you.

Yes, Arthur.

MR. LEVIN: I just want to take us back a little bit to Keystone because I think it's not so easy to certify Keystone compliant as we're making it seem. One of the -- while this was a consensus process, you'll note if you read the report there were some points of nonconsensus in the report that was submitted to the Secretary and actually some options asking the Secretary to choose between some competing options to deal with certain issues.

We certainly had a lot of discussion about

some gold standard or seal of approval, Good Housekeeping, UL, whatever, but then the question was: who evaluates the material to award that seal of approval?

And that was one of the issues on the evaluation of the material going forward in which we had some serious inability to reach consensus and which in the report we made two competing suggestions.

Interesting enough, one of them, which came from the minority of members of the Keystone Group, principally consumer members, was to have an FDA advisory committee process that would evaluate not just the progress of meeting the goals for 2001 and 2006, but evaluate the quality and usefulness of the information independently.

And so in sort of a backwards way we've sort of gotten there, but I don't think we could talk about people representing themselves as Keystone compliant just by representing themselves that they're Keystone compliant. We have to have some independent, objective way of evaluating the quality of that information.

And maybe that's something this committee can get involved in, but it's easier said than done.

CHAIRMAN GROSS: Yes, Michael.

DR. COHEN: Just you mentioned before that there were some pharmacies, I guess, chain pharmacies, that were providing their own information, producing their own information. Can you give us an idea of how frequently that is done?

DR. COSTER: No, if that's what you understood, I don't know of any chain that's producing their own information. What they're doing instead of using a software vendor, they produce their own software and license the information directly from the database company rather than a pharmacy contracting like Sharlea's with a software vendor.

I'm unaware of any pharmacy, chain pharmacy, that's writing their own written information. I think everyone buys it either through a licensing agreement they have with a vendor or through a software company they might --

DR. COHEN: Well, some of the mail operations, for example, are very large organizations that might have their own drug information sections that do this. I'm not sure that, you know, that isn't done. I thought maybe you'd know something about that.

DR. COSTER: I can't speak on behalf of what the mail order companies or what any other setting,

for that matter. Hospitals might be doing that in the out-patient setting. I just don't know. It's possible.

CHAIRMAN GROSS: Yes, John.

DR. SULLIVAN: It seems to me that we're highly dependent on, if you like, the translation for what comes from the highly regulated package insert to what the database companies produce, and obviously the information has to be sort of accurate, timely, and understandable, and it's unclear what the sort of quality control is on this.

So I think that's sort of one of the issues that you were alluding to where we have to sort of look at it and evaluate it as we go forward.

DR. COSTER: I guess, you know, unlike the mandatory -- there's a mandatory med. guide program which FDA has and then there's the voluntary program. I mean, the mandatory program was a part of the original rule and wasn't finalized back in '96, but was finalized later on, and then there's the voluntary program.

So, you know, our perspective from pharmacy at least is that this information is voluntary provided by pharmacies. We want to continue to work through the private sector to improve it because the

concern is that ultimately there'll be FDA regulation of pharmacy practice, which is really a state board issue.

So I guess we're trying to work within a private sector plan to move forward and providing quality written information and trying to avert any type of government regulation of the practice of pharmacy or medicine for that matter. I don't know if you're going to hear from AMA later, but I remember back when we were doing the Keystone criteria. They had some of the same concerns about the potential prescriptiveness of written information or FDA regulation of written information.

So there's a way you can strike the balance without regulating the voluntary provided information. That's what we would prefer in terms of moving forward.

CHAIRMAN GROSS: Okay, Arthur.

MR. LEVIN: I certainly don't want to go back and relive this discussion that went on for four months at Keystone, and certainly preceded Keystone in terms of the discussion of mandatory versus voluntary.

I might note that the only folks who spoke up in favor of a med. guide program as proposed in August of '95 at the meeting held in February were

patients and consumers, the people who I think have the most important reason to be interested in getting this information.

Every other stakeholder spoke against the '95 proposal.

I mean, again, not trying to rehash that discussion, but I would be curious to find out what problems the few mandates have caused. I mean, we've had a requirement that information be dispensed with estrogen, with hormonally based products for some time. I think UDs required a patient package insert for some time.

We've had drugs that require medication guides under the '98 statute. So, I mean, I'd be curious. Now that we have these sort of little test cases, what's the problem? Why is this something that pharmacies should be concerned about?

What is the kind of problem, you know, and how is it interfering in the practice of pharmacy? I don't get it.

CHAIRMAN GROSS: Sharlea?

MS. LEATHERWOOD: I think that any time that we get more mandates and, you know, one mandate after another, our practice becomes overlaid with sometimes difficult things to fulfill.

I always give information, but there have been cases in my professional practice where you had to be very careful about how you gave that information and helped the patient understand it. It took more time.

When you have a mandate, that means that you must give it, and I've even had physicians who have asked me not to give it in the same complete manner as others.

And I realize the patient has that right to know, and I feel that they do, and I've tried to help them understand that, but the mandate then would require that you give it no matter what their situation is, and that's one aspect.

Again, as John said, we are regulated by state boards of pharmacy, and we really do not need another overlay of another government body to license us. We are inspected regularly, and you know, the NABP and the boards of pharmacy -- certainly any issues that need to be addressed with the professional pharmacy, I think, should come through that channel and a way to improve what we do.

I know you said the oral information. The requirement in Missouri is that you ask the patient if they have any questions. So in the busy, high volume

settings that we have today, the question is asked, and it may not even be asked in a way that would have the patient answer it.

So that being said, a mandate doesn't necessarily mean that it's going to get you where you want to go. It doesn't necessarily mean that the patient is going to get the best written information all the time.

It's there; it's available. It's required by law. It isn't done. So I think if we can get voluntary compliance and work through the current system rather than to create another overlay of regulation, that it will be a win-win for everyone.

CHAIRMAN GROSS: Okay. Thank you, Sharlea.

I think we'll move on now to Bonnie Svarstad. Dr. Svarstad will present a report of the evaluation of the written patient information, penetration, and usefulness, and with a Hollywood flair. This is Part I, like Men in Black, Part I.

(Laughter.)

DR. SVARSTAD: Okay. Thank you to the committee for inviting me to present the results of this report. And I thank every who took the interest and the time to attend today, and I hope that you will feel free to ask questions as the time permits during

the question and answer period, and I hope this report is useful to you.

First, I'd like to acknowledge my colleague, Professor Jeanine Mount at the University of Wisconsin, Madison. She's at another meeting, so can't attend today. But she certainly was very helpful in getting this report to fruition, as was our whole research team.

I think it's important, first of all, to acknowledge that this study was a very collaborative study in the sense that it was done in cooperation with FDA and the staff, especially, I think, Dr. Ellen Tabak, who has been providing us with assistance and support from the very beginning.

This study was done under very tight time constraints, and sh was very helpful in making sure that we were able to do that.

I also thank the NABP, the National Association of Boards of Pharmacy, for providing their support, and certainly to the national expert panel who has played a very critical role, and I'm glad that Sharlea is here to answer any questions about what that was like and what the role that she played.

The national expert expert panel was made up of 16 individuals. These individuals, the majority of

them were nominated by NABP. To get to this list of individuals, NAPB, as I understand it, invited seven pharmacy organizations to nominate individuals from their organization to serve on this panel.

We also made nominations based on our understanding of individuals around the country who were specialists in drug and health communication and pharmacotherapy. So it was a collaborative process, one in which in the end we had individuals who were then either experienced pharmacy practitioners and/or experts in pharmacotherapy and communications hoping to get a broad perspective.

We had faculty from nine different colleagues and universities, and I'd like to just list the panelists so that you can see who was involved. You may not know all of these individuals, but I think they've been very active nationally in these issues:

Mary Amato

Heidi Anderson-Harper

Bob Beardsley

Dr. Chester A. Bond

Marie Gardner

Betty Dong

Carole Kimberlin

Sharlea you've met.

Duane Kirking

Matt Osterhaus

Anthony Provenzano

Mary Pubentz

Betsy Sleath

Jenene Spencer

Judith Hanson

Gayle Dicter

And myself as chair.

We operated as a committee largely through modern technology. We mailed things to them. We used E-mail a lot, and they returned things to us via Fed.Ex., et cetera. So we tried to do this as efficiently as possible. And I thank them for all of their efforts.

Their role, I should have said, was diverse. First off, they looked over the criteria and commented on the criteria. They also commented on the expert evaluation forms and other features of the study methodology. But their main role, I think in the end was to actually evaluate the information sheets.

Now, I should say just a couple of things about past studies that have been done here. As several speakers have already noted, I think it's important to note that the distribution of patient

information has increased dramatically. From 1982, one of the first studies, nationwide studies done by FDA, they found 16 percent of the patients reporting written information, some kind of written information, increasing to 74 percent in 1998.

In the interim study, that is, the study that was done in 1999, in eight studies we found that 87 percent of the patients or shoppers who went into the pharmacies were given some kind of information, but the quality was highly variable.

And I will talk about how we define some information. In this case, in this study, and as in the previous study, we included any written information beyond the individualized prescription label. So if it was one line, it was considered information. If it was two lines, it was considered information. If it was two pages, it was considered information.

So we will try to break that down for you as the study goes on, but it's important to see that when we say a certain percentage of individuals received information, it's meaning information of all kinds or of all lengths. Okay?

Now, how is this particular study different? One of the most important differences is that

pharmacies were sampled from a national electronic list. In the previous study we only looked at eight volunteer states. So this makes it, as far as I know, the only nationwide study of drug information conducted in the world, and I'm familiar with studies that have been done in other countries.

Professional shoppers visited the pharmacies. In the prior study we had some inspectors and some temporary staff. These varied from one state to the other as to how much training and experience they had. In this particular case, professional shoppers were hired by the same professional research firm to visit all pharmacies. So I think the standardization was improved.

Both experts and consumers rated information. In the previous interim study only the experts. So I think we have a very important addition in this study by asking consumers to rate the information.

We also performed additional analyses.

Could someone bring me the water glass? John, thank you very much. I'm kind of fighting the aftermaths of bronchitis and sinus infection. So thank you.

Primary aims of this study are shown here.

What percentage of the patients receive information? How do experts and consumers rate it? And how well does it meet the criteria?

These are the primary aims of the study. Recently, in the last few months, we received additional support from FDA to do some additional analysis as to how expert and consumer ratings compare and to identify some of the factors that influence the variability and information. Is it influenced by pharmacy type as well as by leaflet characteristics?

The objectives for today are really to review the study design and procedures and to get questions, to review the evaluation criteria, and to show you the forms, and to present results in two parts, leaflet distribution in the first part, in the second part factors that might influence the ratings.

Now, for the study design, I think as most of you know shoppers acting as patients presented four prescriptions at each pharmacy. Leaflets were mailed back to us at UW. We then mailed them out to the experts and to the facilitators for the consumer evaluation, and all of those came back to UW where we ultimately did the analysis.

Now, about the sampling of the pharmacies, you can hopefully read here the pharmacies that were

excluded. We excluded some states. I wish they would have included them, Hawaii and Puerto Rico so that at least I could have gone to a warm place.

But we decided or the FDA decided to limit us to that in that respect. We did not include government settings and hospitals, clinics, long-term care, mail order, et cetera.

This left though a large number of pharmacies nationwide, 57-some thousand, and it's the 57-some thousand that these pharmacies were selected from.

Ultimately after discussing different procedures, we decided to do a simple random sample of 384 pharmacies, making it an excellent, I think, sample.

And in the end we had 65 percent of the pharmacies were chain or what I should refer to as multi-unit and 35 percent independent, and I think the previous speakers have noted that this is pretty representative.

We know, for example, at least these statistics vary from one year to the next. The statistics that I looked at, for example, in terms of the volume of prescriptions that are dispensed in different settings, I think the data that I saw were

66 percent of the prescriptions were dispensed in chain or multi-units. So I think we're pretty close, but of course, we do not have mail order.

Data ended up being collected in 44 different states. Now the observer protocol.

As I noted, shoppers were hired by a professional shopper firm. Seventy-two percent of the visits were by females, 66 percent by persons 45 and over, with a mean age of 50.

Now, the reason for that really is to make this realistic since these medications were for diabetes, heart disease, et cetera. You don't want someone 20 years old going in and presenting a prescription for nitroglycerine for obvious reasons. We wanted it to be as realistic as possible.

All shoppers had a standard scenario to make this uniform from one state and one pharmacy to the next. The standard scenario briefly involved these four new prescriptions: atenolol, glyburide, atorvastatin, nitroglycerin sublingual.

And we can talk about why those medications were selected during the period if you wish, but I think it's interesting that these prescriptions are among the top ranking or top most frequently dispensed prescriptions. Certainly the diagnosis of diabetes

and hyperlipidemia are among the top ten reasons for patient visits.

So I think we have a scenario here that's not looking at the bizarre or not looking at the rare, either rarely prescribed drug or rare diagnosis. We're looking at common and frequently used medications.

The patient was encouraged and required to not ask questions or initiate talk. In other words, they should not be seeking information. They should let the process unfold. This, in fact, is probably quite realistic as most pharmacists would tell you. The patients do not generally seek information or ask many questions; fairly passive.

If asked though, the patient was prepared to respond with the standard scenario, and they were told they had a scenario, and that was given in the final report. I don't want to try to read it here, but if you have questions or interests in that, you can go to the final report and see exactly what the patient was asked to tell the pharmacist if they were asked, "Why are you being given this medication? How did the circumstance arise that you got these prescriptions?"

Basically they were to tell the pharmacist that they had recently, very recently, just been

diagnosed as having diabetes and some heart disease, very vague. And they were to say they had never used the medication before, if asked.

So this would be typically then a patient who does generally, I think, need information, if you will. They've not used the medication before.

The shopper mailed the materials to the shopper firm. The firm removed identifiers so that the experts and the consumers would not have privileged information. All leaflets, brochures, and other materials then mailed to us, all items, as I said before, referred to as leaflets.

Now, let's talk about the evaluation forms. Each included the eight general criteria that Tom talked about before. To operationalize those criteria or to quantify them, there were 62 to 63 subcriteria for each form, and these were drug specific.

In other words, there were four forms, one for each drug. The eight criteria were from the 1996 action plan for useful information, and the subcriteria as much as possible were based on approved labeling unless the committee felt that there was some reason to deviate from that or to add something that they were aware of that was evident in the professional literature.

The forms were revised until all panelists approved. So, as Sharlea would tell you, this was an iterative process. Materials were sent out. Panelists commented. Comments were incorporated. They were sent out again until the 16 individuals were comfortable with the forms.

Now, these are the criteria, and I won't go through them again since Tom, I think, did that quite nicely, but if you have questions about really any of these particular criteria, I would be glad to comment later on their significance from a consumer's perspective.

I've been doing research on consumer understanding of their medication regimens and patient adherence, as well as patient's perceptions of their medication since 1968. That's a confession. Patient adherence and education are my areas of research interest, and so I've paid some attention to this issue, and I'd be glad to comment.

I'll just give a few comments here on a few of them. If you take the first one as an example, you might say, well, why does the patient need to k now both generic and brand names. That's a perfectly reasonable question.

Well, one reason is that people go to

multiple physicians. They may get multiple brands or they may get a generic from one physician and a brand from another. They look at these two names. They don't look like they're the same, and they end up taking both products. Sometimes people are too compliant.

So I think it's quite important, for example, that the patients ultimately learn both the generic and the brand name and so when the Keystone criteria cam out with this, I thought that's a good idea.

And we could go through each of these. If you look at number three, specific directions about how to use, monitor and get the most benefit, there are empirical studies to show that patients who get more specific information about how to take the medication are, in fact, more adherent. So I think this is something that consumers really need and benefit from.

Five, six, seven, and eight are, I think, all pretty obvious. I probably should comment about eight. This has always been a challenge to try to define this, but I think we've done considerably better this time around than we were last time because in the 1999 study, many of the criteria were lumped

together, collapsed in a way that was hard to separate them out.

The forms in the latest study though are broken down in a very explicit way, and we did that, I think, for a couple of reasons.

One is so that ultimately the pharmacies, the pharmacy organizations, the vendors and other interested parties could see specifically where leaflets have strengths and limitations.

And, secondly, they could see how it is that these general criteria from Keystone were operationalized. So, for example, instead of just saying it's easy to read, we need some specific points under that to say, well, what makes it easy to read.

Well, the literature on aging and the literature on education of adults would say, for example, that putting information in bullets is helpful to the consumer. Using a certain font size is helpful to the consumer. Putting space between the lines is helpful to the consumer. Using headings and separating those headings from the text is helpful to the consumer.

On in this particular evaluation and rating form, we separated out and put each of those points and then tried to measure it as objectively as we

could.

I should relate one story so that it's not totally serious here, but I normally, when doing research like this, like to do what I'm asking people to do so that I see how it's going. So I actually conducted one of the consumer evaluation groups myself, and it ended up that the consumer group that was rating the sheets were pretty typical of folks that use nitroglycerine, glyburide, et cetera. In other words, there were quite a number of widowed women in their late 70s and 80s.

And at one point as we were getting started, the woman said, "Would you mind if I could go home for a minute?"

Why would you want to -- "excuse me?" I said.

"I need to go home, just next door, and get my magnifying glass."

When you see something like this, it kind of comes home to you about why it is that things like font size space, et cetera, are important. So I probably come to this experience from watching consumers.

But those are the eight criteria. Now, the scoring method. Each criteria rate by four to ten

subcriteria. Each subcriteria rated as to whether there was full, partial, or no adherence, and we wanted to separate that out rather than lump it together as it was done the last time.

Computer calculated the percentage of all points obtained, and we were aiming to get a scale from zero to 100 percent so that ultimately you could have a standard scale, if you will, for comparative purposes.

Now, is this the point that I said I was going to show the form? Now, the committee has seen this in the report, but this is primarily for anyone that's not seen the report.

How is that in the back of the room and for the committee, I guess, primarily? Can you see that?

Okay. You can basically see that the criterion of -- the first of the six criteria are whether the information is specifically specific, comprehensive, et cetera, for the patient to be able to use the medication, and the first criterion is that the leaflet includes the drug names and indications for use.

In this case it's for a atorvastatin, and you see that under that, this is the general criterion, and here at the subcriteria. In this case

there is six subcriteria, and over here there are two little boxes.

If it was fully met, both boxes would be checked. One would be checked if it's partial adherence; blank if noon of it. Okay. So you basically have the possibility of six times two, 12 points for this particular criterion.

You'd go to the second one. In this particular situation it's contraindications and what to do if applicable. Do not take this medication if you are, and they list the three subcriteria, again, two boxes. In this case, tell your provider or pharmacist if any of these exist, two boxes, and so on.

Specific directions about how to use, monitor, and get the most benefit. The third criterion, and the items are subcriteria under that.

In this case, there are nine subcriteria. Again, two boxes for each. So there would be 18 points for this particular section. For example it's important to take this medication regularly or to help you remember, take it at the same time each day. If you miss a dose, take it as soon as possible, and then be more explicit about that. Do not take two doses at the same time.

Splitting it out enhances the reliability, that is, the agreement from one person to the next. What we're trying to do is to get criteria that are explicit enough so that if Expert A picks it up, goes off to this room, Expert B picks it up and goes to this room, they'll come back with the same score. It has to be reliable.

Precautions, fourth criterion.

Fifth criterion, symptoms of serious or adverse reactions and what to do. Notice how these are split out by what you should be telling, that is, how serious, and splitting out the serious ones from the less serious ones, and those that the patients can tolerate. Merely report it if it doesn't go away or bothers you versus those that are serious.

So the criteria are kind of interesting in the sense that they not only spell out the side effects, but something about what you should be doing, an action implication.

Now, the scoring categories, as you might guess when you've got so many points, you want to try to figure out how to represent and report this to audiences like this and to committees like this. So what we decided to do was you can report from zero to 100 percent, which tells you what the mean score was

or what the individual score was, but it's also helpful sometimes to report levels so that when you see graphics, you can see, well, what percent fell at this high level, moderate level, low level, or very low level.

So we've categorized the information by these scoring categories here. That's level of adherence to criteria. See, Level 5 is the optimal or the highest, I should say, 80 to 100 percent, and Level 1, here, is only zero to 19 percent.

In other words, if a leaflet met 80 percent of the points possible, it would be in the fifth level of adherence. If it met zero to 19 percent of the points, it would fall into Level 1.

So when I show the graphs now, we will be referring back to this Level 1 through 5.

Now, before we went anywhere, we tested in a very usual and standard way and whether, in fact, the experts were able to agree after rating things independently. So each expert was assigned to one of four drug groups based on their expertise or experience.

They then were given a subset of the leaflets and asked to rate them independently, in other words, without talking with anyone, which is

easy. They were at different places.

We then analyzed the results. The first time we did it, we found some issues especially with Criterion 7, which is on scientific accuracy. They tended to rate them as low on that criterion when they didn't present much information.

So we tried to clarify, no, this is really accuracy regardless of length or accuracy regardless of amount or accuracy regardless of content.

So we discussed that and then redid it again, and there is much better agreement. So we cleared up any problems or disagreements or confusion about the criteria so that things were clear, and we made corrections to the form so it was clear.

At that point then, the final reliability test, we got excellent reliability statistically speaking, and we've used other methods here, and I won't get into the technical side of that except to say that we've got good agreement.

Now, how were these leaflets actually rated? The process, once we got to the reliable form, each expert stayed in their one of four groups. This enhances reliability. So you basically have one group of four individuals rating all of the nitroglycerine sheets; one group in the glyburide group rating all of

the glyburide, et cetera.

What this means though ultimately is that there are four experts rating the leaflets for a single pharmacy. Okay? Now, each leaflet though is rated only by one expert, and not duplicated once we got reliability.

In the end, experts rated 1,367 pharmacy generated leaflets. That's a lot of paper.

They also rated 31 manufactured generated nitroglycerine leaflets, and I'm not going to give the results on those today. They're in the final report though if you have an interest, and we certainly can talk about that later.

Now, let's go to the consumer evaluation form, one form with 12 items. It had to be fairly straightforward. We didn't have a drug specific form. We wanted a generic form because consumers were not rating scientific accuracy. Instead they were rating issues that can be rated by consumers and of interest to consumers.

The items, we tried to take and build on the 1996 action plan and to make it consistent with that, and we also had a pilot study that was done in 1999, Krass, et al. Basically that study tried to validate the items, and I can go into that a little bit later,

but it might sidetrack us a little bit here if I go into that too much.

The most important point, I think, is that these 12 items were rated using semantic differential scale. That means that they're given words, and they're asked to rate the leaflet on a score of one to five for each one of these items, and these items go from poor to good.

So if it's very poor, they'll rate it a one. If it's very good, they'll give it a five, and in between, two, three four.

So 12 times the number of items means that, again, you can standardize this into the percentage of scores possible. So we, again, can either report item by item, or we can report the total possible points from zero to 100 percent.

Level of adherence. We're going to try to use the same for the consumers, but I'm also going to report some item-by-item findings because that can be kind of interesting.

To repeat, at the very high levels of adherence it's a five. At the very low, it's a one, and I'll show you the form. You can kind of see how this form is laid out.

Below is a list of words describing the

attached information sheet. For each item, circle one number that best describes how you would feel if you were taking this medication for the first time and received this information sheet from the pharmacy.

And I'm going to go through these items in the slide shortly, but you'll see that there are a number of specific items, and then we have some overall assessments at the end.

Overall, what is your opinion about this information sheet? Please circle one number that best describes how you would feel if you received the information sheet. Hard to read, easy to read; hard to understand, easy to understand; not useful, useful.

Now, we've done some factor analysis for those of you that are statistics mavins, but I'm not going to go into that in detail, except to say that what we were trying to do was to get some items that measure legibility. How easy is it to read? And comprehensibility, how easy is it to understand, which are two different constructs or two different concepts, if you will.

The three specific legibility items are with regard to print size, print quality, and spacing between the lines. There's one overall item that relates to readability: how hard/easy is it to read?

Those items actually correlate quite well. The six comprehensibility items are listed up here. In this case it relates to how well the material is organized, its length. It can be either too short or too long.

Whether it's clear; whether it's perceived to be as helpful in a global sense. Completeness, is it incomplete/complete? And how easy is it to find important information? Now, that is if a person starts taking the medication and they keep the leaflet, they might want to go back to that leaflet and find that information again on side effects, for example, or the consumer can interpret this as they wish, but that might be the thought behind it.

The three summary items, again, reading, understanding, and useful.

Now, it doesn't make sense for the consumer to agree with each other because we've got different ages, different levels of education, et cetera, but it is important that the same individual will give you the same answer three or four or five days later, and that is called test/retest reliability. That is agreement from one testing to another.

So we did that, and we did some work before, but the final test was to take nine consumers who

weren't affiliated with the project, ask them to independently rate 18 leaflets at two different sessions, and we got good test/retest reliability. And that's the point at which we said, "Okay. We're ready to go."

The consumer rating process was that we identified consumer facilitators in different parts of the country, usually people from pharmacy colleges because they have graduate student slaves who can go out and do things for you.

We had people in 11 states. We asked them to identify consumers towards the older range because we did not want to -- we wanted this, again, to be as realistic as possible and to at least be somewhat representative of the people who might be using these medications.

They recruited ultimately 154 consumers. They did it at senior centers, clinics, work organizations. Sometimes they met in church basements, apartment buildings, et cetera, different locations.

The process occurred in this way. The facilitator, after identifying a potential rater, arranged to meet with these individuals, eight to 15 individuals per session, and the reason for doing that

was so that the facilitator could hand out a packet to each consumer, and the consumer then would open the packet. They would get instructions about how to do this, and then they would be asked to rate the materials in that packet.

In other words, this was not a focus group session where people are discussing this with each other. They're trying to do this independently. Each rater independently rated about ten leaflets.

Rater characteristics. Mean age, 61 years; range, 20 to 89. So we had quite a bit of variability, and you can see that the raters are probably consistent with what we know about medication users. Sixty-eight percent female; that is a little bit predominant females. Eighty-nine percent white, which is not totally representative of the U.S. population, but it does have some race/ethnic diversity in it.

Seventy-seven percent used medication daily. We asked them whether or not they used medications and how many.

And then we had some educational diversity. Now, I think we can talk about representativeness of this group later on, but I think probably the most important thing to say here is that when you look at

national health statistics, surveys that are done of prescription medication users we find obviously that the percentage of individuals who use medication increases dramatically with age.

And by the time you are getting to the older age levels -- let me see if I can find some statistics that I wrote in the margin here.

If you look at those individuals under 18, about 21 percent use medication. Of course, we did not include children. They had to be 18 years or older.

In the 18 to 64 year range, 39 percent of the individuals nationwide used one or more prescription medications, and when you look at 65 or older, fully 74 percent use one or more medications.

So I think what we're trying to do here is to have raters that reflect the medication users.

Okay. Let's move on to the results, Part 1. The percentage of observers given any written information you can see in this table here. That is, for atenolol, close to 90; glyburide, 89; atorvastatin, 89; nitroglycerine, 88. In other words, it was pretty much the same across medication type.

Now, let's look at the expert ratings. All criteria combined for 1,367 leaflets. Remember we're

going to look at the five levels up here. This is the lowest level, zero to 19 percent adherence. This is the highest level, 80 to 100 percent adherence.

Down this side we have percent, percent of leaflets actually hitting that level, and then down here at the axis, here I have the different drugs so that you can see whether or not there are any differences by drug.

This is the first for atenolol. Now, let's kind of look at this for a moment. What you see is, first off, there are no Level 5s here. Zero percent of the leaflets met the highest level. Twenty percent of the leaflets met Level 4. Fifty-six percent of the leaflets met Level 3. Ten percent of the leaflets met Level 2, and three percent of the leaflets met Level 1, according to the expert ratings.

It's interesting that these patterns or the trends are pretty similar for the glyburide and atorvastatin. A little bit better ratings for nitroglycerine, but you note again that there were no leaflets as distributed anyway that met the highest level.

Now, what we did next was to look at the individual criterion or criteria, one through eight you remember. The highest ratings overall were for

scientific accuracy, criterion number seven.

The next highest ratings or moderate ratings were for number one and number three, that is, the names and indication and durations.

Low ratings though were observed for numbers five and six, that is, the side effects information, what to do, and general information.

And the lowest ratings were for Criteria 2, 4 and 8, that is, the risk information, contraindications, precautions, and legibility comprehensibility, according to the expert.

Now, what i've done in these next few slides here is to simply show graphics for one of the four drugs. I'm picking atenolol because it's the first one that we looked at before. Otherwise I think we'd get snowed with detail here, and I do this so that you can kind of see what the distribution is like for each one of these criteria.

You see immediately that the Criterion 7, which is scientific accuracy unbiased and up to date, was met very well in terms of 95 percent of the leaflets meeting Level 5, and that's pretty much the same for all drugs.

The moderate ratings though for Criteria 1 and 3 are seen in this slide, and you see that 32

percent met Level 5 and 11 percent met Level 4 for name and indications. That is, you begin to see the variability now of information here.

On directions you also see variability, 19 percent at Level 5, 47 percent at Level 4. If you put that together, that's about 63 percent meeting four or five, if you want to look at it that way, but there were some that were quite low here, too.

Now, in the low category, this is Criteria 5 and 6. This is for Criterion 5, adverse drug reactions, and in what to do, only about 13 percent met that criterion at the Level 5, and about 14 percent met it at Level 4. And these were in the pretty low category here, about 48 percent of them getting in the Level 1 or 2 on adverse drug reactions.

And general information, remember general information can include a variety of things, including the publisher name and date and encouragement of the patient to ask questions.

Criterion 2 and 4, now, these are the lowest ratings. You see the variability again, but on contraindications five percent meet this level. Twenty-seven percent meet this level, and these, of course, are at the low level. Seven and 14 percent of the leaflets meet the criteria at the higher levels

for precautions.

Now, the lowest ratings were in the area of legibility, comprehensibility, and you see that according to the experts and the subcriteria that they laid out none of the leaflets that were obtained met Level 5. Eighteen percent met Level 4.

Now, if you want specific data on which of these subcriteria were met or not met there, those are in the tables, five to eight, and we can talk about that later.

Now, let's look at the consumer. Consumer ratings, all items, that is, all 12 items, and we have here, again, our levels, and here we have percentage of leaflets meeting a given level, and let's start with atenolol, as we did with the professionals.

Now, what you see here is a little bit higher rating by the consumer because you do have them rating 24 percent of them meeting this level, but if you look carefully at the professional, you'll also see that they have more at the low level and fewer in the middle, which is kind of interesting.

I think that's because readability is quite an issue with the consumers, and four of the 12 items for the consumers related to legibility. I should say legibility to be clear here.

So they're a little bit more positive in the sense of here, but they're more negative down here. So they, like the experts, are rating the leaflets as variable in quality.

You pretty much see the same trends for the other three drugs. Twenty percent of the glyburide are given the highest level; 28 percent to atorvastatin are given the highest level; and 29 percent of the leaflets for nitroglycerine are at this level.

It's quite remarkable, and you should see similarity pretty much if the standard format is being used within a pharmacy and with these different drugs. So you see that consistency as you did for the professionals.

Now, let's look at item by item because I think there's a little bit of interesting findings there. We look at scores varied by item, and if you look at the item, the lowest scores were for print size, print quality, spacing, and overall readability. Moderate to high scores were for easy to understand and useful, and I guess one way of summarizing these data, which I'll show you in a moment, is that 36 percent of all leaflets -- and consumers rated nearly 1,300 leaflets -- but 36 percent of all leaflets were

given lower ratings on readability, that is, a Level 1 or 2.

Remember that they rated each item one to five. So now we're looking at the item to avoid any confusion. We're saying what percentage of the leaflets were given a one through five on this summary item.

This one is ease of reading. It was one of the bottom items or one of the three overall items, and you see that they considered that 20 percent were at level 5, that 19 percent were at Level 1 or poor, and 17 percent were at Level 2. That is, that's where I got the 36 percent.

Thirty-six percent of the leaflets were rated a one or two, that is, at the poor level, when we look at readability. In the final report -- and I think that the report sent out to the committee -- those tables were quite misaligned. So what I would encourage you to do is to go to the Web version where there's a PDF version file that will show these tables in detail if you wish further detail than what's there.

Now, in terms of ease of understanding, you notice here that the percentage of leaflets, that there aren't as many leaflets rated poorly by the

consumer. They saw ease of understanding as being a little bit better than readability. About 19 percent were in the poor level there.

Usefulness, 17 percent were either a one or two in terms of usefulness, 30 percent at the high Level 5, 32 percent at the four level. In other words, they were clearly making distinctions between or among these leaflets.

Now, let's just say a few words about expert versus consumer ratings before we stop the presentation of the first part of results.

The question arises, you know, as to how the consumers' rating compares with the expert rating. I think it's difficult to do this because in a sense, the expert is rating items or concepts that are different than the consumer.

For example, we didn't ask the consumer to evaluate scientific accuracy. Okay? We didn't ask them to evaluate that particular criterion. So it's kind of like comparing apples and oranges a little bit, not completely, but a little bit.

So I caution us to be careful when comparing expert and consumer evaluations.

It's also important because remember of the 12 items for the consumer, four of them, three

specific items and one overall item, pertain to legibility, and eight items refer to comprehensibility.

And so in a sense you have a different somewhat weighting for the consumers, weighted on those things that I think the Keystone and others would agree is more important for the consumer to evaluate.

With that said, let's look at an overview of what we found, and more analysis still needs to be done on this because this is a fairly new analysis.

Overall we found low correlation between the expert and the consumer, but I think it's important for me though to say that they were significantly related.

In fact, the behavioral scientist would probably say that's pretty interesting that they're related at all, but the correlations for total scores, that is, the total percent, zero to 100 percent for the expert rating and the consumer ratings were related in the .25 level, which is pretty low, but it's still related.

So I conclude that the two evaluators are bringing different things here. They're bringing a different perspective to the rating process, both

being important.

When we look at the experts' total rating of usefulness and the consumer's rating of usefulness, we do see a significant association, and I'll show you a slide on that in a moment, but when you look at expert rating of usefulness with the consumer readability, that's where you see no association, and that to me is pretty expected.

That is, why should you expect that scientific accuracy is related to readability? It's kind of as you would expect.

This table shows you in one case the issue of consumer rating of usefulness, which is down this side, with the mean overall expert rating.

Now, I need to explain this a little bit. This means we're talking about an item here. The consumer rated the leaflet on a one to five score from poor to good, and I've got the aggregate item for the expert over here, and what you see is that for those leaflets that were rated poor in terms of poor usefulness by the consumer, the expert rating was only 40 percent adherence. Okay?

And if you look at the fifth level, that is, the good level, according to the consumer, you see 55 percent as the mean expert rating. That is, s the

consumers and the experts kind of agreed here in a linear way on the poor to good items, higher for the leaflets identified as not to at all useful. The experts also gave them the lowest rating. That's what I would conclude form this.

That's a long way of getting around to that, isn't it? Okay. Let me try to just summarize a few key points here, and then I will stop for this part of the results.

First, I think that we found that 89 percent of the consumers nationwide in this particular study were given some sort of information. That information can range from one line or two lines to a page and a half, and I'll talk about length when we get to the next part of the results.

Secondly, I think we saw that both the expert and the consumer ratings vary by the criterion. For the experts, they were most critical -- experts were most critical on the contraindications precautions and legibility comprehensibility, and for the consumers, I think they were most critical of readability.

I think those are the main findings and perhaps the most obvious thing here is that they still vary quite a bit from one to the other.