UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

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CENTER FOR DRUG EVALUATION AND RESEARCH

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CURRENT STATUS OF USEFUL WRITTEN PRESCRIPTION DRUG INFORMATION FOR CONSUMERS

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THURSDAY,
JULY 31, 2003

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PUBLIC MEETING

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The meeting was held in the Boardroom of the National Transportation Safety Board Conference Center, 729 L'Enfant Plaza, S.W., Washington, D.C., at 9:00 a.m., Paul Seligman, M.D., M.P.H., Chair, presiding.

FDA PANEL MEMBERS PRESENT:

PAUL SELIGMAN, M.D., M.P.H., Director, Office of Pharmacoepidemiology and Statistical Science, CDER, Chair
TOM McGINNIS, R.Ph., M.P.H., Director of Pharmacy Affairs, Office of Policy, Planning, and Legislation, Office of the Commissioner
VICTOR RACZKOWSKI, M.D., M.Sc., Director, Office of Drug Safety, OPASS, CDER
ELLEN TABAK, Ph.D., Health Science Analyst, Division of Surveillance, Research, and Communication Support, ODS, OPASS, CDER
ANNE TRONTELL, M.D., M.P.H., Deputy Director, Office of Drug Safety, OPASS, CDER

ALSO PRESENT:

DAVID BLAIR, R.Ph., Managing Director, Medical Care & Outcomes, Inc., Criteria Committee, National Council on Patient Information and Education (NCPIE)
WILLIAM RAY BULLMAN, Executive Vice President, National Council on Patient Information and Education (NCPIE)
TERI BURNHAM, Acquisitions Editor, Drug Facts, WoltersKluwer Health Clinical Tools Division
JOHN COSTER, Ph.D., R.Ph., Vice President, Policy and Programs, National Association of Chain Drug Stores (NACDS)
ALAN GOLDHAMMER, Ph.D., Associate Vice President, Regulatory Affairs, Pharmaceutical Research and Manufacturers Association (PhRMA)
LINDA GOLODNER, Chairperson, National Council on Patient Information and Education (NCPIE)
GERRY D. HOBSON, R.Ph., Research Manager, Cerner Multum
STACEY KAUFMAN, President, Scriptchek
ARTHUR AARON LEVIN, M.P.H., Director, Center For Medical Consumers
PETER F. MAYBERRY, M.A., Executive Director, Pharmaceutical Printed Literature Association (PPLA)
GERALD K. McEVOY, Pharm.D., Assistant Vice President for Drug Information, American Society of Health-System Pharmacists (ASHP)
MUKESH MEHTA, R.Ph., Vice President, Regulatory Affairs and Labeling, Thomson Healthcare, Inc.
JOHN ROTHER, Director of Policy and Strategy, American Association of Retired Persons (AARP)
LEE RUCKER, Implementation Committee, National Council on Patient Information and Education (NCPIE)
BONNIE SVARSTAD, Ph.D., University of Wisconsin-Madison, School of Pharmacy
SUSAN C. WINCKLER, R.Ph., J.D., Vice President, Policy & Communications and Staff Counsel, American Pharmacists Association, Education Committee, National Council on Patient Information and Education (NCPIE)

SIDNEY WOLFE, M.D., Director, Public Citizen's Health
Research Group

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

P-R-O-C-E-E-D-I-N-G-S

(9:01 a.m.)

CHAIRMAN SELIGMAN: As there are not large crowds waiting in the foyer, I think we'll go ahead and begin. Good morning and welcome to the public meeting to discuss the current status of the private sector's efforts to provide useful written prescription drug information to consumers pursuant to Public Law 104-180. My name is Paul Seligman. I am the Director of the Office of Pharmacoepidemiology and Statistical Science in the Center for Drug Evaluation and Research at the Food and Drug Administration and I have the pleasure this morning of serving as the Chair for today's meeting.

Joining me today on the dias is Tom McGinnis, who is the Director of Pharmacy Affairs in the FDA's Office of the Commissioner. To my immediate right and I suspect who's probably stuck somewhere on the Metro will be Dr. Victor Raczkowski, who is the Director for the Office of Drug Safety, the Center for Drugs. To my left also on her way to the stage as we speak, is Dr. Anne Trontell, who is the Deputy Director of the Office of Drug Safety, again, for the Center for Drug

Evaluation and Research and then to my far left is Ellen Tabak who is the program lead on this issue and a Health Policy Analyst in the Office of Drug Safety as well.

Before we begin this morning, a few ground rules. Each speaker is allotted 10 minutes to make their remarks. After each group of speakers, there will be a 20-minute question and answer period. We ask that each speaker keep their talk focused on the questions put forth in the Federal Register and try, as best they can, to stick to their allotted time. At 10 minutes, I have the honor of reminding each speaker to try to conclude their remarks.

This meeting is recorded and will be transcribed. Information for obtaining copies of the transcript is on the back of the agenda program. For your comfort, as you came in, the rest rooms are located in the registration lobby area. Also for your safety, please note the emergency exits in the room which are out the back and on both sides of the dias to the front here.

Finally, it's important that no drink or food be brought into the auditorium. There is a room provided at the rear behind the glass of the

auditorium with a television screen where food and drink may be consumed while one partakes in the live action that is occurring here in the auditorium. Thank you for cooperating with this NTSB rule. It's important for us here at the FDA for them to allow us continued use of this very fine facility.

With that housekeeping concluded, it gives me pleasure to introduce Tom McGinnis from the FDA's office of Commissioner who will set the stage for today's discussion. Tom?

MR. McGINNIS: What I wanted to do this morning is set the stage with some history on how we got here. FDA has been interested in consumers receiving adequate information with their prescription drugs in order to avoid some serious risks that prescription drugs do present. Back in 1979, we initially published a patient package insert rule. That rule was initially just for 10 drugs or drug classes for consumers to get industry produced FDA reviewed and approved information with their prescription drugs.

Up to that time we only had one patient package insert and that was for estrogens or conjugated estrogens. We went through a formal

rulemaking process to get that into estrogen containing products to make sure consumers, especially women, got those inserts to tell them about some serious warnings, contra-indications with those products.

FDA wound up withdrawing that patient package insert rule in 1982. There was a lot of controversy at the time, paper going through the distribution system in the United States would be cumbersome. Pharmacies, many of them with small prescription areas, would have to put a file cabinet in there. There were not computers at the time. You were lucky if you had an IBM Selectric typewriter in the pharmacy in the department. Most of the time it was those manual Underwood typewriters that were very hard to use.

So the pharmacy would have a difficult time managing paper. A lot of these inserts were updated fairly frequently. Some of the products that are coming on the market now, over the first year they're updated two or three times. So the pharmacist would have to remember to get out the older version, put in the new version, a very cumbersome process in a busy pharmacy department. So FDA withdrew that rule. The private sector came

forward and, you know, wanted to do this. Said they could do it very well. FDA did a survey of how many patients were getting a piece of information back in 1982 and our national survey came back at 16 percent of patients getting some type of written information, no look at the quality of information at that time.

In 1991 we redid that national survey and the number of patients telling us that they were getting a piece of information with their prescription drugs had doubled. It was 32 percent of patients in 1991 getting some type of information with their prescription drugs. When FDA revisited the issue in 1994, the national survey showed a response rate of 55 percent of consumers now getting useful information. So 12 years had passed and we're just over 50 percent of consumers now getting any sort of information with their prescription drugs.

That prompted FDA to publish a proposed rule called Medication Guides or nicknamed Med Guide Rule. The Medication Guides were industry approved information reviewed by FDA and they were only going to be for serious and significant side effects. In addition, FDA was still disappointed

with the private sector initiative to get patients written information with their prescription drugs and the agency proposed some performance standards and those performance standards were distributions targets of 75 percent by the end of the year 2000 and 95 percent -- we had a five percent statistical variation in our national surveys. So by the end of the year 2006, virtually everybody should be getting written information with those prescription drugs. FDA also proposed some broad criteria as to what we felt would make these pieces of information useful to patients.

On February 14th and 15th of 1996 we held a workshop just like this, to talk about that rule and explain what the agency was proposing with the mandatory part of the rule and then the performance part of the rule. Congress got involved in the issue in 1996 and on August 29th, Congress passed a law and the President signed it into effect, that's Public Law 104-180.

That law essentially directed the Secretary of Health and Human Services to facilitate the development of an Action Plan, a long range plan that met stated performance goals. It would give the private sector the opportunity

to meet distribution and quality standards set forth in the plan. The statute pretty much codified FDA's performance goals under the Medication Guide Rule. The Secretary, not wanting to review many plans and choose one, contracted with the Keystone Center, which is a non-profit consensus building alternative dispute resolution organization. The Keystone Center had 120 days under the statute to develop an Action Plan from interested stakeholders.

They immediately set forth and selected 34 private sector organizations to develop the Action Plan. The government was not involved in that process other than serving as a resource person. The collaboratively developed Action Plan was accepted by the Secretary in January of 1997. It set forth criteria to determine the usefulness of information being given to the patients. It endorsed the broad criteria set forth in the Public Law and describes specific criteria that must be met.

Consistent with the Public Law, the plan called for periodic assessment of the quality and distribution of written information. Specifically, the criteria set forth in the

medication information section was that the drug name and contra-indications for use had to be in the information. Contra-indications were very important to tell the consumers if you had this condition, if you were taking these other prescription drugs or OTC drugs, you might avoid this medication or talk to your physician about taking this. How to use the drug, monitoring the drug to get the most benefit from the drug, to know what foods not to avoid were also important in the development of useful prescription information.

Precautionary information was important to the group, what to avoid while taking this medication. The serious and significant side effects or frequent side effects were also important to include in this information. Most of the consumer groups there felt this information was not going to scare consumers, would not have them avoid taking their medication or following prescribed therapy. Consumers needed and wanted this information.

General information was to be included with encouragement of consumers to ask questions of their doctors and pharmacists. The information was supposed to be scientifically accurate, not

promotional in tone or any other manner. And finally, the information was to be comprehensible. It needed to be brought down to the sixth to eighth grade reading level and it needed to be legible. Some samples of information that we had seen over the years coming off of dot matrix printers was illegible in many cases. So they were concerned that the information be legible.

In the end of 1998, on December 1, the Agency published a final rule on just the first portion of what we had proposed in 1994 and that was industry produced FDA reviewed and approved information on those small number of drugs that the Agency was being asked to approve that had serious and significant side effects. The Agency estimated that there'd only be five to 10 of these type of products reviewed and approved by the Agency each year that would need such a medication guide. Medication guides again, were just reserved for those drugs with serious and significant side effects.

And the Agency's estimate was actually a little bit too high. To date, we only have 15 such medication guides for those drugs that have very serious side effects or very serious concerns

to the Agency and they are for both drugs, prescription drugs and prescription biologics. And I'm going to turn it over to Paul to finish the introduction part.

CHAIRMAN SELIGMAN: Thank you, Tom. Well, based on the results of the 1999 pilot study, in June 2000 the FDA began plans for a formal assessment under contract with the University of Wisconsin School of Pharmacy and the National Association of Boards of Pharmacy. A sample of 384 pharmacies were selected from across the nation and a professional shopping service was used to purchase four widely used prescription drugs and basically collect the information that was provided with the prescription at the point of sale. Am I in the right place? Yes, okay.

Over 1300 pieces were collected during this particular process to be evaluated by a panel with expertise in pharmacy, medicine, and drug information. A consumer panel was also used to score these materials as well. The goals of evaluation were clear from the legislation. How frequently are these materials distributed, and do they meed the criteria for the usefulness that was set out in the Action Plan. In a nutshell, 89

percent of the prescriptions filled were accompanied by information meeting the year 2000 distribution goal, of 75 percent. However, many of the criteria used to define usefulness of this information was simply not met.

Dr. Bonnie Svarstad, the principal investigator for this evaluation, will be presenting the key findings of this study following my remarks and the full report on the FDA website.

In July 2002, FDA convened its Drug Safety and Risk Management Advisory Committee to review the evaluation and to provide advice to the Agency on the next steps. Part of the review involved understanding how information flows from the FDA approved professional label and from other organizations like the USP that provide important drug use information to the consumer. It became clear to us that there are a number of intermediate steps from the PI that involve groups that package the information in and more consumer friendly format to groups that manager the software, pharmacy integrators for retail pharmacies and finally the actual pharmacy that prints the information and distributes it to the consumer.

This flow diagram sort of outlines sort

of that flow of the information from sort of more of the formal sources like the USP, FDA and the pharmacy manufacturer to the data vendors, to the pharmacy integrators and finally to the retail pharmacies and patients. Prior to the Advisory Committee, the FDA concluded the progress was being made to meet the legislative mandate and that the 2006 goals could be met if the private sector actively engaged in this issue. The Advisory Committee strongly encouraged the FDA to take a more active role in insuring that the 2006 goals were met.

To achieve these goals, we feel that attention needs to be focused on three areas; implementation, education and evaluation. In the area of implementation, we believe that major quality improvements are needed from what the consumer receives, that a clear understanding of the expectations laid out in the Keystone Criteria must be held by all of those in the information chain and that barriers at each stage of the process must be identified and overcome where they exist.

Second, we were told by many in the private sector that they were simply unaware of

that criteria and the legislative requirement. Clearly, if we are to be successful in implementing this effort, all parties must be educated regarding their responsibilities under the law. And finally, all parties must understand how we use the Keystone Criteria to evaluate the information collected in 2001. These methods should serve as a template for the type of evaluation that will be conducted in three to four years from now.

Dr. Mark McClellam, Commissioner of the FDA, has identified consumer information as one of his top five initiatives. In a speech before the National Consumer League on February 28th, 2003, Dr. McClellam stated, and I quote, "It is one of our highest and most public health effective priorities to provide consumers with reliable, accurate, relevant, user friendly and helpful information about FDA regulated products". We need action. We are eager to learn what steps are or will be taken and what plans are being developed to meet the 2006 target. Today we are interested in receiving input on the four questions published in the Federal Register to address this need. The first question; what steps is the private sector taking to improve the usefulness of the written

information patients receive with prescription drugs and to meet the year 2006 goal? The second question; what barriers exist for the private sector to meet the year 2006 goal and what plans exist to overcome these barriers? Third; what role should the FDA play and -- what should be the FDA role in insuring the full implementation of the Action Plan to meet the year 2006 goal?

And finally; what other initiatives should the FDA consider for providing patients with useful written information about prescription drugs as endorsed by Public Law 104-180? Again, thank you for participation in today's session and with that, I'd like to introduce Dr. Svarstad who will be providing a review of the 2001 study. Dr. Svarstad?

DR. SVARSTAD: Thank you. Thanks, everyone, for coming today. Before I begin, I would like to acknowledge several people that contributed significantly to this national evaluation. First of all, my colleague, Dr. Jeanine Mount is Professor of Pharmacy and Law at the University of Wisconsin was very helpful and secondly, I'd like to thank NABP and all the folks there that facilitated the data collection through

Second to None, Incorporated, et cetera. And to the FDA staff, Dr. Ellen Tabak and her colleagues. It would not have been possible without these people.

Okay, what I'd like to do this morning in the time that I have here is to -- first to briefly review the criteria and scoring methods. I'm assuming or hoping that many of you have had an opportunity to read the full report on the website; however, it's useful, perhaps, to review briefly what -- how it is that we went about evaluating the information sheets.

Secondly, I'd like to summarize the major deficiencies, so that we know perhaps what the most important points of improvement need to be and thirdly, to examine some ratings by leaflet type and vendor. This analysis was done subsequent to the evaluation and is not included in the website. However, it has been done since then with some help that we have at Wisconsin. Basically there we're trying to understand why it is that some leaflets were rated more highly than others. Does it vary by type, vendor, and/or pharmacy type.

And finally, I brought along a few copies of sample leaflets so that you can see what

we found in the National Evaluation. The study differs from past evaluations in several ways. First, the shoppers presented four new prescriptions at 384 randomly selected pharmacies in 44 states. The earlier study was in eight states. To my knowledge, this probably is the largest study that's ever been conducted internationally, so it's quite, I think, something that we can feel was based on a random sampling in a wide number of states.

Secondly, the expert raters in this particular evaluation were nominated by seven pharmacy organizations and they include the full list of pharmacy organizations from National Association of Chain Drug Stores, American Pharmacists Association, American College of Clinical Pharmacy, American Society of Health System Pharmacists, the Academy of Managed Care Pharmacists Pharmacy, National Community Pharmacists Association and of course, National Association of Boards of Pharmacy.

The intent there was to try to get people from a wide variety of environments so that we had practitioners, pharmacy practitioners, who were currently working an independent pharmacy, at

least two of them, pharmacists affiliated with a chain pharmacy, at least two of them, pharmacists affiliated with hospital and clinic to get a wide perspective.

The panelists, the expert panelists, that is the pharmacy panel, used eight criteria from the Action Plan and we tried to be very careful about adhering to the Action Plan criteria, not adding criteria that the panel thought the original Keystone Group should have. If anything, I think the panel might have wanted to be a little stricter on a number of points that we can bring up later, but that's not my intent now. The point I want to make is that they tried very hard to stick with the Keystone Criteria.

Unlike the pilot study, consumers also rated the leaflets and I'll say a little bit about how we did that. The eight criteria were mentioned by Tom McGinnis, so I won't go through those carefully except to say that its important to see out of those eight criteria that about six of those or seven of those actually relate to the content of the information and the other relates to legibility and comprehensibilities. So the intent is to try, I think, as I understand the Keystone Criteria, to

make sure that the information is sufficiently specific and complete or comprehensive and secondly, that it's accurate and up to date, not promotional in tone and thirdly, that it's legible and comprehensible and that kind of goes through those eight criteria and their intent. And I think that also makes it somewhat unusual in terms of an international evaluation.

Other countries are now looking at these criteria and beginning to evaluate their materials using the Keystone Criteria, an interesting development, I think. Now, a word about the expert rating forms themselves. Each form had eight criteria and under each criteria, there were sub-criteria for a total of 62 to 63 sub-criteria and each one was intended to be kind of a checklist type of thing, so that the panelists could do this in an objective and a reliable way and independent of all other panelists.

The sub-criteria -- each sub-criterion was worth zero to two points; zero if it wasn't at all included, one if there was some attempt to address the issue and two if the issue was addressed according to Keystone Criteria. We used -- we took all of those forms from the panelists

and submitted them to a survey research form and then entered the data into the computer and the computer calculated the percentage of points obtained for each individual leaflet obtained and there were over 1300 of them as Pharmacist McGinnis noted. The adherence to criteria then was calculated over all of those four drugs and so forth and the -- each leaflet could get a score of zero to 100 percent. This is an attempt to standardize the rating of each leaflet across drugs in the pharmacy.

And finally, we established five levels of adherence and I'll be reporting this in kind of a bar graph because if you look at the main report, there's a lot of figures in there and so the attempt here is to simplify it as much as possible. Level 5, the panel considered the ideal level because there you have 80 to 100 percent adherence with the Keystone Criteria. Level 4, 60 to 79 percent and so on down to Level 1, where you had only zero to 19 percent adherent to the criteria.

Now, let's just say a bit about the consumer rating process. We identified facilitators who might assist us at other pharmacy colleges and schools across the country, in fact,

in 11 states. Those facilitators recruited a total of 154 consumer raters who were asked to rate the leaflets using a standardized form that we had pretested in a previous study. The facilitator arranged with these consumers eight to 15 of the consumer raters per session and each rater was given an envelope with about 10 leaflets in it and they were asked to rate each of those leaflets independently, that is not to discuss with each other or to discuss with the facilitator.

And each leaflet was rated then on 12 items with one to five points each in a semantic differential format, that is on one end of the scale would be poor and on the other end of the scale would be good, one being poor and five being good. The consumers were asked to really rate in two general areas; one the area of comprehensibility, how well the material was -- how understandable it was and legibility. In the area of comprehensibility, we asked the consumer to comment on whether the material was poorly or well organized, whether it was a poor or good length, for obvious reasons. If it's too short, it doesn't include enough information. If it's too long the consumer will lose interest and everyone will be

burdened.

We also asked them to evaluate the clarity, whether it was unclear or clear, unhelpful, helpful, incomplete, complete, hard or easy to find important information. Legibility items, asked them to comment on the print size, whether it was poor or good print size, poor or good print quality, poor or good spacing between the lines, all of which -- all of these items were listed incidentally, in the original Keystone Plan and so that's where we really got these and I think as I understand it, the Keystone Committee got these items from the educational literature, that is studies that have identified areas or dimensions of educational materials that facilitate their understanding and usability by the reader.

We also asked consumers to give us a summary rating about the overall ease of reading, the overall ease of understanding and the overall usefulness and I'll show you some bar graphs on that in a moment. Now with the results, to summarize.

The first thing that we're summarizing here is the distribution, the percentage of shoppers who were given any information, regardless

of its length, regardless of its quality, regardless of its content. And you see in the first column there that the percent of shoppers given a leaflet ranged from 88 to 90 percent. On the left-hand side you see atenolol, glyburide, atorvastatin and nitroglycerin, those were the four drugs. So we calculated the percentage for each drug. It's quite remarkable, I think, that the rates are the same for the drugs, indicating that pharmacists are not making -- not being selective about which drugs they're giving leaflets for. If they give a leaflet, they pretty much give it for all the drugs that the patient has.

Now, on the mean expert rating, that is what percentage of all those sub-criterion were met, you see that the rating ranged from 51 to 55 percent and that is probably the area where we have the most concern, that is that it did not meet the criteria or it met only 51 to 55 percent of the criteria. Now, let's look at the criteria themselves to get some idea about which criteria were met, which ones weren't, which might help us to understand why this rate overall. So let's look at the expert ratings for all criterion. This is for 1367 leaflets that were evaluated by the panel.

And across the top you see five levels, red meaning Level 1 or zero to 19 percent of the criteria being met. The highest level would be Level 5, that is the most -- 80 to 100 percent and in between. Along side you have zero to 75 percent. You have the four drugs shown there. You'll see for atenolol, that none of the leaflets met Level 5. Twenty percent of the leaflets met Level 4 and 56 percent of the leaflets met Level 3, so you kind of see where they fell out. Very few leaflets fell down into the lower categories but there are 13 percent there that were very low and I'll have comments about those 13 percent later.

With glyburide, it was pretty much the same. You can kind of see the same trend. None of the leaflets met Level 5, 24 percent Level 4, et cetera. Atorvastatin, only 17 percent met Level 4, none met Level 5, 59 percent met Level 3. Again, you see kind of the same shaped curve. Nitroglycerin looked a little bit better, but again, you'll see that none of them met the highest level which the panel had set using the sub-criteria. So the overall picture here is one in which none really of the leaflets are meeting the highest level, when you look at the overall rate.

Now, let's look at the individual criteria of these eight. The highest ratings were for accuracy and lack of bias or promotional in tone. That is, when information was given, it was rated as accurate rather than lacking in accuracy. Moderate ratings were given for the criteria name, drug name and use, criterion 3 for directions. The lower ratings and the lowest ratings were on the right-hand side there. Criterion 5, with regard to adverse drug reactions and what to do received relatively low ratings as well as general information. The lowest ratings were in the area of contra-indications, precautions, and legibility. Now, let's look at each one of those a little bit.

This graph tries to summarize a number of tables that were in the final report and what I did was to put the criteria from -- criterion from the Keystone Action Plan down on the left-hand side, so you see Criterion 1 through 8 and I've only shown the percentage of leaflets that met Level 4 or Level 5, so that you can see which criteria were met better than others. You see here, for example, that on the first criterion, inclusion of drug name and its use, 32 percent of the leaflets met that criterion at Level 5.

Contra-indications, only five percent of the leaflets met that criterion. Nineteen percent Level 5 for directions and you see it dip down again for precautions where only seven percent met the precautions sub-criteria and 13 percent adverse drug reactions, likewise for general information. And you see 95 percent meeting accuracy. Now, it's important not to confuse this meaning of accuracy. This is kind of a summary term here. Accuracy, again, means, that when they did provide information, it was accurate according to the experts. It wasn't necessarily complete, or it's not necessarily readable, or it's not necessarily specific, but it was not promotional or inaccurate.

And finally, you see that none of them met the legibility and comprehensibility. Now, we can see the -- in a little bit more detail what the data show for contra-indications and precautions. This is just repeating some of the things that I said earlier but you see again, that five percent met the highest level for contra-indications, 27 percent, Level 4 and then you see the other levels there. This is in the final report. You see the same thing for precautions. If you lump or

collapse Level 4 and 5, you see that 21 percent of the leaflets had 4 or 5 -- Level 4 or 5 on precautions. That is, the majority of the leaflets did not meet even Level 4. And on legibility and comprehensibility, again, same situations. Those are the three criteria that I think had the lowest ratings, area of contra-indications, precautions, legibility, comprehensibility.

Now, let's look at what the consumers told us. Again, we're collapsing this data into Level 1 through Level 5 for the sake of simplicity and we're showing it for atenolol through nitroglycerin for all four drugs in other words, and you see here that the consumers are a little bit more favorable, but they too are not giving the majority of leaflets the highest level of rating. You see here that 24 percent of the atenolol leaflets met Level 5 according to the consumers and 30 percent met Level 4.

About the same shape of the curve for glyburide, atorvastatin. I think you've got the message, right? I'm not going to go over all of that and get sidetracked here. Now, let's look at the items that the consumers commented on and try to identify where their concerns focused most. The

lowest ratings by far of all those items that I presented earlier, the comprehensibility and the legibility, the lowest ratings by far were in the area of print size, print quality, spacing and overall readability. In fact, 36 percent of the leaflets rated by the consumers were given a low rating on the area of readability.

When you looked at their summary ratings for readability and understandability, you can see here in the first set of bars under reading, that 19 percent were considered very poor and 17 percent received a two, that's where I got the 36 percent. In other words, 36 percent of the leaflets received a one or a two rating, indicating that the consumer had concern about it. They were more favorable with regard to ease of understanding. I have to tell a little story here on the ease of reading. To make sure that tools are useable and valid, et cetera, I generally try to use it myself at least one with a group of consumers. So I did a group of about eight consumers and we were seated -- they were seated around a large dining table in someone's home and before we started rating them -- and, you know, I gave them all kinds of stern instructions about how

you can't talk to each other and you can't talk to me and, you know, they were being very polite and one, I would say probably 80-year old woman raised her hand and she said, "Bonnie"? "Yes". "Do you mind if I go back home and then come back"? And I thought, why would -- "Go back home"? And she said, "Yes, I'd like to go and get my magnifying glass".

In other words, she was having so much difficulty that she wanted to go home and get her reading aids. Of course at that point, I was a little unsure of what I should do but I said, "Well, why don't you just try to evaluate what you have in front of you and it's okay to look down close without a reading aid". So I think this ease of reading is pertaining to legibility and not to the terms that are used.

Useful, I think about 62 percent of the consumers gave a four or a five on usefulness, so I think they're fairly favorable about these leaflets overall, although you see that eight percent, nine percent received very low ratings there. And I've brought a couple of leaflets to show you the ones that they think are not useful. Now, what factors were linked to ratings. And this analysis pertains

to atenolol, largely because we needed to focus on one of the drugs and make it somewhat manageable this task.

We examined a number of factors and the first factor that we looked at was the leaflet type. What we noticed was that -- the obvious that pharmacists know and that is that some of these leaflets were very short or abbreviated. We defined that as less than 75 words. These leaflets sometimes are called warning messages, sometimes they're called counseling messages. In any case, they're very short messages or abbreviated and standard leaflets, those with 75 or more words. Notice that we found 48 pharmacies or 38.7 percent of the pharmacies giving out abbreviated messages only. And the remainder that gave leaflets, 86 percent gave standard, so we'll talk about that as a problem later when you see the results.

The second thing that we looked at was leaflet vendor and version. We were quite interested to find, as I think others have noted that most leaflets came from one vendor. That vendor, of course, had different version, Versions 1 through 3 that we were able to identify. Basically, what we found was that 87 percent of the

sites examined were using leaflets produced or published by Vendor 1. We found a few vendors that we couldn't identify because there was no vendor name or publisher put on the information sheet. We found 13 percent of the leaflets fit that category.

Because we did not collect data from hospital pharmacies or clinic pharmacies, we decided that it might be useful to include leaflets that are commonly found in the hospitals, so we identified a comparison leaflet, I'll call the Vendor 2, and we included those in the consumer and expert packets to determine how it is that they would have rated those, so you will see in these results when you're referring to Vendor 2. That's not because we collected them in the pharmacies as part of that original sample, but we included kind of as a comparison leaflet.

And finally, we looked at leaflet format and pharmacy type. Now let's see what some of the results were. Now, this bar graph shows the expert ratings by leaflet type, vendor and version. Now, let me try to walk you through this. The colored bars are for standard leaflets, that is those leaflets that are 75 or more words, and the

white bars are for the abbreviated or short leaflets. You will also see next to each bar a term V-1 or V-2 or small v-2, 1, 3. Those are -- the large V-1 refers to the vendor, so it's Vendor 1 or Vendor 2 or vendor not ascertainable and the small v relates to the version.

So the first bar is a standard leaflet by Vendor 2. That is the comparison one. Now, you see there, that leaflet was rated by the experts at 75 percent adherence level. Now, that finding, I think, is kind of interesting because that suggests that it is possible to produce a leaflet that will meet this criteria, the criteria, whether the Action Plan or Keystone Criteria that we're talking about here, are not so high that they cannot be met by existing leaflets out there. This leaflet is out there and is being used by many hospitals. I've not identified the publisher but can do so.

The second bar relates to standard leaflets by -- the second and third bar, Vendor N/A, N/A, 2 or 1 with 40 percent rating and a 50 percent rating, those were vendors that we could not identify and what you see is that second bar, it tells you that for that vendor, the rating was somewhat lower than for Vendor 1, so that we did

see variability by vendor.

You see also the fourth bar, the fifth bar and the sixth bar, Vendor 1, Version 3, Vendor 1, Version 2, Vendor 1, Version 1, were weighted similarly, 55 percent, 59 percent, 54 percent. I put this up there simply to show we found different versions and there was some variability but not very much. What's most interesting to me though is that these abbreviated or short leaflets receive very low ratings, 25 and 26 percent, whether they came from Vendor 1 or another vendor.

So what can we conclude? That expert ratings do vary by leaflet type, somewhat by vendor and very little by version, but leaflet type is definitely something that has to be addressed. Let's look at the expert ratings of standard leaflets for this particular drug just to see how it is that Vendor 1 and Vendor 2, Vendor 1 meaning the predominant one out there in the market and Vendor 2 being the one that we selected from hospital system, you'll see that on name and indication, there was some variability with Vendor 2 receiving a higher rating. You see that contra-indications received a much higher rating by Vendor 2. You'll see little difference in directions and

little difference in precautions. You'll see quite a bit of difference in adverse drug reactions where Vendor 1 received a 44 percent rating and Vendor 2 a 99 percent rating, very little on general information, very little difference on accuracy and quite a bit of difference, almost a two-fold difference on legibility. And I have brought samples so you can kind of see this.

Now, let's look at consumer ratings. What was interesting here was that the shape of the -- shape of the results resembled the expert ratings that I showed you a few moments ago. You'll see that Vendor 2 leaflets received an average, a mean of 89 percent by the consumers. They clearly preferred this leaflet over existing leaflets. You see that the non-ascertained vendor, the second bar, received lower ratings than all other vendors, according to the consumers, as well as to the experts and then you'll see the ratings for Vendor 1, varying very little and you'll see very much lower ratings for the abbreviated or short leaflets. Neither the consumer nor the expert gave acceptable ratings to those short leaflets. Consumer ratings varied somewhat by criteria on these Vendor 1 versus Vendor 2. You'll

see that under easy to read, they gave an average of a score of 3 versus a 4.7 for the Vendor 2. There was some difference in ease of understanding but not as much as on readability and they considered both of them useful but the second one more useful.

Now, by leaflet format and what we did here was to identify leaflets that did meet criteria on font size, did meet criteria on readability, spacing and bullets and we analyzed whether or not consumer ratings really differed here, and what you see is that for leaflets that met the criteria on font size consumers did give them a higher rating independently. Those that had better reading level, that is as measured by readability indices, there's some difference but I wouldn't really consider this a marked difference although it's statistically significant.

On spacing, you do see some difference and on leaflets that use bullets, you see that the consumer rated those leaflets 81 percent versus 64 percent. This criteria -- sub-criterion was in the Keystone Plan suggesting that when you separate material by bullets or space, white space, et cetera, it is easier for people to read and it

showed in their ratings. Now, what did we find with regard to leaflet distribution by pharmacy type?

We found -- we've compared here pharmacies that are identified as independent pharmacies versus those that are chain pharmacies according to the national data base that we had access to. You see that there was a significant difference between independent and chain pharmacies in the percent of shoppers given a leaflet, 79 percent versus 98 percent. There is some difference in expert ratings, although not terribly marked and you see quite a bit of difference also in consumer ratings.

What's interesting, I think, most to me is that it appeared to be the independent pharmacies that are using the short messages rather than the chains. You see here that 32 percent of the independents gave a short message as opposed to a standard length leaflet. Now, my last slide, what are the conclusions, four conclusions that I would suggest for deficiencies, if you will.

Eleven percent of the pharmacies gave no leaflet whatsoever, so regardless of what you do with vendors or with software people at the point

of distribution, there is an issue for one out of 10 pharmacies. Thirteen percent of the pharmacies gave an abbreviated or short leaflet. This means then that 11 plus 13 percent, 24 percent of the pharmacies either gave nothing or a leaflet that was considered too short or incomplete by both experts and consumers a little disagreement there.

Thirty-six percent of the leaflets are hard to read according to consumers in terms of the font and spacing and I think this is an issue that does not relate to information content or criteria. It relates to the printing of these materials. And as an aside here, I think, unfortunately the pharmacists that I talked to, practitioners, some of them are not even aware that they can change the print size or font in their particular pharmacies, even though it might be very much possible to do that, so some of these are practical problems that probably just need to be addressed by those that are down at the line of distribution.

Finally, I think we conclude that the leaflets generally failed the content criteria, six out of seven of the content criteria. Most seriously, perhaps, are the criteria with regard to contra-indications or precautions, where 90 percent

of the leaflets did not meet Level 5. I would identify those problems as they're different problems and they're at different points in the process. Some relate to problems that can be corrected by the vendor. Some relate to problems that can be corrected by the pharmacy manager and some may be the problem that gets down to the level of the pharmacist as to his or her decision as to whether to distribute the leaflet. And with that, I'll end the slides and I'll show you a couple of examples while I still have a couple of minutes.

Okay, can someone help me make the transition? Now, you cannot read this, but this is a typical abbreviated message. I've not -- this is the exact size of the print and this is all the consumer got. It basically says, "Follow directions", period. "Do not stop without doctor approval, may cause drowsiness, dizziness, drive with caution, notify your doctor if you intend to become pregnant, check with doctor before taking any other medicine, promptly report unusual symptoms, effects to doctor, inform doctor/dentist prior to any type of surgery".

This is a second type of abbreviated message. I won't go through all the details. It

lists one side effect, no contra-indications, but it gives probably a few more specifics than the last message. "Use exactly as directed by the doctor, must be compliant with therapy". This is also for atenolol. "Check with the doctor before discontinuing", which -- this one illustrates the small font size and the typical size. I should say that on the length, when we measured the length of the leaflets, 38 percent of the leaflets were under five inches long. Forty-two percent of the leaflets were 5.6 to 11 inches, that is they used a page or less and only 19 percent of the leaflets went over one page, and most of the time they went over by only a paragraph. So these are not long leaflets.

This is the leaflet from Vendor 2 that both experts and consumers gave either 75 percent to 89 percent rating and you can see a couple of things about this leaflet. It goes over one page slightly. I'm not showing you the second page but there's a few side effects on the next page. Basically, you see that the headings are separate on a line. They use bullets. They have plenty of white space and the font is fairly large and then when the experts reviewed the content, the content

included higher ratings on contra-indications than the other leaflet. So I brought that to basically show you what it is that the consumers and experts thought was more acceptable.

With that, I'll stop and appreciate your attention. I'll take any questions you might have.

CHAIRMAN SELIGMAN: Great. Thank you very much, Dr. Svarstad for an excellent summary of a very complex and thorough study. We do have time now for any questions for Dr. Svarstad about the study and the evaluation. Please either identify yourself and your affiliation if you're going to come to the microphone. Yeah, please use the microphone in the aisle way.

MR. SALZANO: Thank you. Ron Salzano from the Pharmaceutical Printed Literature Association. You mentioned that there were some other criteria that you would have added to the eight. Can you speak on that, please?

DR. SVARSTAD: It probably wouldn't have been an additional criterion but it would have been higher expectations with regard to monitoring parameters. So for example, if someone was receiving a medication for cholestral, they would

have put more specific information in about what the patient should be expecting in terms of treatment outcomes. And you might think in the case of medication for high blood pressure, you might even suggest at what level their blood pressure should be but that was not a Keystone Criteria so they suggested including it, but I had them discuss it and they said, "Well, I think the intent was to stick with the Keystone Criteria but the panel could make those recommendations to future people that are looking at the criteria themselves". My guess is that -- or I guess my perception on this is that criteria are likely to change over time as more information becomes available on certain -- on drugs and that maybe that our -- that consumer's expectations and professionals' expectations of what it is that consumers really need to know changes over time.

I recall, for example, going and having -- several years ago asking consumers to evaluate material for neuroleptics and their chief criticism of the existing leaflets was that they didn't tell them what the odds were that they would improve. They told them what it was for but they knew that. They wondered, "How likely is it that I'm going to

improve". It's a reasonable statement. Yes.

MS. CHOW: Hi, I'm Belinda Chow. I'm with Consumer Health Information Corporation. I was curious about the demographics of the consumers that rated the leaflets. Do you have any information on that?

DR. SVARSTAD: Yes, it was provided in the final report. I can't draw it out off the top of my head but what we -- what we tried to do is to get approximately the same age distribution of the people that would be using these drugs. So I think the mean age was in the fifties, but we had people much older than that and must younger than that. That was the main thing. We did not have a very good racial ethnic distribution. And we did not try to evaluate Spanish speaking or other language materials, a limitation on the study to be sure. Yes.

MS. PAUL: I'm Kala Paul. I'm an independent consultant. I was curious to know if there was a formal health literacy evaluation for reading level. I know you talked about readability and comprehensibility but I believe before you presented some health literacy statistics on this, the study.

DR. SVARSTAD: You mean the consumer's literacy, we did to a readability assessment using --

MS. PAUL: Yes, the actual grade level.

DR. SVARSTAD: Yes, we did, uh-huh, we did, and the specifics are in the final report. It wasn't serious. I think it was actually pretty good I would say, yeah. You'll find it in the appendix of the report and I can pull it out if you'd like me to but we did do a systematic assessment of that and we also adapted the existing reading level measures. We did not count, for example, drug names as a large term for example, otherwise I think it would have been inflated high, inflated too high. Yes, any others? Uh-huh.

MR. LEVIN: Is this on?

DR. SVARSTAD: Yes.

MR. LEVIN: I guess I have a question relating to sort of some of the criteria that received very high marks by the expert panelists and I guess my concern that both the Medication Guide Proposed Rule and then the Action Plan criteria which really are almost a mirror image of those, are complex and involve a lot of interweaving between the criteria. So for example,

if I remember correctly from reading the report and from the material you presented this morning, unbiased in content and tone gets very high marks. Yet in there, in the description of that criteria is the information should represent a fair balance between descriptions of the benefits and descriptions of the risk.

We hear that on contra-indications they get low marks. So my concern is and my question is, how did the expert panelists tease out this kind of sort of sub-issue that's embedded in unbiased in tone and content which goes way beyond just simply being non-promotional but I think most importantly asks for a very balanced presentation and the experts find that that -- that some components are not -- they didn't do very well with in terms of the information.

DR. SVARSTAD: Well, that's a good question. They told -- I think my impression was that they felt that there wasn't adequate information on benefits either and that that's probably why they would not grade them low on that. When you say a medication is for cholestral and it doesn't really talk about the benefits of it or how that's going to improve your -- you know, anything

beyond that, there are really very limited information on benefits. That -- my guess is that that's what they would say.

They struggled with this accuracy promotional fair balance issue, too. This is very hard work to evaluate these leaflets and to develop that criteria for them. And they ultimately decided that what they had to do in the accuracy one is to talk about -- and talk almost in terms of negatives, lack of promotional, lack of inaccurate information, et cetera, but that's a good point that you make.

CHAIRMAN SELIGMAN: Any other questions or comments for Dr. Svarstad?

DR. SVARSTAD: Thank you very much.

CHAIRMAN SELIGMAN: Again, thank you very much. And why don't we then start our break a little bit early and convene at 10:20 for the panel?

(A brief recess was taken.)

CHAIRMAN SELIGMAN: Again, if folks would please find your seats, I'd like to begin. Our first speaker on this morning's panel is Dr. Sidney Wolfe, the Director from Public Citizens Health Research Group. Dr. Wolfe?

DR. WOLFE: Thank you. Twenty-two years ago, in 1981, we carefully researched regulation requiring FDA approved patient information leaflets to be dispensed with prescriptions was canceled by the Reagan Administration just before it was to have gone into effect. It was supposed to go in effect in May and July of `81. This abrupt reversal was at the behest of drug companies, pharmacy organizations, and some physicians groups and private sector designed leaflets not approved by the FDA, thereby continued to be the norm. They were the norm, although as Tom mentioned this morning, getting distributed to a smaller number of people that were there precipitating the effort by Dr. Goyan and others in the FDA to get the publicly approved program going.

This meeting marks the start of the process that must culminate in the restoration of FDA approved patient information leaflets as a safer alternative to the dangerously failed voluntary private sector design labels. The private sector is quite good at printing up information that is accurate. The private sector currently prints up information on the FDA approved

professional labeling and I'm sure it could do that same thing, so it is the design not the printing process that is at fault here.

The fact that a private citizen had to file suit in Federal District Court in February of this year to compel FDA to hold this public meeting on the failure of private -- of voluntary private sector designed programs to provide consumers with useful scientifically accurate written drug information escapes all reason. The law is clear. Dr. Svarstad's excellent presentation this morning concluded by saying it failed six out of the seven criteria. If private sector initiators fail to achieve the information quality and distribution goals defined in the Public Law 104-180, the Secretary of HHS quote, "shall seek public comment on other initiatives that may be carried out to meet such goals", and it was our impression based on the absence of asking for a public hearing that the progress which is certainly there in the percentage of people getting something, was swamping out the fact that it failed to meet usefulness.

You've heard the presentation by Dr. Svarstad. The failure was not at all surprising

and is consistent with the private sector's performance since and before the creation of NCPIE in 1982 with significant support of the pharmaceutical industry. Again, this is the design of the leaflets, not the printing. The FDA announcement last year of the findings of the University of Wisconsin was remarkable in two respects. First of all, the FDA said, quote, "Overall usefulness of the information provided as measured by eight objective consensus based criteria was about 50 percent". That's what you heard this morning. The notion that consumer drug information can be 60 percent -- can be 50 percent useful is unfathomable. It's either useful or not and it's not even what we used to think about failing which was 65 or 70 or something like that. Drug information that communicates only half of what it should is misleading and misleading drug information is potentially dangerous.

Second, the FDA's conclusions or recommended course of action was extraordinary. Quote, "Because the Agency sees progress in meeting the goals under the law, FDA will continue to meet with private sector partners to improve the usefulness of patient information and meet the

goal in the year 2006". Amazingly the FDA determined that the failure of the results shown in the study to comply with the Action Plan guidelines was quote, "Progress".

The public citizen had no option but to file suit since FDA seemed content with the progress thus far and wasn't planning to challenge the well-documented failure. Underscoring the lack of public access to useful scientifically accurate drug information are the results of a survey just concluded by a public citizen assessing the content quality of black box warning information intended for consumers. The survey involved all 23 of the top selling drugs in the United States in 2002 that are required in the professional labeling to include a black box warning. It should be noted that the above-mentioned Wisconsin study that you just heard, commissioned by the FDA did not include any drugs, none of those four drugs, had black box warnings. This is not a criticism of the study but just to point out that we are looking at something that was not really looked at because none of the four drugs did have black box warnings. Using the guidelines of Public Law 104-180, the major results of the survey are one; none of the patient drug

information leaflets, zero out of 23, being distributed in the Washington, D.C. CVS Pharmacy are available on the CVS Pharmacy website for those top selling drugs with black box warnings complied fully with the guidelines. This is First Data Bank data produced by First Data Bank, the leaflets that is.

Two, none of the information, zero out of 23, from the USP Drug Information, USP DI advice for the patient used to license under -- used under license to Micromedex, a business of Thomson HealthCare for these drugs meets the quality goals for communicating black box warning information to consumers. Very similar to what you heard described in the methodology of the study presented, we had explicit criteria made up of what was, in fact, in the black box warning approved by the FDA and the question was, did it meet this criteria and the answer was as we've heard.

And finally, information for only four drugs, four out of 22 for MedMaster because one of those 23 drugs is not up there and these latter two are off of websites which we believe are probably the same as the distribution in the pharmacy, information for only four out of 22 from MedMaster,

a product of American Society of Health System Pharmacists, ASHP, fully complied with the quality guidelines concerning black box warning information.

These results are extremely troubling. First, the information contained in black box warnings is the most serious type of warning FDA can require and is the most important to the health and safety of prescription drug to consumers. Second, information by Micromedex and ASHP was downloaded from a website at a National Library of Medicine's Medline Plus website. This is a site the proclaims that both health professionals and consumers can quote, "depend on it for information that is authoritative and up to date", even though it's inaccurate.

We find it irresponsible that the management of NIH, National Library of Medicine, uncritically features on its website drug information that is unregulated and fails to meet minimum quality standards and we're going to urge the NIH Dr. Lindberg to eliminate this and replace it with accurate and more complete information. Consumer access to useful drug information through FDA regulation or by voluntary private sector

programs is at the center of a contentious debate for more than 25 years. It was really 25 years ago that some effort began to end the private sector design of these information leaflets. The divisions have been along ideologic lines with industry professional trade groups and industry supported organizations such as the National Consumers' League favoring a marketplace for information and consumers preferring a government regulated program with quality standards and oversight, much as we have for professional labeling.

Research has been done, history is clear, there's no longer any legitimate argument in continuing to consider voluntary private sector programs as a solution for providing consumers with useful, scientifically accurate written drug information. This is a failed paradigm. The fact that manufacturers are required to write professional product labels that must be approved by the FDA before they're distributed but that consumer drug information has been left in the hands of unregulated commercial information vendors who have consistently failed to follow voluntary quality guidelines is irrational for the following

reasons.

One; FDA has the authority to require Agency approved written consumer information to be distributed with each new and refilled prescription for a limited number of drugs under a rule that took effect in `99. As Tom mentioned this morning, there are about 15 drugs under that heading now. Only a slight modification of this rule would be needed to cover consumer information for all drugs. I think most shockingly and in contrast to what is going on here is that multi-national pharmaceutical companies operating in the EU, not UK yet but the EU, have been required for a decade to produce and distribute written consumer drug information based on the drug's professional product labeling that is approved by member states' drug regulatory authorities. Why does government regulated consumer information exist for al drugs in Europe and not in the U.S.?

Now, some of these might not meet the explicit Keystone Criteria, but it would certainly be a good starting point as would be the now revamped or in the process of being revamped professional labeling which will start out with an important -- in some reading, the most important

points. We certainly will continue to advise people not to take the inadequate handouts that are given in the pharmacy now and to ask for the professional labeling as it becomes more readable and prioritizes the information.

Three; the infrastructure already exists in the U.S. for distributing written information to the majority of the prescription drug consumers. The University of Wisconsin study found that 89 percent of consumers were receiving some sort of information even though it was clearly substandard. Obviously, the cost of distributing this information has already been passed onto consumers and it would be no more expensive to distribute useful scientifically accurate information than inferior information.

Again, as mentioned earlier by Tom McGinnis and by Paul Seligman, Dr. McClellam has listed as one of his top five priorities helping consumers to get truthful information about products they use so they can make informed decisions. The Commissioner can go a long way in achieving this priority by immediately moving forward with a long overdue initiative to require the mandatory distribution of FDA approved written

drug information with each new and refilled prescription. It is time to end the double standard wherein doctors and other health professionals use and are informed by FDA approved labeling but patients, like second class citizens, get whatever the out of control purveyors of patient information leaflets choose to have dispensed to them with their prescription drugs. Just in the context of this meeting, we received a belated response as in five years after it was filed, to a petition we filed asking for FDA to at least take control over more of these labels under the authority they have.

It was occasioned by the death of a young child, the only child of two parents. The child got a drug at a dose that was way too high for an indication that was unapproved and other information that should have been but wasn't in a patient information leaflet would have saved this child's life. We think it's time to stop this -- I mean, 25 years is the short version of how long this has been going on. It's much longer and I don't know what further evidence is necessary to have the government take control over what is going on. Thank you.

CHAIRMAN SELIGMAN: Thank you, Dr. Wolfe. Our next speaker is Arthur Levin, the Director for the Center for Medical Consumers.

MR. LEVIN: Thank you for the opportunity to present comments today. As Paul said, I'm the Director for the Center for Medical Consumers, a non-profit consumer advocacy organization located in New York City. We are a 501(c(3) organization that does not receive any funding from any manufacturer of drugs, devices, biologics or medical equipment. I guess I could just say ditto to everything that Sid said and save some time, but I have some self-interest and my own way of saying it, so I think I'll go ahead as planned.

You should also know in the spirit of disclosure that I was a member of the steering committee that devised the Action Plan and that I am currently the consumer representative on the Drug Safety and Risk Management Advisory Committees which a year ago reviewed the University of Wisconsin's study and made recommendations to the FDA. And my comments are probably over 10 minutes and I will go very quickly and cut out what I think is repetitive.

Since its founding in 1976, the Center has advocated on behalf of the rights of consumers and patients to know everything there is to know about a prescription drug or a medical device. And I believe that open access to this information is critical to patient safety and an absolutely necessary condition of informed decision making and informed consent. And I would suggest that the demonstrated decades of failure of the various private sector interests to provide high quality written prescription drug information to consumers should be a matter of urgent concern from what is after all a public health agency.

People define the goals of providing consumers and patients with written information about their drugs from different perspectives. Some see it as a means to improve patient compliance with drug regiments. Others see it as a way to encourage people to take the drugs prescribed to them and still others see it as a means of educating people about proper use. I have a different set of priorities in mind. The first is that of protecting consumers from the risks inherent in prescription drugs. Second is providing the means by which a patient can give

informed consent to taking a drug in the first place. And third is optimizing the benefits of the medication.

The FDA asked us to comment on four questions, two of which really belong to the industry to comment on and the last two of which I think are appropriate for consumer advocates to respond to any anybody else who wants to. The first is what should the role of the FDA be in assuring full implementation of the Action Plan to meet the year 2006 goal? To my mind, the answer is simple. The FDA should mandate the distribution of useful written consumer drug information with all prescriptions and only count as useful the written information that conforms to the Action Plan guidelines for content and format. These guidelines represent a set of criteria for judging the quality of the information and after their development by the Steering Committee were formally accepted by the Secretary of Health and Human Services.

Useful written drug information for consumers is an urgent public health priority. In its 2001 report, Crossing the Quality Chasm, the Institute of Medicines Committee on the Quality of

HealthCare in America wrote, "HealthCare today harms too frequently and routinely fails to deliver its potential benefits." The preventable patient harm for prescription drugs is an urgent public health problem is to my mind beyond question. Consider the following; pharma trends and industry data analysts firms estimates that 3,340,000 outpatient prescriptions were written in 2002. That's an average of 10 prescriptions a year for every man, woman and child in America. That's also 3,340,000 opportunities for a patient to be injured by a preventable medication error, to be unaware that a drug's risks may exceed its benefits or not to understand that perhaps they shouldn't have been prescribed or dispensed a particular drug in the first place.

The evidence of serious harm to patients as a result of medication error, adverse drug reaction and drug interaction is substantial and growing. Because of this overwhelming evidence, I believe it is unconscionable for industry and health professionals self-interest to be permitted to take precedence over the well-being and safety of patients but that's exactly what's happened over the past 25 years. In my view, the

time for government's continued reliance on a demonstrably failed voluntary private sector is over.

Why is written drug information for consumers so important? Well, for one thing experts have suggested that a meaningful reduction in patient harm could be achieved if consumers and patients were better informed about the drugs they take. In its 1999 report on medical errors the IOM's Committee on the Quality of HealthCare in America recommended that a major unused resource in most hospitals, clinics and practices is the patient. Not only do patients have a right to know the medications they're receiving, the reasons for them, their expected effects and possible complications, they should also know what the pills and injections look like and how often they are to receive them. Historically, face to face prescription drug counseling by doctors and pharmacists has been viewed as the principal means to inform patients. In fact, physicians like to refer to their roles as the learned intermediary. Unfortunately, there's considerable evidence that suggests that prescribers and dispensers spend little or not time counseling patients about the

prescriptions they take and in our currently financially stressed healthcare system, doctors, nurses and pharmacists complain that they have less and less time to spend with individual patients.

And there are logistical complications; just consider prescriptions ordered over the Internet and delivered by mail. There is no face-to-face in that encounter. And there's also good reason to believe that the drug information imparted by prescribers may not necessarily be scientifically accurate, up to date or free of professional specialty buyers. I'd also suggest there's little disagreement among experts in safety and quality that the amount of information flowing from published studies, the NIH, specialty society guidelines, protocols, care maps and the like is simply overwhelming. Many experts believe it's humanly impossible for a single clinitianer, a single practitioner to keep up. In other words, your intermediary may not be so learned.

It seems unlikely based on what we know or don't know about changing professional behavior that rapid progress can be made to change professional behavior so that evidenced based prescribing and dispensing is the norm. And it

would take a revolution in the way that healthcare is currently organized and financed to encourage sufficient time and incentive for doctors, nurses and pharmacists to spend the time necessary to counsel patients and to do so without any bias based on their professional or entrepreneurial interests.

And lastly, we cannot ignore the permissive influence of industry's intense promotion to doctors and pharmacists in shaping doctors' and pharmacists' knowledge base about the safety and effectiveness of prescription drugs. Because of these realities an FDA mandate the prescriptions be accompanied by high quality written consumer drug information is, I respectfully suggest, a critical absolutely appropriate safety net intervention to protect patients from harm.

Well, here we are 35 years in the making, it's really 35 years since we started this in 1968, and we're still counting and Tom gave us a history of the details and to save time, I'd just like to say from time to time the FDA has tried to do the right thing, but under the pressure of intense lobbying from opponents in industry and

professional groups, and because of the resonance with conservatives in Congress who don't like government to do anything to interfere with the private practice of business, we have been unsuccessful in getting a program that is a mandate and evaluated and supervised by FDA.

I think FDA admitted in 1995 when it published the Medication Guide Requirements, that the private sector effort was a failure. Consider this quotation, "During the hearing that led to the withdrawal of the 1980 PPI regulations, promises were made by representatives of the pharmaceutical industry, medical and pharmacy community that if the FDA withdrew the PPI regulations, the private sector would develop a variety of systems that would meet the goals in the proposed PPI program. These premises have not been met." So I think in `95, the promises weren't met. I think as Sid pointed out, what we heard from Bonnie today, the promises have not been met.

Twenty-five years, it's time, it's over and it really is, I think unconscionable to continue down this path. It is time to make this a mandate and to make sure that the FDA approves the content of information for consumers. I'd like to

address very briefly the last question which was what other initiatives should the FDA consider for providing patients with useful written information about prescription drugs.

I think, and I guess I'd be happy to hear from folks who think otherwise, that it really is time for the U.S. to move to unit of use packaging, because I think unit of use packaging which is, I guess, the norm in Europe, solves a lot of the concerns we have about how to get -- first of all, it eliminates the problem of compliance with dispensing goals. If you get the drug, you get the information.

Secondly, it really, I think, creates a chain of responsibility to the drug manufacturer to be responsible for providing the information for meeting the criteria and the FDA has clear authority, I think, to do that. It would allow, you know, a pre-approval process during the approval process for a drug for that labeling to be approved before the drug could come on the market. So I would just like to urge that these two issues may really be related. How do we get material to 100 percent and how do we get material to 100 percent that's 100 percent quality I think is the

important question and I think it could be addressed coincidentally with a real reconsideration of unit of use packaging and make that the norm in the United States rather than the exception.

Thank you.

CHAIRMAN SELIGMAN: Thank you for your comments. John Rother, our next speaker, is the Director of Policy and Strategy from the American Association of Retired Persons, AARP. Mr. Rother?

MR. ROTHER: Good morning. It should come as no surprise that the availability of high quality written information about prescription medicines is important to AARP members since so many of our members use these medicines, often multiple prescriptions every day. High quality refers to both the content and the format of this information. As we all know, vision can diminish with age and for this reason, written materials must be properly designed to insure that older consumers can read them. There is general consensus that high quality written information about prescription drugs geared to consumers can have a strongly beneficial impact on public health. This information can reduce preventable,

medication related problems by clearly highlighting potential risks and possible side effects. With so many people failing to take their medications as directed, this information can also help improve compliance.

There is a continuing disagreement, however, about how best to provide this written prescription drug information. Should it be mandated by a government regulation or can it be successfully implemented through a voluntary program? AARP has consistently supported a mandatory approach to the provision of written information because we believe that this is the best way to insure that useful information reaches the greatest numbers of consumers. Today we once again urge the FDA to reconsider a mandatory approach to providing written prescription drug information and we suggest some options for the Agency to consider.

At the same time, however, we recognize that FDA may choose to give a voluntary program more time and for this reason, we also offer some suggestions on what both the private sector and the Agency must do to make the voluntary program more effective. Why do we believe that it's time to

consider a mandatory approach? Well, I think Bonnie's research provides the answer. Despite the widespread distribution of written information, the quality of this information is seriously lacking. The expert panelists who participated in her study found the leaflets with written prescription information that are currently being distributed are deficient in many areas especially relating to risk information.

In addition, the consumer participants were particularly critical of the print size, print quality and overall ease of reading. The fact that we are already six years into the voluntary program and there is still such significant problems with the quality of the written leaflets that are being distributed is why we fear that the voluntary program will ultimately not be successful.

Even though AARP supported a mandatory regulation in this area, we also participated in the development of the Action Plan that is the blueprint for the voluntary program. We were instrumental in drafting a form guidelines for written information and the sample information leaflets that were included in the plan. Here is a sample leaflet from the Action Plan. I would like

to know why there aren't more prescription drug leaflets available today that look like this one. It's printed in readable type size and style. It uses headings in the form of questions and arranges information using bullets. The results, a leaflet that is easy to read. I'm concerned that one of the reasons why we haven't seen more pamphlets like this one is because the Action Plan itself has not been widely distributed. This may be due to the fact that the law that established a voluntary program failed to establish any procedure for implementation.

The sample leaflet I just held up looks a lot like the food label and the new drug facts label that is now required for all over the counter drugs. That's because all three were designed by the same advertising firm. The experience with the food label here, I believe, is quite instructive. After years of a voluntary program for providing nutrition information on food labels, it took a mandatory regulation to finally assure that consumers receive consistent, easy to read information about the foods they eat, information that helps them make more healthful food choices. AARP believes that when it comes to prescription

drugs which can even have a greater impact on health, consumers deserve at least or better information.

Some have expressed concern that mandatory regulation might be too resource intensive for an already over-burdened agency. We believe this concern in over-stated because the FDA need not re-invent the wheel here. There is existing regulation governing the mandatory distribution of medication guidelines for drugs that present serious and significant public health concerns. This regulation can be a starting point for the Agency which can then consider appropriate revisions in light of the Action Plan.

Further, the FDA could consider alternative approaches to enforcement that would minimize any undue burden. Currently FDA pre-approves the mandatory medication guides for all serious and significant drugs. For other drugs, however, the Agency may not need to pre-approve every written information leaflet. As in the case with the nutrition label, the regulation could set up all of the requirements, including specific format guidelines and samples and the Agency could then rely on post-market surveillance of

information leaflets to insure compliance.

This approach would require additional resources but these would not be as significant as those required with the pre-approval system. In addition, FDA could take other action short of issuing a mandatory regulation. For example, the Agency could issue a policy statement or guidance document governing written information leaflets. Although not enforceable, like a regulation, such a statement or document developed by the regulatory agency often has more weight than one developed outside the agency.

If FDA determines that the voluntary approach deserves more time, then the private sector must make a serious commitment to making it succeed. This requires a commitment to spend the money and time necessary to disseminate the Action Plan and assist in its implementation. The private sector must move quickly to insure that the voluntary program meets the year 2006 goals established by law and it must insure it meets specific timetables and targets because without these, the program has little chance of success.

We believe that FDA still has a central role to play here. First, it could do more to

assist in the dissemination of the Action Plan. For example, a simple step would be to provide a link to the Action Plan on the FDA website. This is particularly important since the website for the Keystone Center which developed the plan is no longer in operation. Most important is FDA's responsibility to assist the voluntary program. Rather than waiting until the end of 2006, to determine whether the voluntary program has met its goal, FDA should engage in an ongoing review of the written prescription information leaflets that are being distributed. Such an ongoing review would allow for mid-course corrections thereby better insuring the success of the program.

I'd like to close by just saying that we have consistently supported public information regarding all aspects of health care. When it comes to drugs that can have serious side effects, I think there's little excuse for not providing the information that consumers need in the most readable, understandable and uniform format so that consumers can become used to what to look for and become better participants in their own healthcare. Thank you very much.

CHAIRMAN SELIGMAN: Thank you for your

comments. Our next speaker is Gerald McEvoy. He's the Assistant Vice President for Drug Information from the American Society of Health System Pharmacists. Mr. McEvoy?

MR. McEVOY: Thank you. ASHP has a long history of medication error prevention efforts and we believe that the mission of pharmacists is to help people make the best use of medicines. Assisting pharmacists and fulfilling this mission is ASHP's primary objective. Components of the Society's efforts in assisting pharmacists in this regard include position and guidance documents for best practices such as those on pharmacist conduct patient education and counseling which we first issued in 1975, extensive publishing activities with a strong focus on professional and patient drug information and educational programs.

ASHP has long held that private sector publishers, including professional associations, must play an important role in the creation and dissemination of useful medication information. For almost 30 years ASHP has been a strong advocate of the role of pharmacists in providing useful written and oral counseling to patients. In addition, ASHP has a 25-year history of publishing

medication information intended for educating patients about the drug therapy.

With release in 1978 of the first edition of the Medication Teaching Manual, ASHP became one of the first private sector organizations to publish medication monographs intended for educating patients. This manual was developed by an advisory committee that ASHP formed cooperatively with the American Hospital Association and the U.S. Department of Health, Education and Welfare's Bureau of Health Education. As a well respected publisher of evidence based drug information, ASHP has applied this expertise in publishing high quality drug information for patients. ASHP is a past recipient of an award of excellence for consumer education materials from the FDA and the National Coalition for Consumer Education and was one of the first private sector publishers to address the guidelines of the 1996 Action Plan for criteria, goals, layout and language on useful prescription medication information in our patient resources.

ASHP's efforts over the years have extended to patient education programs conducted by healthcare professionals in a variety of settings

and directly to consumers through resources like ASHP's SafeMedication.com website and the National Library of Medicine's MedLine Plus website. ASHP's quick response to the Action Plan resulted in a major revision or reformatting in 1997 and 1998 of its medication teaching manual to improve their usefulness ASHP has continued to enhance its patient information data base, two examples of which included a major black box warning initiative employing a prominent box format as described in the 1996 Action Plan and the inclusion of the national toll-free hotline number in the overdose section that connects consumers to poison treatment and prevention experts 24 hours daily, seven days a week.

I am -- I would like to reiterate ASHP's commitment to the quality of its content and welcome Dr. Wolfe to identify those drugs that are currently missing black box warnings as identified earlier. Other enhancements to ASHP's patient drug information data base included a major restructuring of its data format into XML, to optimize data development, revision, extraction, maintenance, formatting and intelligent electronic interchange and considerable investment in software

tools to manage its drug information resources.

XML structuring allows ASHIP to deliver its patient drug information to vendors and customers with style sheets that produce leaflets in a format that adheres to the guidelines included in the 1996 Action Plan. Therefore, ASHP believes that it has a long and consistent record of devoting considerable effort in improving the development, maintenance and dissemination of useful high quality patient drug information, a record that has been recognized both by the Federal Government and others. Through its efforts with other stakeholders, including FDA, ASHP also has been actively engaged in steps aimed at further improving the usefulness of patient drug information including participation in NIPIE's Criteria Committee.

Prior to FDA's Drug Safety and Risk Management Advisory Committee in July 2002, ASHP viewed the 1996 Action Plan as providing useful guidelines for meeting the goal of improving the quality and availability of useful consumer medication information. ASHP applied the document in its original stated intent of providing direction to developers of written patient drug

information while not being overly prescriptive. Useful information was to be sufficiently comprehensive and communicated such that consumers could make informed decisions about optimizing their therapy while avoiding harm.

The guidelines for both content and format address the essential elements and characteristics of useful information and the preferred methods of presentation. As defined in the Action Plan, the consumer medication information is intended to be a summary that does not include all actions, precautions, adverse effects, side effects or interactions but that is flexible in addressing what is considered applicable and relevant to the consumer. Even inclusion of all black box warning information is not required by the Action Plan, but rather it is open to interpretation as to addressing that which is considered relevant to the consumer.

Likewise the Action Plan includes flexibility regarding which precautions to include stating not that all precautions should be addressed but instead the precautionary statements are encouraged in serious situations. These are the guidelines ASHP applied. Although ASHP still

considers the guidelines embodied in the Action Plan as useful in providing direction, the latitude applied by Dr. Svarstad's study in interpreting the Action Plan and in applying a more stringent interpretation of usefulness has challenged the original intended flexibility of the guidelines. ASHP did not agree with the interpretation of Dr. Svarstad's report in 2002 and does not agree with the interpretation today.

Instead, ASHP believes that this study should be viewed principally as a further refinement of the definition of useful. In fact, the Action Plan states that as it is implemented, it is expected that the additional information will be gained regarding what constitutes useful. Careful inspection of the criteria used in the report indicates that usefulness was defined in many cases by criteria that were not specifically required or enumerated by the Action Plan.

An examination of the criteria in the Plan versus the sub-criteria applied in this report reveals that only about two-thirds to three-fourths of the sub-criteria were explicitly required by the Action Plan, with the remainder being optional, open to interpretation or having no direct tie to

the Action Plan criteria or to the FDA approved professional labeling. Therefore, if patient drug information is to be held accountable to criteria that are more stringent than those embodied in the Action Plan, a broad based consensus development process and wide dissemination of the drug specific criteria must be in place before the usefulness of selected patient drug information can be fairly evaluated.

ASHP continues to interact with FDA staff on this issue and has joined stakeholders through the efforts of NCPIE to work cooperatively in helping the Agency achieve the 2006 goals. One thing to not lose sight of is the fact that FDA approved patient labeling for nitroglycerin faired poorly in Dr. Svarstad's report. In fact, on disturbing finding in the report was the absence of information on the contra-indicated use of sildenafil with nitroglycerin. Fully five years after approval of viagra and the FDA approved contra-indication on concomitant use with nitrates, the Agency has not required manufacturers of nitrates to incorporate this information in their labeling.

Not only is the contra-indication

missing from much of the patient information provided by manufacturers, but FDA has been remiss in requiring manufacturers of nitrates to include this critical information on a potentially fatal interaction in the potential labeling. In fact, of the currently available professional labeling for 10 nitroglycerin products reviewed only two included the contra-indication while five included no mention of sildenafil and the remainder include a warning rather than the stronger contra-indication. This is just one compelling example of why the voluntary efforts of the private sector publishers are important in insuring the dissemination of useful patient drug information.

ASHP reiterates its 2002 recommendation that FDA continue to solicit advice in the form of an advisory panel of experts and public and private sector stakeholders regarding further refinement of the definition of usefulness and the associated specific criteria that will be used in evaluating the definition of usefulness. Mechanisms should be developed for insuring the publishers and providers of consumer medication information are fully advised about such ongoing developments so that appropriate changes can be implemented.

Likewise, attention should be given to possible implementation of other recommendations included in the 1996 Action Plan. As part of this strategy, priority areas and interventions for improving the usefulness of consumer medication information should be identified. The role and importance of outcomes research in the context of measuring the usefulness of consumer medication information also should be addressed. Thank you.

CHAIRMAN SELIGMAN: Thank you for your comments. Our next speaker is John Coster, Vice President of Policy and Programs from the National Association of Chain Drug Stores. Mr. Coster.

DR. COSTER: Thank you. Good morning, everyone. Thank you for the opportunity to speak. I'm going to break the pattern a little bit and have a few slides which I hope is okay. I, like Art, was a member of the Keystone Group from 1997 so I can say we've been around the block a couple of times on this issue and what I hope to do today is look at some of the reasons why we are where we are today in terms of the system, what's going on in the system in terms of the distribution of written information to consumers, because I think only then can you identify where the problems are

and what the solutions might be to this.

First, as -- I'm with the National Association of Chain Drug Stores. NACDS is a trade association of about 200 chain companies and we represent about 35,000 pharmacies, community pharmacies. The other about 21,000 are independently operated pharmacies but our membership exists all the way from the 4,000 entity operations like a CVS or a RiteAid all the way down to two, three, four, five chains and we have many chains that are 50 stores. So we run across the board in terms of the size of our membership. Our members, it's estimated, provide about 70 percent of the approximately 3.1 billion prescriptions that are dispensed. You heard Art talk before about 3.4 billion prescriptions. They're all in the same ballpark. It actually depends on how you count prescriptions but there's more than 3 billion prescriptions being dispensed and our membership dispenses the majority of them. We employ about 100,000 pharmacists as well. And I guess one point that we'd like to make is I don't think anyone in this room would disagree that consumers should have access to high quality useful written prescription information. We may disagree on how we get there

but I'm here to tell you that our industry is committed to doing what's necessary to achieve that goal and we view consumers as our partners in trying to reach the objectives of the 2006 Med Guide goals.

I want to provide just a few perspectives on where we're coming from on voluntarily provided written prescription information. We believe that we should build on the progress that has been made to date by the private sector. Dr. Svarstad's study looked at the state of play at a particular point in time in the marketplace, but I think if you look at FDA studies and other studies that survey the quantity and quality of written information that's been provided, we have made significant progress over the past 10 years. We may not be where we want to be or where others want us to be, but we have made progress and if you looked at a longitudinal study of that, I think you'd find that we've come a long way. We still have a ways to go but we have come a long way. And if you look at some of the information that's being provided, it clearly is unacceptable.

Now, I'm a pharmacist and I've

practiced. I don't do it now which is a good thing for everyone but the quality of information being provided in some cases is just, you know, is just poor and that needs to be definitely improved. We think, the written information being provided should reinforce but not replace the counseling that patients receive from their physicians and their pharmacists and I would agree with comments made earlier in today's overly stressed healthcare system, that oral counseling by both physicians and pharmacists may also need to be improved and I think that is improving as automation is built into pharmacy distribution system, it frees up the pharmacist's time to talk to patients more frequently and more regularly and that the written information being provided should not be the primary means of communication. It should be a supplement to what the patient receives.

I know, myself, when I pick up prescriptions that, you know, I can't remember everything I'm being told and I am a pharmacist. Patients can't. They're busy focusing on other things. What they take home should help reinforce and be a reminder for them of what they've been told by the physician and the pharmacist. We think

written prescription information has to be balanced. We don't think it should include every potential problem with the medication, every potential adverse reaction. It has to provide adequate balance on risks and benefits. It has to encourage the patient to take the medication and one thing -- one reason I might posit that you see lack of completeness on the contra-indications and warning side is, frankly, there may be some pharmacists or others that are editing that information out of concern that it might be communicating too much risk information to consumers and not encourage them to take their medications.

Whether that's right or not, that may be one thing that is going on, that that information is being edited down so that it doesn't, in other words, scare patients from not taking their medications. We also think, and this is a systems issue, that the distribution and the printing of the information has to fit into the current ways that pharmacists provide information to consumers. Now the next chart I'll be a little more explicit on this, but this is part of an entire system that leads from the time the

information is produced by the data base companies to the time it's provided to the consumer when they pick up their prescription. That information is generally printed by the pharmacy as part of what's called a single pass document, where it's run through the computer and what comes out with that written information is other things that the pharmacist needs to fill the prescription, for example, the actual prescription label, auxiliary labels, receipts, warning messages, refill information.

I did bring an example of that and it's obviously going to be difficult to see. Let's see if I can find it, but when we talk about providing information to consumers, we have to consider the fact that there are highly specialized computer systems in place -- I have it here. It's a single pass document and what is shows is, here is the written information that will be provided to consumers. It may not be in a font you'd like or it may not be spaced appropriately but here's the written information, here's the prescription label. Here are those counseling messages which were talked about before and I think it's important to note that there's a distinction between the

counseling messages and the written information that's more Keystone compliant. There's information regarding refills. There's a place here for the patient to sign that they've picked up the prescription and some other information. So this is how it's currently printed out and when you talk about how do we improve this, I think on our end, in terms of operations and efficiency, you have to consider how that fits into the systems that are currently in place to provide information to consumers currently.

Okay, this may be a little difficult to see but I think this is an important slide and will build upon what Dr. Seligman showed before in terms of how the information flows through the system. The production of the information has to start somewhere. Pharmacies do not sit in a back room and write this stuff. Although we may be involved perhaps in showing how it's formatted or maybe editing some of the information, we don't write it. We rely on the data base companies, the Medispans, the FirstData Banks, the Facts and Comparisons to produce information and hopefully that information that they are producing is quote "Keystone compliant".

In some cases some of our larger chain members purchase that information or more appropriately license that information directly from the data base companies and that that information is then directly fed into the chain pharmacy systems that process prescriptions as I showed you before. In other cases, and Gerry McEvoy may have some comments about this, institutional pharmacies may purchase or license their products from ASHP or they may produce their own and then they use that information both for in-patient purposes and out-patient purposes.

Then you have to look at the other side, taking away both the chain pharmacies that produce their own or license their own and the institutional pharmacies that license their own, I would say that a good 50 percent if not more of the other pharmacies license get their information through their software vendors. Many pharmacies work with software vendors to provide systems that help them process and track and dispense prescriptions and these software vendors, in turn, license that information from the information vendors. So there's an intermediary in there and these are the companies like PDX, QS1, RNA and I

never could pronounce this correctly, Etroby or Etroby. Some of them may produce their own information themselves but most of these software vendors license their information from the information vendors and then they provide those to independent pharmacies and what goes on at that level is of interest because we don't know, for example, with 80 plus of these vendors around, what's going on with the information when it gets down to their level. Does it get edited. If it does, is it by them, is it by the pharmacist? Those are questions that, I think, still remain unanswered but are key to finally, you know, assuring that the information reaching the patient is Keystone compliant.

One other issue, I think that must be considered is 95 percent is the goal for 2006. Is it 95 percent of what, what is the denominator going to be? In Dr. Svarstad's study I think they only looked at independent and chain provided information. Well, the fact is, you cannot get to 95 percent of prescriptions dispensed in the United States if you do not include the other dispensing sites. Mail order is a rapidly growing component of the distribution system. You must, I would say,

consider the type of information they're providing. Hospital out-patient pharmacies, a small part but still, you know, a part of the system.

Public health service clinics, VA, Department of Defense, even dispensing physicians, are they going to be included in the denominator when the ultimate survey is taken? So I think it's important to understand how the information flows through the system in order to understand where you need to target in a potential action plan to assure that we reach the goals of 2006.

CHAIRMAN SELIGMAN: Mr. Coster, your time is about up, sir.

DR. COSTER: Okay, I'm sorry.

CHAIRMAN SELIGMAN: So please conclude your remarks.

DR. COSTER: Let me see then if I can just wrap up by saying some of the challenges we have to reaching the 2006 goal while obviously not insurmountable, things we have to focus on. Do we include all the other out-patient practice sites or do we focus just on independent and chain? What is useful? You can develop criteria that are objective where you would say this is what we think is useful versus subjective where we try to tailor

the information more to the needs of consumers. What do we do about the millions of Americans that either don't speak English as a primary language or aren't literate or have visual impairments of some type. They're entitled to as much information as high quality in ways communicated as any other individual.

What type of flexibility will we provide to help professionals to tailor the information to special needs? Given the increasing number and amount of technology that we have, the potential inter-operability of healthcare systems, what should we be considering in terms of new technologies to reach patients. So the bottom line is NACDS remains very supportive. You'll hear later from a group, National Council on Patient Information and Education. We support very much their initiatives to continue to reach the 2006 goals. We will commit resources to doing that and hopefully we won't have to have another one of these hearings in 2007 to move forward from that. So thank you very much.

CHAIRMAN SELIGMAN: Thank you for your remarks. Our final speaker on this morning's panel is Mukesh Mehta. He's a Vice President of

Regulatory Affairs and Labeling from Thompson Healthcare, Incorporated.

MR. MEHTA: Good morning. I appreciate the opportunity to be here today to discuss this very important topic of providing useful medication information to patients. Thompson Healthcare is committed to help achieve the goal adopted by Public Law 104-180. As provided in the Public Law, by 2006 95 percent of individuals receiving new prescriptions will have access to useful written information about their medications. For 58 years physicians and other healthcare professionals as well as patients have depended on the authoritative prescribing information found in Thompson Healthcare's products and services including the Physicians Desk Reference, PDR. We continue this long tradition with the most comprehensive publications, data bases and services for the entire healthcare community.

Today through the products such as USP DI advice for patients, DrugNotes documents, the Care Note system and the PDR Family Guide to Prescription Drugs Thompson Healthcare is a leading provider of useful prescription medication information written specifically for patients.

Thompson Healthcare participated in the Keystone Committee's Action Plan for the provisions of useful prescription information and hopes to remain an active contributor to this process. I would like to take the opportunity to speak with you today about what Thompson Healthcare views as the three critical issues in ensuring the 2006 goal is met.

These issues are, number 1, meeting the criteria for useful medication information as defined by the FDA in the Action Plan. Number 2, identifying the barriers associated with dissemination of the useful medication information and Number 3, the FDA's vital role in insuring the goal is met. First, Thompson Healthcare currently provides useful written medication information as that term has been defined. The FDA's 1995 prescription drug product labeling medication guide requirements and the Action Plan for the provision of useful prescription medication information both establish the criteria for written patient medication information.

The FDA defined useful in the 1995 proposed rule as written in non-technical language and containing a summary of the most important

information about the drug. The FDA has also determined that the patient information will be evaluated according to its scientific accuracy, consistencies with standard format, non-promotional tone and content, specificity, comprehensiveness, understandable language and legibility. The Action Plan includes similar criteria that written prescription medication information must be scientifically accurate, unbiased in content and tone, sufficiently specific and comprehensive, presented in an understandable and legible format that is readable -- readily comprehensible to consumer, timely and up to date and useful.

Thompson Healthcare has created and revised its patient education information to specifically meet this criteria. For example, our patient education product DrugNotes is written in non-technical easy to understand language. Compliance with this internal standard is verified using standard literacy testing tools on each document. The most important information related to adverse effects contra-indications and warnings are summarized in bullet points.

Content undergoes a rigorous standardized peer review process utilizing subject

matter experts to ensure scientific accuracy. Documents are created according to a standardized template to provide consistent presentation. Our medication information for presentation is unbiased and non-promotional in tone and content. Information is presented in an explanatory fashion and does not promote specific brand, manufacturer or distributor. Further, Thompson Healthcare meets the Action Plan guideline that the prescription medication information is sufficiently specific and comprehensive to enable patients to correctly use their medications, receive maximum benefits and avoid harm.

Documents include information on administration, storage, missed doses, contra-indications, warnings, interactions and adverse effects. Expanded, more comprehensive information on each of the sections is available in USP DI advice for the patient. We employ full time patient education expert and consult with outside expert as needed to insure that the medication information for patient meets the defined term of "useful".

Our clinicians and writers use sources, including approved prescription drug labeling, USP

DI drug information for the healthcare professional, the drug date system, our comprehensive evidence based drug information data base and the PDR to create useful medication information for patients. Although useful medication information is available in the private sectors from companies like Thompson Healthcare, the second critical issue I'm addressing today is the identifications of the barriers to meeting the 2006 goal.

There are three prominent barriers to insuring that patients have the needed medication information. They are the difficulties the community faces in dissemination of useful medication information, the need for heightened recognition of the importance of such information, and the cost involved in meeting the 2006 goal. Ensuring that the 95 percent of individuals with new prescriptions will receive useful written information is a worthy but very aggressive goal.

Thompson Healthcare believes that to meet this goal we should consider multiple means of reaching patients. The Internet has become an increasingly accepted method of dissemination of information. However, studies have shown that

approximately 37 percent of households in the United States do not have Internet access. In addition, the GAO report to the congressional committees on electronic dissemination of government publications recognized that some individuals may have difficulty accessing and using electronic information. These individuals may lack computer skills or are unable to navigate the Web environment.

Because of this limitation, additional delivery system must be available to provide medication information to patients. These additional methods would include books provided within the pharmacies and the public libraries. Medication information available in a physician's office, written information attached to prescriptions and traditional means of dissemination of information such as mail and faxing, all will be needed to meet the 2006 goal.

In addition to providing information through multiple delivery systems, healthcare providers interfacing with patients must recognize the importance of patient education materials as defined in the action plan and the need to provide such information as a routine practice. Both of

these issues point to the largest barrier in reaching the 2006 goal and that is who bears the cost of creating and disseminating useful medication information.

No simple solution exists to resolve these issues. Overcoming these barriers will be difficult and therefore, the third issue today is a discussion of the FDA's vital role in ensuring the 2006 goal is met. While the FDA has provided criteria for useful information and Keystone Committee has offered further guidance, difficult questions remain unanswered. Foremost is the issue of off-label uses of drugs and the best means to inform patients about their prescribed drugs for off-label uses. FDA guidance in this area may be needed.

Further, the FDA should continue to support initiatives that ensure patients receive the best available medication information. One example is the FDA's work with the Pharmaceutical Researchers and Manufacturers of America, PhRMA and other manufacturers and pharmacy organizations on Paperless Labeling Initiative. This initiative will insure that every dispensing site in the United States and its territories will have access

to the most current FDA approved prescribing information. The ultimate impact is that the patient will benefit by receiving better information from the healthcare providers.

This effort will also promote better healthcare and patient safety by reducing medication errors due to the use of outdated describing information. Thompson Healthcare has been a thoroughly committed contributor to establish a nationwide paperless labeling system on behalf of PhRMA and the rest of the industry. These difficult issues must be addressed before the 2006 goal can be met. The FDA needs to lead the discussion on these issues and if resolution is not eminent, set those necessary standards to meet the stated goals.

Thompson Healthcare would like to work with the FDA to develop any guidelines that the providers of medication information should follow.

In closing, Thompson Healthcare believes that the private sector with support and guidance from the FDA, is capable of meeting the challenges and providing the useful patient medication information. We remain a committed partner with the FDA in making this goal a reality for all

Americans. Thank you.

CHAIRMAN SELIGMAN: Thank you for your comments and thanks to all the panel. We now have time for questions and comments for the panel and I guess first I'd like to turn to the FDA representatives on the dias. Tom, do you have a question?

MR. McGINNIS: I'd like to follow up with two of the panel members who mentioned a need for an FDA guidance. And what do you envision would be in that guidance document?

MR. MEHTA: As I mentioned earlier, a lot of drugs are used for off-label indications. The information providers need some guidance from the FDA on how we should handle this off-label indication.

CHAIRMAN SELIGMAN: Could you turn on your microphone, please?

MR. ROTHER: As an alternative to -- or as a first step, putting out examples or criteria in more applied ways as guidance to the industry about what would satisfy standards. I know it's imprecise but I think our suggestion is along the lines of examples.

MR. McGINNIS: Thank you.

CHAIRMAN SELIGMAN: Yes, Dr. Wolfe, did you want to make a comment?

DR. WOLFE: Well, I mean, the Action Plan is, in fact, a guidance. It's interesting to hear that when someone seeks, as they should, to interpret it and explain it as in the very nicely done study by Dr. Svarstad, it's attacked by another participant here as being too rigid. I think that there are enough examples in that study and the previous study of what it takes to fail that I don't think there should be any problem understanding what the guidance or that Action Plan means.

It's interesting also to hear people heap on FDA the responsibility for educating people either through a guidance of the Action Plan. I mean, we have three or four companies printing almost all of these things and if they are not aware now seven years later of what the Action Plan is, I think that's pretty pitiful. I don't think that's really where the problem is. I think they are aware of it and they are choosing just to interpret it very sloppily.

And just finally, the Action Plan itself on the topic of the black box warning said

that the black box warning or the information of the black box warning, A, has to be right at the beginning underneath the name of the drug and the content has to be consistent with or derived from black box warnings that are on the FDA approved professional labeling. And in our little study, amongst things that were left out, for example, Serzone, an anti-depressant that we have asked FDA to ban because of its liver toxicity, in the black box warning the FDA has approved, it says you should not use this in people with liver disease or elevated blood levels of liver enzymes. This is omitted from the warning at the beginning of two -- at least two, I can't remember whether it's all three of the sites we looked at, certainly the CBS one is missing. And there are other things that are very important, that's why they're in the black box warning and yet, they're omitted.

And so I think that the guidance or the Action Plan, such as it is, was obviously, capable of allowing Dr. Svarstad to design specific criteria. Those criteria could obviously be used but haven't been in all of these years by these companies. So just a further argument for the FDA taking this over.

DR. SVARSTAD: If I could -- oh, go ahead, please.

DR. TRONTELL: As I recall the Action Plan, there are prototypes in the appendix.

MR. ROTHER: Yes, there are. I think the gentleman from AARP referred to those templates in the appendix of the Action Plan.

CHAIRMAN SELIGMAN: Yes.

MR. LEVIN: For better or worse, I'd also like to point out that I think the Action Plan does give some direction on off-label use. It, frankly, is not the direction that a group of us public citizens and the center and others that were involved in the process wanted. We gave the Secretary two options as a committee and the Secretary chose the one that we didn't favor but there is some guidance there and as some other people have mentioned, given the rapid advancement in technology, it strikes me that it's time to sort of rethink that part of the guidance, because what we talked about a lot in that committee was that inclusion of off-label information might be most appropriate if you could customize the information and I mean, the concern was that there were many of us -- or at least some of us around the table who

felt that patients should know that when they're getting a drug that is not -- for a non-approved indication, when they're getting it as an off-label use.

And that in our view, the only way to know that was if the drug -- if the written information contained the FDA approved indications and then if they didn't fall in that category, they would understand that they may be getting it for an unapproved use and I think we did in the content, and Tom correct me if I'm wrong, in the content and format part, sort of suggest some generalize wording that the drug may be prescribed for an indication that isn't here and you can ask questions about that and so forth.

So it was sort of a generalized statement to alert patients that they might -- who didn't have one of those indications that they might be getting this drug and that, you know, there was a process they could follow to sort of get more information. But I think in light of improved technology and the ability to customize information, that is something that maybe needs a second look, not only that but all of the information. We talked about and we've gone back

and forth for example, in the meeting on Accutane two years ago now, Tom, to sort of beef up the patient safety and risk management stuff, we talked about, for example, is it appropriate to have the pregnancy warnings, all of those pregnancy precautionary warning and informed consent and signed documents for males. And we went back and forth, yes, it's a good idea, it's not a good idea, but I think it's time to really revisit the customization issue because there is the means now to do that and it may make more sense and actually be more protective of people if the information is very focused on that. And hopefully, we'll get to the day where we know the patient has a liver problem and there's something on there that says you shouldn't be getting this drug, you know, and if you've been prescribed this drug, you should go talk to your physician.

DR. TRONTELL: To follow up on Tom's question on what form the guidance might take or its contents, I'd like to invite all of the panelists to address in FDA's regulatory definition of guidance which typically has been directed to the pharmaceutical industry, how you would -- what would be the audience and authority for FDA to

write a guidance other than one that's informative as opposed to having some influence.

CHAIRMAN SELIGMAN: The conundrum.

DR. TRONTELL: Yeah, we struggled with that question a year ago at the public meeting when we first discussed the results of Dr. Svarstad's study and I had just one additional question, really more of a request. I was very interested in the information that you presented, Dr. Wolfe from your black box warning survey and I wanted to know if you had plans to share that and its methods with the Agency.

DR. WOLFE: We're just finishing the write-up on it and we'll get it to you probably in the next several weeks or so, yes.

CHAIRMAN SELIGMAN: Any questions, comments, from the audience or from other members of the panel?

DR. RACZKOWSKI: One of the things that is done with over the counter drugs labeling is that it's tested for its comprehensibility before the label is approved and I wondered if the panel has any comments about whether information that is being passed out to consumers in pharmacies for prescription medications should or should not have

a similar requirement.

DR. WOLFE: There was quite a bit of field testing, whatever you want to call it, back in the `70's preceding the finalizing of the regulation for FDA approved labeling. They actually came up with a bunch of labels and worked them through and there were some significant changes. As of May and June of `81 they were ready to go with labels affecting as I remember something like a tenth or whatever of all the prescriptions filled in this country and a lot of those drugs are still around now but the -- I think the answer to your question is that the FDA has already gone through a mechanism like this and it was obviously very helpful and useful and wound up with labels that had been found to be much more comprehensible and were ready to go. So you might just look back at that. I'm sure that -- Tom, there are still records of those surveys.

CHAIRMAN SELIGMAN: Yes, Art?

MR. LEVIN: I mean, I think that again, in the Action Plan deliberations, I mean, there was -- there's a tension between wanting to have very complete information and the issues of not only the logistical issues of how do you fit all this on a

certain size piece of paper or whatever, but the concerns about the patience of people to read long, you know, a lot of words on a piece of paper, the issue of reading level and the issue of format and type size because clearly as you get a format that's easier to read and larger type size, you begin to run into pages and pages depending on how complete you want to be.

And to that issue, I want to say that that's why I think it's important for everybody to be on the same page is on the question if you want a patient to take nothing else away from this written information, what is it that you want that patient to take away because you're not going to get everything on it and you're particularly not going to get everything on it if you deal with these other concerns which are really important concerns of readability, legibility and comprehensibility.

And I think getting on that same page is a problem because I don't think we're all on the same page, we're maybe never going to be on the same page. My point of view and I think probably Public Citizen as well, is you want the issues that protect the patient from harm to be, if nothing

else, the patient should know, "Why am I getting this drug", so they can figure out if it's appropriate for them, and two, "What are the risks I face here", and three, "What should I do if I encounter any of those risks", because frankly on the benefit side, boy, they get a lot of stuff.

They just have to turn on TV. They're being sold and promoted prescription drugs all the time. I'm not quite clear that that's a problem for the American people, but they don't know, there's a drug for almost anything that they may feel and that there's probably more than one drug for everything that they may feel. So the thing they don't get in those ads and in those promotions and usually don't get from their physicians and often don't get from their pharmacists are the risk issues, "What do I need to look out for and what do I do if I feel this, is this something I should pay attention to".

And so it seems to me if we can ever get on the same page on that, what is the basic message we want people to take away, then we can sort of figure out -- you know, we can deal with these other problems. But as long as we have sort of differences of opinion about that, we just keep

running into the same, you know, sort of conundrum, we want more information but they we have to shrink the type size or we run into the computer only spits out an 11-inch page piece of paper.

CHAIRMAN SELIGMAN: Are you suggesting that in the criteria that are provided by Keystone that some of the criteria are more important or that when we evaluate them again in the future, that we should give different weight to some of the usefulness criteria, because --

MR. LEVIN: I think I am in terms of waiting and I think if you -- if anybody ever had the patience to look back, I don't know whether those were transcribed or not. These -- I don't know, we had what, eight or nine meetings, John, and lengthy ones and we talked a lot about this and there was -- I mean, there were differences of opinion around the table. And I remember Jerry Halpern saying to me at a meeting, "Arthur, you're so negative about drugs". And I said, "No, I'm not. I just think that there are lots of other opportunities for people to hear the benefit side of the equation. There are a minimal amount of times that they hear the risk side".

And if I want them to come away with

nothing else, I want them to be aware what the problems are and I think the IOM, you know, sort of put their finger on it. In this system that we have, we have -- patients have to be sort of able to take care of themselves. I mean, there are lots of safety problems, lots of quality problems and everybody is talking about sort of the consumer as a solution. I don't buy that all the way, but if the consumer is any part of the solution, they have to be well enough informed to act in their own best interests. And it seems to me the most critical issue is, "How do I protect myself from harm, how do I make sure I'm getting the prescription I should be getting, how do I make sure I'm getting dispensed the prescription that I was prescribed and in the right dosage, in the right form", and that's to me the most critical issue.

So if I were evaluating it, I would weight. I would certainly give different weights to those criteria.

CHAIRMAN SELIGMAN: Dr. Wolfe.

DR. WOLFE: This is a belated response to Dr. Trontell's plea for authority to paraphrase you. I mean, I think the authority is clearly there in the public law that we have talked about

all morning and the public law did not envision an unending and infinite series of failed private sector efforts before it stepped in, so I think that the answer to your question is that FDA has all the authority it needs right now to essentially invite companies -- I mean, as you know, the initiator in the ultimately FDA approved professional labeling is the company. They write the label. It goes in there and FDA says, "Well, we like this but we don't like this", and there's a negotiation.

So it's not as though FDA would have to go de novo and write all of these things from scratch. The combination of the existing government approved European labeling and the almost there in terms of Art's comment about priority, beginning now with even the U.S. professional labeling of having the most important things, I think that the amount of work -- I understand that FDA has priorities. They are getting funded through PDUFA to look at new drug applications. They are not getting funded through PDUFA unfortunately to do the work, some work, I don't think it's as much as it's been made out to be, of putting this program into place. So the

authority is there and I think it's really just time to start.

I think that we're done -- remember the experiment so to speak, was done with only a small fraction of drugs back in the late `70's the reason being, let's try it, test pilot it, get it right and it got through. And I think that to start out that way would be less labor intensive and would really get us much more quickly to where we want to get.

DR. COSTER: I guess I could comment on all of the above issues but I think going back to something I said, I would not characterize the initiatives of the private sector as failed. I mean, that may be the opinion of some but I think looking at the progress that has been made over the last 10 years, we may not be where we want to be but, you know, we have made progress in providing more information to consumers and I think Keystone has helped to do that. I would ask, what would you propose to do in a guidance?

The data base companies, and it's correct, there's probably three or four, maybe five, that produce all this information, have been moving their information maybe slower than we would

like, to a place that is quote "Keystone compliant". What would you propose to do, create new criteria for compliance with written information which would potentially set us back? I mean, I think we're on the right track. The question is, how do we continue moving there and I think one of the things that I was not able to say in my comments was that there is now an initiative to keep the private sector focused on this when, frankly, I think after Keystone was disbanded, I don't want to say everyone went their own way but there wasn't a focused initiative to continue to move us towards Keystone and I think that's what you'll hear about this afternoon, a continued private sector initiative to focus us on moving in that direction.

My concern is FDA would, through some guidance, do something that would set us back by creating new criteria or freeze in place potential innovations in the delivery of information which would not be useful to anyone, would not allow us to take advantage of customizing information, would not allow us to take advantages of new technology, so you may have the authority, you may have it now.

My caution would be, you know, look what -- be

careful what you do because you may freeze us in place or set us back rather than moving us forward.

MR. MEHTA: Well, one area this morning, I think Art mentioned about the new format for prescription drug labeling. The Agency as been working on this proposed rule to reformat the prescription drug labeling with the highlight section, the index and the comprehensive prescribing information. We would like to see that final rule published as soon as possible. The highlight section would allow the private sector to form their patient education information because this is the information that the Agency and the manufacturer consider to be the most important information, number one.

Number 2, the proposed regulation was only for the new drugs and the recently approved new drugs. We would recommend that the final regulation should cover all drugs, all prescription approved drugs rather than just the new drugs.

CHAIRMAN SELIGMAN: I wanted to get back to three of Dr. Svarstad's conclusions, one of which was that 11 percent of pharmacies provided no leaflet, 13 percent of others gave an abbreviated leaflet and 36 percent of them were hard to read.

And I wanted to just challenge the panel to sort of give FDA some advice as to how it is that -- why this finding was observed, why it is that pharmacies aren't able to provide either a leaflet or provide a leaflet per the current Keystone guidelines and why it is so difficult to get something that people can read.

DR. COSTER: I might try that. There are 56,000 pharmacies in the United States. As I said before, about 35,000 are chain operated and the bottom line is not every pharmacy is as technologically advanced as the other. You may find some chains have the highest technology, they do laser printing. You know, they can integrate all their systems together, but I'll bet you, you'll find a substantial number of pharmacies in the United States whose technology is not as advanced, who still use dot matrix printers, so I think technology may have a lot to do with it.

Other issue is pharmacists may just not be aware or their software vendors, who they rely on to provide them with their software system, the prescription processing system, are just either not aware of it, don't license information from the data base companies, don't offer it as a service.

So I would offer those as some potential reasons and again, there were products in the market at the time the survey was done that were not Keystone compliant and some of that may be that data base companies hadn't updated them yet. Other cases may be the pharmacies kept using them even though they knew that they weren't Keystone compliant or were ignorant of the fact that they weren't Keystone compliant.

So I think these are some technological issues and there's some educational issues all contributing to that fact. That would be my opinion and I think there's -- I don't think the pharmacists are consciously saying, "I don't care about Keystone, I'm not going to do it". It would just be a level of non-education or ignorance about it.

CHAIRMAN SELIGMAN: Yes, Dr. Svarstad.

DR. SVARSTAD: I don't think that the problem is dot matrix, although that may be with a few cases, but I think the main concern that consumers had was that the print size was small and this usually comes from a lazer printer. So I don't think it's really dot matrix and I'm not -- in other words, it's not really a technology issue

at that -- for that problem.

Now, I don't think we really know why it is that one out of 10 pharmacists are not giving a leaflet. We have not collected data on those. We were not given permission to interview the pharmacy managers. You could easily do that to verify whether or not they had a data base. My suspicion is that they had the data base but that in certain pharmacies it is a discretionary thing whether or not the pharmacist wants to print it out and that they simply weren't printing it out, but that can be checked very easily in a very small study.

MR. McEVOY: I think just to add to what John Coster said, a related issue which is technologically based is probably legacy where pharmacies may not have advanced to the next level of technology in terms of their equipment. They may have been using forms, for example, that had very limited amount of space on them. John showed an example of that where they were putting in a receipt, the label, everything on basically an eight and a half by 11 page and to really present it in a readable format, you're looking at documents that typically are two pages long. So

again, it may be that current technology is not an issue any longer but my guess is that there still are pharmacies out there that haven't moved up a step with the technology that they have that would permit them to accommodate a two-page document, for example.

MR. LEVIN: I guess I would suggest that what I'm hearing about the problems of pharmacies getting their technology in line or whatever, if it isn't a technology issue, convinced me that what I said earlier makes more and more sense at least to me which is talking about unit of use packaging and incorporating the information with unit of use packaging and requiring -- making this a requirement of the manufacturer, because I think one of the failures here has been on the part of pharmacies to be able to get this information and there may be lots of good reasons why.

I'm not suggesting this is something that they've connived to do at all. I'm just saying there may be logistical reasons and technical reasons and all sorts of reasons that it isn't getting done. So it seems to me we have to think out of the box and that's what I think question 4 was about that you posed to us, which is

what else should we be thinking about, what other initiatives and maybe we have to sort of link these two together and move them forward as sort of in tandem, I don't know.

DR. COSTER: Well, my only response, there's other issues involved with unit of use packaging which, I think, some in our industry support and others aren't quite there yet, but as Art said, in Europe they use a lot more of it than we do here but that would require probably substantial revisions in medical and pharmacy practice acts. For example, the unit of use package is typically a 90-day supply but a physician writes for 100 tablets in that particular prescription. What's the pharmacist to do?

You know, generally, they have to dispense the quantity requested by the physician. So, I mean, there's -- we've started to look towards unit of use packaging but like so many other issues, there's operational, administrative, technical, implementation issues that probably aren't appropriate for considering in context of this issue, but, you know, maybe at another public hearing we can do that.

CHAIRMAN SELIGMAN: We have a question

from the floor. Please state your name and affiliation.

MR. KAPSASKIS: My name is Tony Kapsaskis. I represent the Challenge Printing Company. We're a provider of pharmaceutical literature to pharmaceutical manufacturers. And I hear the information and the opinions about the unit of use and I heard Dr. Wolfe's presentation earlier and my question is this; shouldn't we try, as much as we can, to have information that's intended for the end user, for the patient, be provided in a similar fashion to the way that information is provided for physicians and pharmacists right now through printed brochures, because technology has made dramatic improvements in terms of being able to combine many of these patient package inserts with one particular dose that's actually -- with one particular bottle that reaches the pharmacy. So the pharmacist can dispense one of these at a time.

Then you would go away from questions like is the printer working or is it down and when somebody tries to fill a prescription. So that's my question.

DR. COSTER: May I just say something

about that? I don't know if this is what you're suggesting but if you're suggesting that pharmacies keep 60,000 brochures on every different drug in their pharmacy, that would be quite, you know, a space challenge for us. I think the reason why you see them being printed now is because the space behind the pharmacy counter is limited and that it's just easier to print them off from a computer system that's integrated into one package. I can't -- I mean, I can't imagine where we would put all that stuff and if your suggestion is brochures that are custom made, they still have to be printed unless we physically stock them in the pharmacy.

MR. KAPSASKIS: If I could refine and clarify my question; that's not what I meant. What I meant is exactly the way that you current receive pharmacist's inserts that are attached to the bottle of pills, for example, you would get in the exact same fashion several patient inserts that then could be dispensed simply pulling one off at a time and giving -- because you fill a prescription out of one bottle, you may fill five or 10 of them, so you would have a 10-pack of inserts already folded and already printed, multi-color applications in any way that actually would enhance

all the legibility issues that we were talking about before.

So I'm not suggesting that you would inventory these. I'm suggesting that with the incoming products to your pharmacy, you would have attached patient information.

DR. COSTER: You can ask the manufacturers about that this afternoon.

CHAIRMAN SELIGMAN: Yes.

MR. MAYBERRY: I think there is a related issue to that as well.

CHAIRMAN SELIGMAN: Please state your name and affiliation.

MR. MEHTA: Yes, hi. I'm Peter Mayberry and I am here today with the Pharmaceutical Printed Literature Association and I just wanted to pick up on this thread and make a small correction in what was just said. A unit of use package contains enough therapy for a course -- for a specific regimen. So it's typically a 30-count and in the current issue of Pharmaceutical and Medical Packaging News which by the way on the front page is "Patient Friendly Labeling", so it shows how this discussion is getting more diverse, there are photographs in here and we have photos

later on that we're going to show today, where a printed document can be adhered directly to a 30-count bottle which is a unit of use format.

And that alleviates the need for pharmacies to keep 60,000 copies of a brochure. The pharmacists simply takes the unit of use package off the shelf and hands it to the patient with the printed literature on the package. And again, this is not Star Trek, you know. These formats are in use now and available.

CHAIRMAN SELIGMAN: Thank you. Are there any other comments, questions? Again, I want to thank the panel very much this morning for their input. It was excellent and we appreciate it. We will reconvene at 1:30 this afternoon. Thank you.

(Whereupon at 11:57 a.m. a luncheon recess was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:32 p.m.)

CHAIRMAN SELIGMAN: Good afternoon, I'd like to introduce Stacy Kaufman, who's is President of Scriptchek. Mr. Kaufman.

MR. KAUFMAN: Yes. Good afternoon. My name is Stacy Kaufman. I'm a business and marketing professional living in South Florida who has become passionately interested and dedicated to medication safety as a result of my own confusion and mix-ups of medications. As a result of my own personal experience, a dedicated team of individuals and I have been working hard to research and understand the sources and media to which consumers are provided with or gain access to vital safety information about the medications they are taking. I know from my own experience that I did not absorb information that I needed to know about my medications and living in Florida and in a community with a large senior population, I recognize that many seniors taking multiple medications are equally, if not more uninformed about the many medications they take.

After researching available literature, published studies, and speaking to countless U.S.

residents as well as retail pharmacists, our team zeroed in on the prescription label itself as being a perfect venue to address this primary objective. Slide, please. Putting the power of medication information directly and visibly in the hands of consumers, we believe, will be the answer. To achieve this goal, however, we realize that more printable space was needed on pharmacy labels versus the current standard format. The label format design that you see overhead consists of one contiguous label with an extended information tab which provides it in the context of current pharmacy systems and easy to implement, consumer friendly, highly visible media through which vital information can be made available to consumers directly on the prescription bottles.

In addition to introducing our work for the first time to the FDA and to the public through this welcome forum, our purpose and goal today is to also apply the FDA and the pharmacy industry's desire to empower consumers with better tools to educate themselves and to monitor and take charge of their own medication safety. In the short time we have here today, I would like to first, by the way of background, highlight some of the most

interesting and relevant findings from our research and end by introducing to the panel the solution our team has been working on and honing for about two years, now in collaboration with several prominent members of the pharmacy, pharmaceutical and medication safety advocacies constituents across the country.

With the number of prescriptions dispensed annually in the U.S. surpassing 3 billion last year and prescription growth forecasted to continue its rapid pace in the coming years, the number of opportunities for medication errors and mix-up as well as the social and economic impact of these occurrences quickly become staggering. Most, if not all of you here today, are likely to be familiar with the Institute of Medicine's 1999 report titled "To Err is Human", which provided many valuable statistics highlighting the importance of medication safety.

With findings of that report and others like it are no doubt in large part the reason we're all here today. Perhaps the most important take-away from the Institute's report is that the sheer volume of prescriptions and their pace of growth are quite simply overwhelming the systems and

processes in place for patient counseling and education as well as for prevention of medication mix-ups, all while pharmacies try to maintain some degree of profitability.

NASDS, National Association of Chain Drug Stores, reports there to be thousands of vacant pharmacist positions in the pharmacy industry today. Reliance on lesser skilled and educated workers is becoming more and more commonplace just to keep up with the pace required to dispense an ever-growing number of prescriptions month after month, year after year. While numerous technology solutions exist to streamline or automate the prescription dispensing process, those solutions are often costly and are complex to implement.

In the face of these challenging forces, how can consumers, our parents, our children, our friends, best be protected from avoidable medication mix-ups? Relying on the 80/20 rule, one answer we believe derives from the following statistics which are summarized on the overhead screen. The U.S. pharmacopea reports that 70 percent of medication errors are dispensing related. In 2001 NACDS published findings from a

nationwide survey they conducted among community and hospital pharmacists asking them about their experience relative to medication errors. Three of the top six reported causes of medication error related to the wrong medication being dispensed where the wrong dose, wrong drug or wrong routine of administration. The others among the top six errors relate to patient safety information, including failure to catch interactions, failure to catch contra-indications and failure to warn patients of potential hazards. Also interesting are the same NACDS survey findings regarding the most common factors contributing to medication errors as reported again by community and hospital pharmacists.

I will highlight just the top five reported factors; work overload, inadequate staffing, look-alike, sound-alike drugs, failure to catch a technician's error and similarity in packaging. Results in findings like these might lead one to a logical and obvious conclusion that at least one solution to the elimination of many common medication errors lies within the pharmacy dispensing processes and procedures themselves, perhaps due to inadequate computer systems,

prescription checking procedures, levels of staffing, pharmacy automation, among others.

Though improvements in most of these areas can perhaps reduce the error rate, the associated costs, disruption and time related to such changes again, can be prohibitive for many pharmacies across the country. Having the advantage, perhaps, of studying these issues from the perspective of the consumer, not a pharmacy or pharmacist, it seems impractical to rely solely on pharmacy operations to eliminate a large percentage of medication mix-ups. Pharmacies are already overwhelmed and financially strapped, yet the prescription volume continues to grow and grow. So as consumers, our focus and approach to the issue of medication safety has been largely directed at empowering ourselves, consumers, by providing highly visible access to critical medication safety information directly on prescription labels. The prescription bottle is an enduring source of information that a patient sees every time they open a prescription bottle and most importantly, stays with the medication for the full life of the prescription.

The label design we came up with we

call the Scriptchek label. In many ways the Scriptchek label can and will meet the same objectives the FDA advocated for with the new easy to read labels for the OTC products. The FDA goals in that case were achieved by requiring a standard format consisting of important and very specific drug safety, use and warning information, thus providing consumers with a clear understanding of the specific OTC product. The Scriptchek label offers the pharmacy world a label that creatively triples the amount of printable space within the context of existing pharmacy systems and printed configurations, thus allowing immediate opportunity to provide a large enough area for specific valuable drug information. In fact, ease and implementation by pharmacies only requires minor print routine modifications.

Shown on the overhead screen is a visual photo image depicting our vision for the Scriptchek label. The sample includes label content developed with inputs from some of the nation's largest pharmacy chains as well as Converging Label Technologies (ph) the nation's largest producer of prescription label stock for pharmacies. I would like to highlight a few of the

label features in the short time I have remaining and would be happy to supply anyone who might be interested with a sample label or e-mail copy of the digital photo.

A few quick highlights on the vision behind the Scriptchek label. The label has sufficient space to include photographic image and text description of the medication prescribed by the patient's doctor to allow both pharmacists and consumers to verify the drug and dose dispensed for accuracy. We have also included an area where a patient, care giver or family member, can write on the label what the medication is used for, so individuals don't get their medications mixed up.

The extra space also allows pharmacies to print label content with much larger type size making legibility of prescription labels much easier, including warning and other safety information a particular benefit for the nation's growing population of senior citizens. The label also provides sufficient space to allow for supplemental safety information such as drug/drug or drug/food interactions or contra-indications to watch out for. There is also space for bar code and compliance feedback, multiple languages and

directions on where to find disease specific information resources.

Perhaps most important in the context of this form here today, we have included in our label version a powerful consumer call to action in the form of a universally recognized stop sign. If you saw a stop sign on a prescription label attached to your medicine bottle, would that not get your attention? Would you not stop and see what it was for? That stop sign and the adjacent text message is there to remind consumers to take a few minutes and read the medication leaflet that accompanied the prescription from the pharmacy. How many people tear open the bag with the prescription inside and throw the bag and the medication leaflet in the trash without reading it? Even if they do take the time to read through the leaflet, which they first get with their medicine, how often do they save it and refer to it at a later date if needed? How often do they read the leaflet when they get their refills? How many people take that leaflet with them to reference when they go on a trip?

Our goal in designing the Scriptchek label was a design that is notably easy to read,

accommodates considerable more information than current pharmacy labels are able to and stays with each medication for the life of the prescription. In addition, the label fits seamlessly with the current pharmacy operating system and processes. We are proud to be able to introduce the fruits of our labor in this public and very relevant forum here today and would like to thank the representatives of the pharmacy and pharmaceutical industries that have guided us along the way.

I look forward to addressing any questions during the community session later this afternoon and by anyone who wants to discuss or inquire further about this Scriptchek label to contact me direct at my office in Florida, 954-423-9798. Thank you very much for your time.

CHAIRMAN SELIGMAN: Thank you very much, Mr. Mayberry. Mr. Kaufman. Mr. Mayberry is next. Peter Mayberry, Executive Director of the Pharmaceutical Printed Literature Association. Mr. Mayberry.

MR. MAYBERRY: Thank you very much. Yes, I'm Peter Mayberry. I am the Executive Director for the Pharmaceutical Printed Literature Association. I just want to provide you with a

very quick overview of the PPLA. We are a not for profit. We're relatively new. We were started in 2001. And our members largely include providers of package inserts, patient/physician inserts, out-outserts, med guides, folding cards, labels and other printed components for the pharmaceutical industry.

Indeed, PPLA members are responsible for printing the majority of package inserts distributed in the United States today. Generally speaking, there are three types of FDA approved copy which are being produced by PPLA members; package inserts which are intended for the physicians and pharmacists who dispense drugs, patient package inserts, which are designed for the general public to assist them in taking their medications properly. PPI's are being dispensed with some drugs by manufacturers on a strictly voluntary basis and they are approved by FDA largely for use with direct consumer advertising for certain new drugs.

And there's a third type, medication guides which are used with a very small number of drugs and they're mandated for use because of the -- without the printed information, the drug is not

considered safe. In our written comments to FDA, in advance of this meeting, we did respond to all four questions that were raised by the Agency, but in the time available to me today, I simply want to focus on the one question of what should FDA's role be moving forward into 2006 and what the PPLA advocates is that the FDA should stop trying to be reactive and start being proactive in terms of insuring that useful patient information is dispensed with every prescription.

We note that in April during the risk management hearings, Mark McClellan noted the printed literature is fundamental to good pharmaco vigilance programs and we note that the need for FDA approved, manufacturer provided information with all prescription drugs is a critical part in the post-PDUFA environment where new -- especially for new drugs that are coming to market much faster.

As has been noted repeatedly this morning, the study that was done by Dr. Svarstad found that only about 50 percent of the information being dispensed currently is useful and we put this problem largely on the fact that there are multiple vendors supplying pharmacies with non-FDA approved

copy which basically translates to a wide disparity of information that's being provided. And the fact that there is no federal oversight in this information that's being distributed leads to inconsistency.

So what we suggest as specific action plans to meet the goals of the Action Plan would be FDA approved copy intended for consumers should accompany every prescription that's dispensed. And the information should be drawn from the PIs but it should be in a PPI or MedGuide format so that it can be used by consumers. And the information should incorporate the six elements of usefulness from the Keystone Action Plan. At a bare minimum, the copy should be in 10 point type and should include information regarding indications and usage, contra-indications, warnings and precautions, adverse reactions, overdoses and dosage administration.

The printed information should be prepared by the manufacturer and sent to dispensing points for all Rx products. This is the only means that FDA has of assuring that approved information is available to consumers. Moreover, this is a technologically and economically feasible approach.

As I mentioned earlier today in a comment, here is an example of a unit of use bottle with an insert attached to it, in this case it would be an outsert and you can see in this slide, the printed literature is taken apart and these are the various pieces of printed literature that are attached directly to the bottle.

Counter to what the representative from NACDS, there would be no need for filing cabinets and 60,000 inserts. Again, the printed literature can be adhered directly to the container, whether it's a bottle or whether it's blister card. We put this slide in simply to show, as I mentioned earlier this morning, that this information is being printed. It is available. This is not something that's futuristic. This is something that I thought was particularly interesting. On the one side you have the patient information sheet and on the other side you have the PI and the two of them can be split in half, so you basically have the same document doing double duty, or one document doing double duty.

The benefits of a -- of the approach that we recommend are that the action plan goals will be met by 2006. Consumer safety will be

improved. The accuracy, consistency and usefulness of information can be ensured, the plan can be implemented rapidly as the CGMP base control procedures for approved copy management are already in place.

Product design, package configuration, and FDA approved copy for PIs already exists which enable the delivery of this information to consumers throughout the supply chain and it's a modest incremental cost that would increase patient safety and improve compliance with pharmaceutical regiments.

With me today are the members of the PPLA Board of Directors and they've traveled from all over the country to show you visually that we welcome the opportunity to work with FDA to ensure that useful information is dispensed with all Rx drug products. We urge the Agency as you move closer to 2006 which is truly just around the corner, to stop trying to make reactive adjustments and start thinking proactively to make sure that patients get the information that they need. Thank you.

CHAIRMAN SELIGMAN: Thank you very much, Mr. Mayberry. Next we have Terri Burnham, the Acquisitions Editor for Drug Effects -- Drug

Facts.

MS. BURNHAM: Hello. My name is Teri Burnham and I'm an Acquisitions Editor with WoltersKluwer Health, the publishing company responsible for producing the Facts and Comparisons and Medi-Span product lines. As one of the primary suppliers of patient drug information, I'm very grateful for the opportunity to talk about the steps that our company has taken to improve the usefulness of written information patients receive with their prescription drugs. I am also here to affirm the unwavering commitment of WoltersKluwer Health to provide consumers with patient information that is unbiased, comprehensive, readable, scientifically accurate and compliant with the Action Plan developed by the Keystone Steering Committee.

Facts and Comparisons efforts to be med guide compliant began shortly after the Action Plan developed by the Keystone Steering Committee was accepted by Donna Shalala in January of 1997. A new data base called Med Facts was created and launched in 2000 based on the criteria set forth in the Keystone Plan. This information is available as part of a comprehensive on-line drug reference

compendium called eFacts which is XML compliant as a CD rom or as information that we license to third parties for their websites. Last year the Medi-Span business was acquired from First Data Bank by WoltersKluwer Health. Medi-Span also has a patient education data base, one that is widely integrated into retail pharmacy systems. Now, Facts and Comparisons and Medi-Span are in the process of integrating their collective product offerings.

Over the next several months, we will be working to harmonize the content of the Medi-Span data base to mirror the content enhancements made in Facts and Comparisons assuring that the content needs of the patients are met. We are also working on a project that addresses the current formatting limitations of the Medi-Span product. Additionally, we are aware that some Medi-Span customers were not printing all of the text sections that are available for the monographs and that some customers were using a series of warning labels intended to be affixed to a prescription bottle. Clearly both practices do not serve consumers well.

A concerted effort is being made to address this practice with our customers.

Additionally, we are devoting a session in our user's meeting in October to the dissemination of patient information. WoltersKluwer Health recognizes that to best serve consumers, we must continue to work collaboratively with the FDA, the National Council on patient information and education, pharmacy associations, pharmacy system vendors and consumer groups. We recognize that we must continue to actively review the patient information that we are producing and that we must invite others to evaluate as well.

But we believe that the precepts set forth in the Keystone Action Plan are still valid. Working together we can all definitively define and refine the criteria set forth in the Keystone Action Plan. I appreciate the opportunity granted today to outline the efforts made by WolterKluwer Health to provide useful patient information and look forward to working together to ensure patient's information needs are met. Thank you.

CHAIRMAN SELIGMAN: Thank you very much, Ms. Burnham. Our next speaker is Gerry Hobson, the Research Manager for Cerner Multum.

MR. HOBSON: Thank you for the opportunity to speak with the group today. Cerner

Multum is classified as a data base company, similar to the data base companies that were reviewed for the content earlier today by Dr. Svarstad. We're in a unique position. We are also -- our primary corporation, Cerner Corporation, is also a software company that provides hospital information system products across the country and across the world, so we fit in the category of data base company as well as software company.

Our company itself was founded in 1992 and was acquired by Cerner Corporation in 1998. We provide a full compliment of drug information. We developed consumer medication information sheets starting in 1998. Our clients are primarily EMR, HIS suppliers such as Cerner and others. PBM, pharmacy benefit management companies, like MedCo Health, pharmacy system suppliers, web portals and traditional publishers. And I'm here today to discuss primarily question 1 of what the private sector is doing to meet the goals for 2006.

As I mentioned, we have been providing patient -- what we call patient education leaflets since 1998. We're in a unique position where we actually started developing these leaflets after the med guide requirements were determined and so

we use those requirements in the formatting structure of our leaflets. Now, I'm going to go back to the previous slide. As our clients -- we primarily fit into the Category B of Dr. Svarstad's presentation in that the majority of our clients are either mail order or hospital clients. Cerner itself has some retail applications and we're starting to integrate our patient education leaflets within those applications. We're primarily clients on the Level B as Dr. Svarstad said, and in that note, we have not had some of the limitations that other suppliers have had in that our leaflets haven't had to be restricted to the label format as of this point. Now, we have a few clients that are starting in retail applications using that and I've had questions if we can reduce the length of our leaflets to meet their needs for label requirements.

And we're working with these sites to try to implement systems, work flow systems where they can print these leaflets and still maintain their work flow within their institution. Our leaflets are drug specific information in English and Spanish. They're written on the sixth to eighth grade level. You'll see all of these are

from the med guide requirements. They're in Spanish, optimized to North American Spanish. They -- and on the bottom of the slide it shows that they provide graphical icons, which I think is a very important part in understanding the medication information.

They are also subdivided into specific sections with a minimum 10 point text and adequate space to optimize reading. Another key piece has been mentioned that several vendors are providing XML leaflets and this is a very important piece where the future trends in pharmacy, we are able to label certain sections of our leaflet which we call tagging the sections, with specific information for certain populations, so we can have age specific information in our leaflet. We can have specific information on renal and liver precautions for those patients, gender specific precautions and by tagging them this way, you're able to then change the output of that section of the leaflet. You can highlight it, you can bold it, you can do many different things to make that section of the leaflet more noticeable for those specific patients.

With the advent of clinician order

entry and the changes that we're seeing in the distribution of pharmaceutical products, there is an emphasis on the physician entering the prescription through some computerized system and transmitting that prescription to the pharmacy for dispensing and keeping HIPA in mind, that affords the ability for the dispensing pharmacy to obtain a lot more information on the patient who they're filling the prescription for. In the past, it's been difficult in the pharmacy to know exactly what reason the medication is being used for unless you ask the patient directly. Several medicines are used for different purposes. It's hard to know the renal or liver precautions a patient would have.

A lot of drugs are dosed based on body weight and it's difficult for the retail sector to have that information. With electronic transmission of information, those all become a reality. With leaflets being tagged for patient specific information, the actual output of the leaflet then can change based on these patient specific parameters.

The difference I would say -- well, I don't know if difference is the right word, but one of the uniqueness of our leaflets are that they're

longer than a lot of the examples that you've seen and I have a few here and they don't actually fit on the screen but the majority of them are two legal sized pages long. I would say about 90 percent of them are two legal sized pages long, so to work within the normal operating procedures of how pharmacies are dispensing medication makes it a little difficult without changing their work flow functions.

We have within our material, tools that allow us to create these leaflets in a very standardized format. We -- and I have a layout sample here which I'll briefly go through. This is basically as you've seen the med guide requirements, it comes right directly from there. We start with the generic name, a pronunciation brand name and then we get to a section called "What's the most important information", and this is where pieces like black box warnings would go, such as liver cautions for Serzone, as is mentioned earlier today, what is the name of the drug and in this section, I want to point out the off-label use that content we create and we tag that content so that a site can determine whether or not they want to use that piece of information with a specific

patient.

Who should not take the drug and in this section, we actually recommend that they discuss with their health care provider any of these contra-indications statements before they elect to not take a medication. We don't want someone based on a written leaflet to decide to take or not take a medication without discussing it with their healthcare provider. Again, it talks about contra-indications, pregnancy or lactation warnings, geriatric or pediatric population information and, again, those can be tagged and displayed prominently for those patients.

How should I take name of drug; this is basically information on how to take the product. Let me go through these a little bit quickly. What should I do if I miss a dose? That's too quick. What should I do if I overdose information. What should I avoid while taking the drug? What are the possible side effects? And here we rank the side effects basically on those that would require immediate medical attention are listed first, more prominently and the less serious side effects and what to do about them follows that.

What other drugs interact with this

drug? Again, as mentioned earlier, the reading level is sixth to eighth grade and that's -- when you get to a section like this, there's a lot of drug names listed in this section and so by removing those drug names, it's sixth to eighth grade reading level but if you include those drug names and it's far higher. Where can I get more information section, what does this medication look like? We actually can have a description of the medication, the shape and the color and also a picture of the medication.

The date and author of the med guide and a disclaimer. Question 2 is what barriers exist for the private sector to meet the 2006 goal and basically I see that Cerner Multum and several other companies have the resources and intellectual property to meet the technology for the year 2006 goal. Major challenges are in the dispensing pharmacies have challenges again, with -- what's been brought up earlier, with equipment, work flow, incorporation and costs. What should the FDA -- the third question -- do to assure full implementation? I think they should encourage independent entities that have no conflict to a sale of their product to provide unbiased well-

researched informative patient education leaflets.

Independent entities will provide a mechanism for consistent formatting of medications across multiple therapeutic classes. They also have the ability to not limit the enhancements that we're going to see in medication processing with the delivery process of medicines in the U.S. advancing today. And I would entertain any of your questions at the end of the session. Thank you.

CHAIRMAN SELIGMAN: Thank you, Mr. Hobson. Our last speaker on this panel is Dr. Alan Goldhammer, who is the Associate Vice President of Regulatory Affairs for PhRMA.

DR. GOLDHAMMER: Thank you very much, Dr. Seligman. It's indeed a pleasure to be here. PhRMA is a strong believer in empowering patients with information on their prescription drugs. Useful information improves patient compliance, helps to avoid preventable errors and results in superior health outcomes. As we consider the issues raised at this meeting today, it's important that there be a demonstrated linkage between the disseminated information and patient benefit. Furthermore, all parties need to consider how and where quality information is being generated and

how collectively we can maximize the dissemination of such information to the patient.

PhRMA member companies are but one link in the information chain. Both the physician who prescribes and the pharmacist who dispenses the drug, are central players along with the manufacturer in insuring that patient questions are adequately addressed. In order to receive maximum benefit from a drug, patients must be aware of the issues related to the drug's administration. For example, patients should know whether the drug needs to be taken with food or on an empty stomach and if there are specific foods, beverages, and/or even other drugs that should be avoided when taking their medicines. It's also important for the patient to understand that drugs may pose certain risks. It's in everybody's interest, the healthcare provider, the pharmacist, and the pharmaceutical manufacturer, to insure that patients are well-educated about the drugs prescribed to treat their medical conditions since this will maximize the possibility of a positive health outcome.

In 1996, PhRMA along with representatives from the medical community,

pharmacy, consumer organizations and voluntary health agencies participated in the Keystone dialogue that resulted in the Action Plan on useful consumer information. PhRMA supported this dialogue and the initiative in its desire to produce useful information, language, format and layout. However, we did have some concerns about the report. I won't go into those. Those are detailed in our comments that we are submitting to FDA.

Since the publication of the Keystone recommendations, PhRMA has partnered with a number of organizations to improve the usefulness of patient information and patient outcome. The goal of all of these partnerships has been to improve this information and I'd like to just go into some of these activities quite briefly. PhRMA was one of the original members, founding members of the National Coordinating Council for Medication Error Reporting and Prevention consisting of leading healthcare organizations. NCC-MERP, which is its acronym meets to collaborate and cooperate to address the inter-disciplinary causes of errors and to promote the safe uses of medications.

One of the key work projects this group

did was to convene a workshop and publish recommendations that have resulted in an FDA proposed rule on bar coding that will reduce hospital based medication errors. PhRMA has also partnered with the National Patient Safety Foundation, Pharmacy Associations, the American Medical Association and the FDA to develop a public service guide to managing the benefits and risks of medicines. You can't see this and I didn't want to just have a single slide, but we've -- this is available electronically from PhRMA and I believe the other sponsoring organizations. We've printed some up and are distributing them to patients as they request it.

PhRMA also has partnered with the Centers for Education and Research on Therapeutics, the CERTs and the FDA on a series of workshops exploring how benefit and risks of prescription drugs are assessed, communicated and managed. And finally, working with representatives from pharmacy and the healthcare provider communities, PhRMA is -- and these groups are working with two vendors on approaches to deliver prescription drug prescribing information, that is the drug label to pharmacies in an easy to use electronic format.

A proof of concept test last year was highly successful and a larger scale test is being planned for later this year. One of the features of this approach is the pharmacists will always have the most current prescribing information on a given prescription drug. And PhRMA believes that IT solutions such as this one should be more readily employed by all stakeholders. It is critical that the FDA see the provision of useful information to patients as a continuum. The landscape of information providers has changed markedly since the Keystone dialogue back in 1996.

Companies have traditionally provided physicians with brochures outlining the use of particular medicines that can be handed out to patients. The rise of the Internet now provides consumers with direct access to significant amounts of information. Many PhRMA member companies have interactive websites that provide consumers with not only friendly patient information but also the full prescribing information, that is the drug label for particular drugs.

Other medical information providers such as WebMD, RxList and MedxScape as well as the

myriad of disease societies also provide significant information on prescription drugs. And finally, the FDA themselves has a very useful consumer drug information page that describes new drugs approved since January of 1998. Directed consumer print advertising of select prescription drugs provides yet another avenue for the transmission of useful patient information. A brief summary of the advertised pharmaceutical must accompany such advertising and over the past year there's been a move to make this brief summary in print advertising friendlier to patients.

I'd like to now briefly address the four questions the FDA has raised. Question number 1, is the steps the private sector is taking to improve the usefulness of information. Pharmaceutical companies are submitting and receiving approval for a great many patient package inserts or as we call them, PPIs. Many of these are included in products that are packaged unit for use -- unit of use. However, consumers often do not receive PPIs due to flaws in the distribution system. The pharmaceutical industry can work to make these PPIs compatible with current pharmacy distribution systems and can support efforts to

make PPIs available to consumers via alternative distribution pathways, that is web based solutions. Also some innovative packaging designs which integrate useful consumer information into the design itself have recently come onto the marketplace.

The second question concerns barriers that exist for the private sector to meet the year 2006 goal. There are a number of third party vendors who supply pharmacies with hardware, software and content that generates leaflets to patients as they receive their prescriptions. PhRMA believes that these vendors should work with pharmaceutical companies to ensure that the information in the vendor systems accurately reflects the current approved product information. Further, third party vendors should use FDA approved patient package inserts whenever they exist. If possible end point pharmacies should not edit, abbreviate or alter these vendor and FDA approved labels.

Finally, if not already in use, IT systems should be developed that will facilitate easily updatable materials to ensure that patients can be certain to receive up to date and accurate

information. As I noted before, PhRMA has demonstrated that the electronic delivery of whole prescribing information is possible and we're moving to a wider test of this approach and believe that this can be fully implemented in the near term.

The third question is the role of FDA in assuring implementation of the Action Plan to meet the year 2006 goal. More patients, particularly those on medication for chronic medical conditions are receiving their prescriptions from mail order pharmacies. The recent survey that FDA conducted to evaluate the level of useful information received by consumers did not look at this distribution pathway. It would be useful for FDA to study mail order pharmacy as it may be playing an increasing role in the future particularly when a MediCare drug benefit is passed by Congress.

Such a survey could lead to markedly different results than those reported by the FDA in 2001. As PhRMA has already noted, there are multiplicity of sources that provide useful consumer information on pharmaceuticals. FDA should examine third party surveys that take into

account many different means of useful information transmission currently available to consumers. Only by considering the totality of useful information to which patients are exposed will FDA be able to place in proper context the written pharmacy information and in turn, fairly assess the full extent of useful information received by patients.

Finally, FDA should work to better establish and understand a direct linkage to benefit from any useful patient information. In so doing, FDA would survey patients and healthcare providers to best determine what information is critical to safe medication practice. And finally, the fourth question about other initiatives that FDA should consider, PhRMA believes the FDA should issue a guidance to industry on the preparation of useful consumer information. PhRMA uses the terms industry broadly referring to both pharmaceutical companies as well as other providers if pharmaceutical product information destined to consumers.

Such a guidance would outline broad agency expectations of the content of such documents containing useful consumer information

and would better level the playing field for all of these providers.

That concludes my prepared remarks and I'd be happy to answer any questions.

CHAIRMAN SELIGMAN: Thank you very much and thanks to all members of the panel. I guess I'd like to, while you're taking your seat, Dr. Goldhammer, direct my first question to you which is, I'd be interested in your reaction to Mr. Mayberry's presentation. Given the multiplicity of sources of information out there, I think one of the implications of his presentation was that maybe the easiest most efficient consistent means of providing high quality information might be provided by the manufacturer to accompany the product either in hard copy or in electronic form and I was -- I heard that sort of theme echoed as well in some of the comments made this morning and I was curious as to what your feelings are regarding that particular approach.

DR. GOLDHAMMER: Yes, thank you very much. I think our feeling is that the manufacturer is the best source --

CHAIRMAN SELIGMAN: Is your microphone on? Go ahead.

DR. GOLDHAMMER: Is it on now? Okay. Our feeling is the manufacturer is the best source for such information. As you know, both the PI and the PPI are FDA approved and as such, represents a fair balance of all the risks and benefits for any given prescription drug. Our feeling is, as I noted, if a PPI does exist and admittedly PPIs do not exist for every drug, but in the cases when it does exist, that should be the first source of information both for the pharmacy to provide, as well as any of the purveyors, third party purveyors of that information because it does reflect at least what in the manufacturer's view are all of the relevant issues that the patient needs to know.

We have discussed one of Mr. Mayberry's other issues and that is to facilitate the delivery of this information moving to more unit of use packaging. We've had some internal discussions on this at PhRMA and one of the big barriers to doing this right now is -- a couple of them -- one are the existing Consumer Product Safety Council recommendations on child proof packaging, but secondly, the multiplicity in many cases of dosing regiments. Now, it's very difficult for a

manufacturer if -- take a good example of an anti-infective which may have a seven, 10, 14, even 21-day dosing regimen, what do you decide on for unit of use packaging. So it's complicated in that matter but we're trying to explore some avenues in that direction as well.

CHAIRMAN SELIGMAN: Thank you, are there other questions from up here on the panel? Let me open it up then to other members of the panel and to the floor for questions and comments. Yes, Mr. Mayberry.

MR. MAYBERRY: Just a quick follow-up. The first thing about unit of use that you have to realize is it can be blisters or bottles. And certainly I'm a proponent of blisters of unit dosing, but when it comes to CPSC regulations, putting the product in -- dispensing in unit of use in a bottle there certainly aren't any CPSC hurdles there.

There are admittedly hurdles with blisters and for another organization I represent we're trying to overcome those through a regulatory change. As for the dosing regiments, this is something which we've heard repeatedly as a reason why the PhRMA manufacturers can't go to unit of use

formats, distribute directly. And I just would like to point out something that I believe all of you know that these same arguments were raised in Europe several years ago that physicians don't -- you know, wouldn't know how to prescribe and that problem just simply hasn't happened in Europe. Physicians very quickly realized to write scrips in counts of 10. And there is an example and I think physicians in the United States are probably every bit as savvy as physicians in Europe.

MR. McGINNIS: Dr. Goldhammer, this morning we -- this is for Dr. Goldhammer. This morning we heard a possible need for a guidance document. Would you elaborate on what you think needs to go into such a guidance document?

DR. GOLDHAMMER: I think our thought is that there are a huge number of different approaches. If one looks at the written DTC usually on the flip side of the glossy picture where the patient information is, there are tremendous heterogeneity in approaches. And one of the things that we observed when DTC first started taking off is that what was being published was a simple redaction of the PI and I think all parties probably were dissatisfied with that kind of

presentation. You know, the type sizes, I always joke was too small and you know, even those of us who have migrated to reading glasses, you'd have to get magnifying glasses to read it all. However, I think that's changed over the last year and there have been some innovative approaches that have been taken going to Q and A formats, to improving even what was the old kind of mini-PI.

And I think to try to address some of the major topic areas in a guidance would be very useful because I think it would not only provide, I think, a greater assistance to the pharmaceutical industry which may or may not be needed, but I think it would also help all of the third party vendors now who were -- who are currently supplying this information which is, I think in my own estimation, pretty good quality. The only issues that we have is that we've heard from some members their interaction with some of these vendors. If they try to suggest corrections, those corrections may not make it into the vendor's material.

So I suspect what a guidance could serve is it would actually level out that playing field to provide what are the expectations from the Agency.

CHAIRMAN SELIGMAN: Additional comments, questions? Yes, sir.

MR. KAUFMAN: I have a question and a comment and the question is, is that from what I've understood is -- this is my first time here as a consumer, not a pharmacist, just a gentleman who has a very big interest in medication error, is that me, as a consumer, I don't understand the information that's written. And what everyone's been discussing is how do we simplify the information that the person understands what they are taking, the proper medication?

All of these PIs are very sophisticated pieces of paper to eliminate any types of legal actions against these drug companies, from what I gather. And me, as a consumer, I don't understand it. The second thing, that's not my question, that's just my comment. The second thing is once this information is on the leaflet, how does a patient read it? What makes them want to read it? And of course, that leads to my particular label which puts the information in the consumer's hand, a visual stimulation and a prompt response of reading the actual information, which is a major issue, from what I understand from our research

that people don't read the leaflet that is attached to the bag.

So you might have this great information on the leaflet but now we've got to get the patient to read it and that's what I think is a big issue because the consumers can eliminate a lot of medication errors on their own by catching the wrong doses or the wrong medication mix and also by being able to label the medication.

From what I've gathered over the past few years of my own research, medications have many uses for a variety of things and a pharmacist cannot list what that medication is for, for that specific person at that time to dispense it. So there is a limitation there of telling that person what that medication is for. When my grandmother goes into her medicine cabinet and sees eight different medications, she often forgets what it's for. And without being labeled on that particular bottle what is it for, that creates another medication mix-up and that's something that I think needs to be addressed as well, is making sure that the patient is able to basically self-help themself through the medication with it properly written as to exactly what it's for.

Whether the pharmacist writes it there, the doctor prescribes it on there and it's specifically done at the point of dispensing and/or the patient itself then writes the information as to what that medication is for on the actual label which we have prepared with the extended tab label. So my question is, once we get all this great information kind of like the OTC Labeling Act, which I think is terrific, an easy to read label. Once we decide what is going to go on the prescription label how are we going to help the patient read it? And I ask these gentlemen here with all the PI's and all the specific knowledge that they have on patient inserts.

DR. GOLDHAMMER: I think that's a very good -- is this on? I think that's a good question and as I've seen it from both the consumer and also working with our member companies, the biggest barrier right now is with the pills, solid oral dosage forms. And again, as we've talked about, they are not packaged by and large, in unit of use. I think if you do move to unit of use and there are some good examples of that, you can use innovative package designs to put information directly on the packing.

Most of the inhalers, eye drops, nasal sprays and so forth do come packaged unit of use in boxes. Again, I've seen two prescriptions that my family members use that have very nice patient information on it, drawings on it, how to use the inhaler or the nasal spray, summarizing the benefits of the drug, you know, what possible side effects. So it is present with some products.

I think the larger challenge and yours may be a very good approach to dealing with that, this is the first I've seen it, is with the solid oral dosage forms.

CHAIRMAN SELIGMAN: Yes, Mr. Mayberry?

MR. MAYBERRY: Well, just to follow up, there are a number of products which have recently come on the market which have very, very good PPIs that accompanied them with pectograms and diagrams and in certain cases color, but I mean, ultimately you can lead a horse to water, but you can't make them drink.

CHAIRMAN SELIGMAN: Yes, sir, a comment from the floor. Please identify yourself and your affiliation.

MR. McEVOY: Sure, Gerry McEvoy, with the American Society of Health System Pharmacists.

This question, initially, at least, would be directed to Dr. Goldhammer. Since you're suggesting that one potential solution is for the manufacturers themselves to be developing and distributing this information, what percentage of drugs currently on the market would you estimate have existing PPIs that the manufacturers have developed?

DR. GOLDHAMMER: I don't have the exact percentage of -- we did have a number a couple of months ago and I'm not quite sure how accurate it was. It was about 150, so it's not every drug and of course, many generic drugs which represent, I think over half of the dispensed scripts, don't have PPIs.

MR. McEVOY: Okay, and then a related issue to FDA is, assuming that the pharmaceutical manufacturers could produce PPIs for every drug that's on the market, what resources does the Agency have to approve all of those in a timely fashion?

CHAIRMAN SELIGMAN: Well, again, as you know, the manufacturer submits them, we review them and clearly it would require additional resources on the part of the FDA to be able to do that. I

don't know -- I can't give you an exact answer as to the extent of those resources but again, if that became part of our requirements in the negotiation with the manufacturer regarding the approval of the product, we would certainly, you know, find the staff and the resources to, you know, participate in that review and approval. We certainly do that, I think for many of the PPIs as well, is that correct? Yes.

MR. McEVOY: But realistically could FDA, if all of the drugs were to have PPIs developed by 2006, is it realistic to expect that FDA, with current resources, could approve all of those PPIs?

DR. TRONTELL: You asked a question that I don't think that we can answer. I think our current resources would be staggered by that but we have as federal employees learned to adapt and share workloads. We have some abilities and there are other components within the Agency that you could potentially shift resources, but I agree it would be a formidable task.

CHAIRMAN SELIGMAN: And again, it might require a period of, you know, phase-in or you know, to be able to accommodate that task. But

it's like anything else, if it becomes a priority for the Agency, the resources will be, you know, found to meet the task.

MR. MAYBERRY: I would like to throw in that perhaps a good role for the health systems pharmacists would be to help work with the existing PI's to synthesize out PPI information, perhaps identify the top 100, 200, 300 drugs that could be met within a given time frame.

MR. LEVIN: Arthur Levin, Center for Medical Consumers, I would agree with Mr. Mayberry. I mean, I think 2006 is a magic number because of the public law and one could -- and it really says that if you don't -- you know, if the private sector effort doesn't get it right by then, then all the restrictions on FDA to mandate a medication guide or a like product are lifted. You have to remember why that law came into being, the history of it, the politics of it and what it said.

I think, as an advocate, I would be encouraged if the FDA could begin an incremental approach and as has been suggested sort of expanding on the current medication guide rule of 1998, it would sort of target drugs which were known to be problematic and it seems to me that's

where the effort is best expended, is to take on those drugs that we know are causing problems of high risk, maybe of less benefit and then to move from there. But as an advocate, I certainly don't think 2006 as a magic end point is the important thing here. The important thing is the principal and to start really a program that protects patients from harm and what better way than to focus initially on the drugs that have the most potential for harm or that we know are causing the most harm and get it underway.

And if it took to 2020 to get all drugs where they approved PPI, I think we would still consider that a victory.

MR. McEVOY: I have a follow-up comment and since Art just mentioned we should focus on all of the drugs that are, I guess, most important from a risk standpoint, one of the major challenges that we as a publisher have had is in identifying those. Black box warnings was an example this morning. I can tell you FDA can't tell you which drugs require black box warnings. So it's not an easy issue to identify all of these risk factors.

CHAIRMAN SELIGMAN: Yes, Mr. Mayberry.

MR. MAYBERRY: From the PPLA

standpoint, perhaps, the best thing about the system that PhRMA is working to implement is that it can serve as an electronic update. In that sense, the systems that are already in place to distribute the leaflets that are coming from the vendors could be utilized to simply make sure that when you get a prescription, it comes with a PPI and if there is a new black box warning or if there's something which has been released within the last couple of weeks or days or hours, that the system that PhRMA is developing could spit you out a piece of paper which says, "In addition to the PPI, be concerned about this".

MR. KAUFMAN: I figured I'd get this sooner or later. The problem is very large as has been presented and there are also some immediate problems that I think could be solved in regards to medication mix-up, wrong doses. I think what needs to be done at the FDA is address some of the problems that are immediate as far as information being dispensed to the consumers. You're dispensing proper information. For pharmacies to make those immediate changes would be very difficult until it's standardized.

However, by providing the patients with

the proper ID of the medication, that would help eliminate medication mix-up immediately, quite frankly, which is a big problem based on the studies. The wrong dose could also be eliminated that way. With having more space more to be put on the label, I think it opens up -- I hope it opens up the FDA's eyes as to what can now be put in a prescription label. In the past, it's been limited based on the amount of real estate and now that we have exposed to you a label that actually is three times the size, I think there is a solution to quickly solve a lot of medication mix-ups, wrongful deaths going on and allow the immediate things that consumers are very well aware of and things that are pressing right now.

It is going to be a huge task to get the proper guidance and the uniformity of the information to be dispensed but in the short term, we can start saving lives now by just providing the proper information so the consumer sees it, reads it and doesn't miss it. And I think that's a big issue that's been overlooked up until now.

The State of Oregon passed a law in regarding to implementing, which I'm sure everybody's aware of, to show the description of

the pill, the markings of the pill, and that's helped elminate a lot of medication error just from having that verbiage on there. We believe with our Scriptchek label, a visual verification of a prescription drug could eliminate that much more medication error and that can make people more conscious. It can also make consumers more aware and would create more interaction between the patient and the pharmacist if they have something to visually discuss with them.

And I think that's a big thing, I think it's been overlooked and I hope that our Scriptchek label offers that insight for some immediate, not years from now, not computer advancements, but something that can be done now because the format that we use, just so everybody knows, is the exact same format that's currently being used now, 11 by 14 piece of paper. Some pharmacies are using duplex printing which enables them to print on both the front and the back of the form, and that's a big sheet of paper to get all the information. And with this label, the pharmacist is in business within a short period of time. And I think that this should be looked at seriously as far as making sure that patients have a tool to protect

themselves from the medication mix-ups at the fulfillment and dispensing basis and that of course, is the information that they receive as well. Thank you.

CHAIRMAN SELIGMAN: Yes, any other comments? Questions? Thoughts? Yes, please.

MR. HOBSON: Yes, I just have a comment on the updating process. When MedWatch warning comes out and PPI would have to be updated, I think there would be a major concern on attached PPIs to packages of -- and making sure you have the right version of the leaflet that would have the information, the most recent information on the MedWatch warning. I think I incorporating the process within the software so that an update can be applied and then you know you have the most recent version of information makes a lot of sense.

CHAIRMAN SELIGMAN: Thank you. Any other comments or questions? If that's all, I would again, thank our five speakers for taking their time and the audience for their questions and comments. And we will reconvene at 3:00 o'clock, for the last session. Thank you.

(A brief recess was taken.)

CHAIRMAN SELIGMAN: Let's begin. Welcome to the final session of today's public meeting. Before I begin, I'd like to point out that the FDA Commissioner Dr. Mark McClellam has provided a statement regarding the issue of written prescription information for consumers which is out at the front desk, just out in the registration area and I encourage all of you, please, to pick up a copy of that statement. It certainly reflects his support as well as interest in this particular important public health arena.

Our first presenter this afternoon is Linda Golodner, who is the Chairperson of the National Council on Patient Information and Education. Ms. Golodner?

MS. GOLODNER: Thank you. I'm President of the National Consumer's League and Chair of NCPIE and I'm going to be speaking for NCPIE today and also for NCPIE's consumer medication information initiative. And I want to thank you for providing NCPIE this opportunity to testify today. A brief background on NCPIE. It was established in 1982 to stimulate and improve communication of information on appropriate medication use for consumers and healthcare

professionals. And the makeup of NCPIE is a coalition of over 130 members, including healthcare provider organizations, consumer and patient groups, voluntary health organizations, healthcare industry and government agencies.

NCPIE participated on the Keystone Committee as well as many of its members to develop the Action Plan for the Provision of Useful Information, Prescription Medical Information. NCPIE, with the encouragement of the FDA, has stepped forward to serve as catalyst and convener to stimulate private sector voluntary efforts to insure that the goals of Public Law 104-180 are met. NCPIE commends Dr. McClellam and the Agency for its commitment to assure that consumers receive useful information about their medicines. That commitment will serve the initiative well as our committees will seek the expertise and advice of the FDA as we move forward.

For nearly six months the initial members of the CMI initiative have met to prepare how to meet the goals of 2006. We formed three committees, Criteria, Education and Implementation, and each of these committees will have a critical role in stimulating the private sector to reach the

goals. It is important to note that participation in NCPIE's CMI initiative is open to all. There is no requirement that an organization be a member of NCPIE in order to participate.

We are all in agreement here that this is a critical medical safety issue. All consumers must have useful, quality information, access to health professionals, including pharmacists so that they can use prescription medication safely. Following my remarks, NCPIE will make four presentations. First we'll have presentations from each of the committees to describe plans and approach, first David Blair, Director of the Medical Care and Outcome, Inc. and as a NCPIE board member will present the Criteria Committee, Susan Winckler from the American Pharmacist's Association the Education Committee and Lee Rucker, Senior Vice President of NCPIE will present the Implementation Committee report.

After these three presentations, Ray Bullman, NCPIE's Executive Vice President will summarize these plans and specifically address the questions that FDA posed in announcing this meeting. The National Consumers League, having also served on the Keystone Committee, is well

aware of the differences among various stakeholders as to how best to insure that consumers receive useful information. While first recognizing that voluntary private sector efforts have made some progress, substantial improvements remain to be made to reach the goals that have been set out in Public Law 104-180. This effort by NCPIE to convene and coordinate private sector activities through 2006 is brought about by the belief that the target goals can be met if stakeholders work collaboratively in a conserted and targeted effort. It must be a consensus process. It will be through deliberation among all the parties that we can reach our goal.

As we move forward, it is also important to recognize that the external environment has changed considerably since the Action Plan was produced in 1997. Some consumers have more access to consumer information than ever. Examples include the FDA's online provision for information on new drug products, increasing provision of information for consumers via mail service, pharmacies incorporation of consumer information on online pharmacy certified by VIPPS, the Verified Internet Pharmacy Practice Sites, and

online provision of CMI by the National Library of Medicine. However, we must keep our focus on information at point of sale, when you receive your medicine. Online alternatives are not a substitute for clear, quality information when you receive your prescription drug. With any other product or service, a consumer receives and expects directions on how to use, warnings and all the other information on how to best utilize that product or service.

Like many medication error reduction activities that are underway, one part of the development and dissemination of useful information is about systems change. Barriers must be identified and changed. The FDA and the private sector have an obligation to fulfill their commitments to patients and care givers to ensure that they have the most useful information available about their medications when they're taking it. We can't accept anything less.

In 1997 when then-HHS Secretary Shalala approved the Keystone Action Plan, there was a flurry of activity of many stakeholders represented here today including NCPIE. Some held workshops and conferences and some started examining and

revising their patient information. But the fact remains that the initial FDA assessment of private sector efforts points out that our efforts haven't met the goals. While the distribution of consumer medication information has increased dramatically, and it has -- it will likely continue, we cannot assume that either the quality, the quantity or the content of these goals will be met without a serious coordinated effort to ensure that our activities are in concert with both the letter and the spirit of the law and the Keystone criteria are met and enhanced, if appropriate.

In the presentations that follow, members of NCPIE's consumer medication information initiative will describe how private sector stakeholders plan to work collaboratively to better ensure quality improvement and distribution targets are met. On behalf of the entire initiative, we appreciate the critical direction and support of our efforts already demonstrated by FDA. A common thread throughout the presentations that follow is the importance of FDA continuing to work closely with the initiative. Thank you.

CHAIRMAN SELIGMAN: Thank you, Linda. Our next presenter is David Blair, the Managing

Director of Medical Care and Outcomes, Inc., who will be talking on behalf of the NCPIE Criteria Committee.

MR. BLAIR: Thanks. Good afternoon. As he said, my name is Dave Blair and I've also been a practicing community pharmacist for 25 years, so the subject is very near and dear to my heart. Today I'm speaking to you as a member of the Criteria Committee on behalf of NCPIE's Consumer Medicine Information Initiative. Again, I'm also a member of their Board of Directors. Thanks for providing NCPIE with this opportunity to testify on this important topic.

My role this afternoon is to describe functions of the Criteria Committee and how we plan to provide services, our services over the coming years. With the exception of AARP, who's a founding and present member of NCPIE's Board of Directors and participated in one Criteria Committee meeting, my comments reflect the consensus of those organizations that have participated on the committee; however, they do not necessarily reflect the individual views of each member of the NCPIE coalition.

Before describing our plans, I'd first

like to acknowledge the work of the entire Criteria Committee and the NCPIE staff. I won't go through it, it's up there on the screen. Well, I will go through it. What's interesting about it is it's a large group of people that are different stakeholders in this whole process. One of the nice things that we've seen about the way we've put the committees together is that everybody fits in, in different spots, all the way from the generation of the information to actually the people who are handing out the information to the patients, the National Community of Pharmacists Association and National Consumer Leagues, people who have a stake in making sure that patients are taken care of.

The primary role of the Criteria Committee is to provide actionable advice on what may be considered useful drug information based on the Keystone criteria. As described in the December `96 report, the Keystone Committee presented a set of broad and conceptual criteria. These are clearly goals that we all endorse and strive for when producing information for patients and consumers. However, when creating information for specific medicines, more specific and operational information is necessary to ensure that

the information produced meets the Keystone goals.

The mission of the Criteria Committee is to translate the Keystone Criteria into concrete requirements. We will seek to make what is required for specific drugs unambiguous. To do this, we plan to develop and apply translational principles that make it apparent how the Keystone Criteria should be applied. In addition to describing such principles, drawing from the Keystone report, we plan to develop CMI prototypes that can serve as model leaflets and benchmarks for the private sector efforts. We realize that by translating the Keystone criteria into actual documents, we will need to resolve differences arising from the clash of criteria. Some of the various Keystone criteria produced contradictory pressures.

For example, information that is fully comprehensible may not be easily understandable to some consumers. In developing these translational principles, we will need to fully define the nature and the style of information that will meet the Keystone criteria. Our intent is to fully rely on the criteria described in the Keystone Report.

However, we will also rely on consumer input and research that provides information about how various CMI presentation styles impact consumer understanding and consumer use of medications.

We plan to develop a research methodology that uses real patients to provide insights into the nature and style of information the patients find useful. By using such outcome data, we'll be able to obtain meaningful insights on how to apply the Keystone Criteria so that the information disseminated is truly useful to consumers. The Criteria Committee will also need to overcome some serious practical issues related to CMI development and dissemination.

For example, what professional sources of information beyond the package insert, if any, may be relied upon to determine scientific accuracy? How do we resolve the need to provide legible and comprehensible information with practical work flow problems that are faced by pharmacies such as the single pass paper system that exists in many pharmacies today? Finding solutions to these problems and others will keep the committee busy.

A second role for our committee will be

to help develop a scoring method for the various Keystone criteria. The Keystone Committee developed a series of overall objectives for CMIs. They also discussed design aspects of patient information and what should be applied to those designs. However, they did not describe what constitutes a passing grade for both individual criteria or collectively. Dr. Svarstad has asked for help in applying the Keystone Criteria to make a determination of what passes as useful and what is to be judged as insufficient. Where possible, we will use objective consumer research and input to better understand how various CMI criteria influence what is truly useful to patients. To assure that we keep the patients' interests in mind, we will engage in a process that is faithful to the patients' interests. Moving forward, the makeup of the committee will be balanced to assure representation of all relevant stakeholders, including consumers and patient representatives.

As previously stated, to the fullest extent possible, the committee will rely on objective data. We will seek input from objective sources, relying on published literature and original research. Luckily, we have a good deal of

previous work on this issue. The Keystone Committee provided not only a thorough listing of criteria to examine, but discussed how they could be more fully validated and studied. Dr. Svarstad has provided a scientific approach to judging usefulness.

The Committee has already begun to review the Svarstad research to understand how the Keystone Criteria was applied to the four prescription medicines used. We will be reviewing these applications against the Keystone Criteria to determine what translational principles may be applied to other medicines. There is a need for FDA input on this. On a general level, whatever criteria applications we develop must be acceptable to the FDA. If FDA disagrees with our judgment and applies different criteria or uses different translational principles when judging the ultimate success of our efforts, our work will be of little value. Therefore, we will seek FDA input into the design and acceptability of our criteria.

One of the basic issues we need to resolve is that of what sources are to be used to judge scientific accuracy? What information to include in the CMI leaflet, and what sources of

information to rely on, have been the focus of many of the debates in the past. We will need advice and input from the FDA on these deliberations. We look forward to undertaking this important CMI work. Thank you for the opportunity to present at this forum. I and other members of the Criteria Committee present today would be happy to answer any questions you may have. Thank you.

CHAIRMAN SELIGMAN: Thank you for your comments. The next speaker is Susan Winckler, the Vice President and Policy, Communications and Staff Counsel for the American Pharmacists Association who will be speaking on behalf of the NCPIE Education Committee.

MS. WINCKLER: Good afternoon. I'm Susan Winckler, a pharmacist and an attorney with the American Pharmacists Association and serve as their Vice President for Policy and Communications, and Staff Counsel. Today I'm speaking on behalf of the NCPIE Consumer Medicine Information Education Committee convened by the National Council on Patient Information and Education. APHA is a founding member of NCPIE -- founding and current board member of NCPIE and a member of the Education Committee. My comments reflect the consensus of

the NCPIE organizations that have participated on this committee and that are shown here but do not necessarily reflect the individual views of all members of the broader NCPIE coalition.

The Education Committee is focused on a core element, something that is essential to meeting the 2006 CMI targets; that is, a comprehensive educational outreach plan. The mission of our committee is to design, develop and support implementation of a broad plan. We see our role as developing messages and programs that continue to raise awareness of the Keystone Criteria and motivate various audiences to achieve the year 2006 goals and to build and nurture clear lines of communication among the parties responsible for fully incorporating the Keystone Criteria. It's important to note that what we're doing in the Education Committee is building on the efforts that are already going on within the private sector but serving a kind of coordinating function and stimulating more of that activity.

The major topics for our educational outreach include publicizing the criteria to appropriate audiences, underscoring the significance and importance of implementing the

criteria, and also how the private sector must adapt to meet the 2006 targets. We have some specific target audiences for these goals. Our target audiences include the data vendors, the system integrators, purchasing managers at chain and independent community pharmacies, pharmacists and other healthcare professionals, pharmaceutical manufacturers and the public. We are developing an action plan targeting each of these specific audiences.

Outreach to these audiences will be phased in gradually. Each organization in the NCPIE CMI initiative will be responsible for implementing outreach campaigns to their own constituencies. This approach is the strength of NCPIE and why I think it's very important that NCPIE is serving this role. By developing core messages and materials, we have some consistent messages that then each of the participants in the NCPIE initiative can take out to their membership groups and the audiences which they reach.

Early phases of our campaign will target audiences that are essential to the content of the information, primarily the CMI or the drug information vendors as well as the CMI purchasing

managers at pharmacies and the system integrators. Subsequent phases will target healthcare professionals, such as pharmacists, who use CMI as an adjunct to the important direct communication with patients. Finally, we plan to launch a national consumer education campaign, touting the benefits of useful CMI. I think one thing to keep in mind here is that we want to make sure that we're distributing useful information. We also want to make sure that consumers know and understand how to use it. That's essential to reach our ultimate goal of improving medication use.

And part of that consumer outreach will be building on an activity that NCPIE has pursued for more than two decades and that's the National Health Observance Talk about Prescriptions Month. NCPIE, the American Pharmacists Association and other coalition members support this effort. The CMI initiative will be fully integrated into this national health observance. Further, educational sessions on CMI will be featured prominently at NCPIE's national conferences on medicine information and education. The next meeting is scheduled for December of this year in Washington,

DC and another in 2005.

Historically, FDA officials including the Commissioner have keynoted the NCPIE conferences. This year we're planning several sessions chaired by those who have worked closely on the CMI initiative. Also, we expect that CMI stakeholders will develop CMI educational programs for their respective members or customers. Such programs will generate additional opportunities for FDA and others to speak out on the CMI initiative. Throughout the implementation period of our CMI education campaign and into 2006, constant and efficient communication among the stakeholders will be essential.

To address this, NCPIE and CMI partners will develop a CMI website. Initially, it's primarily to facilitate communication among the internal stakeholders but will be modified to serve patients and consumers as well. One example of stakeholder-specific communication vehicles is the National Association of Chain Drug Stores' proposed CMI assessment guide. This assessment guide would help NACDS members, the chain pharmacies, assess if their current CMI leaflets meet the criteria for usefulness. With input from the criteria

committee, we'll be able to provide NACDS members with specific benchmarks that will permit necessary adaptations. These types of tools will be essential for all members of the private sector to evaluate their own efforts and to check our own progress towards these goals.

In early 2003, NACDS distributed a two-page assessment tool that listed all the Keystone Criteria for written information. Another example of the proactive work that's being done here is a NCPIE-produced overview article about the CMI issue. Written in June 2003, this article will be reproduced in various internal publications of NCPIE members and participants in the CMI initiative. For example, APHA will carry this in our news periodical "Pharmacy Today" that builds on that NCPIE information. The overview article will also be adapted for state newsletters of the National Association of Boards of Pharmacy.

And NCPIE is planning an ongoing series of CMI updates that CMI initiative members can customize and use in their own print and electronic newsletters. In addition, CMI outreach is planned for many stakeholders' educational conferences. At next month's NACDS Pharmacy and Technology

Conference and at the American Society for Automation in Pharmacies annual meeting in September, members of the CMI initiative, including NCPIE will speak. These are just a few examples of our education committee's efforts. As we build upon these preliminary opportunities, we envision developing an immediate plan to inform, motivate, and reinforce behaviors that are necessary to meet the year 2006 CMI goals.

Education is essential to all of the efforts we've talked about today. As someone who participated in the Keystone process, I have a good familiarity with the issue but we know that many people were not in those rooms and while many groups have been educating members about CMI, we obviously, have additional work to do and need invigoration and coordination. That's where the NCPIE CMI education initiative comes in. We thank you for the opportunity to present the NCPIE CMI Education Committee's plans. I, or a member of NCPIE staff, will be pleased to answer any questions when we complete the panel. Thank you.

CHAIRMAN SELIGMAN: Thank you very much. The next speaker is Lee Rucker from the NCPIE staff, who will be talking on behalf of the

Implementation Committee.

MS. RUCKER: Good afternoon, I'm Lee Rucker, Senior Vice President, Policy and Public Affairs with NCPIE and I'm speaking on behalf of our CMI Initiative Implementation Committee. My comments reflect the consensus of those organizations that have been participating in our CMI initiative but do not necessarily reflect the opinions of our individual NCPIE members.

I would like to acknowledge our Implementation Committee members, the American Society for Automation in Pharmacy, which represents the system integrators, Catalina Marketing, Merck Research Labs, National Community Pharmacists Association, the Boards of Pharmacy and NACDS.

Some of you may have read Don Berwick's OpEd piece in the Post a couple days ago this week and his piece is about preventing medical errors and he referenced a quality guru, if you will, by the name of Tom Nolan, who identifies three pre-conditions for improvement of anything; will, ideas and execution. You've been hearing this afternoon about our will to meet the goals and you've also heard that from many speakers today before our

panel as well, and we're sharing our ideas and the Implementation Committee is about execution, I'm sorry, Implementation Committee.

We will be providing coordination and feedback and monitoring progress on meeting the goals, of course, as we go along, coordinating the work of the Education and Criteria Committees and vital to, we believe the private sector's success in all of this is working side by side with the FDA. The committee work must be faithful to the process envisioned by Keystone and to FDA's scoring system used to assess success at the end of 2006. The Implementation Committee will plan and manage the research goals needed to support the CMI effort. Several forms are envisioned, for example, coordinating the Criteria Committee's research on consumer reaction and impact of various formats on CMI leaflets and learning what is truly useful to patients. And we do expect to have the opportunity to develop some prototypes perhaps specifically with senior audiences for CMI.

Also commissioning survey research to measure progress of the private sector in meeting the CMI goals. Such research can provide important information to the Education Committee on where

their efforts are most needed. We'll also provide the Criteria Committee with feedback on how the private sector is adapting materials. In addition, the Implementation Committee will keep an eye towards patients who, perhaps, are not the ones that we originally have in mind when we are designing the CMI but those who suffer from low literacy and which is estimated, unfortunately at perhaps 40 percent of consumers in the U.S. do not have basic literacy skills.

And I think those of us who had trouble finding our way to this conference room, we all wish we had GPS but being able to read the signs if you could even see them, just imagine if you couldn't read any of the signs for those of us who were trying to find our way here this morning. No life and death consequences, however, in finding this room as it is with medicine information. In addition, the Implementation Committee will provide or coordinate certain services suggested by the Keystone Committee. We will provide feedback to CMI developers on whether their products meet criteria. As I mentioned earlier, we will develop prototype CMI leaflets and work closely with the FDA to assure that the definition of useful is

universally accepted by all parties.

Evaluating the effects of improving the quantity and quality of information provided to patients will require considerable care. Using the process discussed by the IOMs, "To Err is Human" and their subsequent report, "Crossing the Quality Chasm", we will lay out our process. We will base our process on the application of a systems analysis. To assure a fair and balanced perspective, the Implementation Committee makeup will reflect representation of all relevant stakeholders. Members of the Education and Criteria Committees will also serve on the Implementation Committee to assure full communication among our committees.

And I would just like to re-emphasize that our process is ongoing and inclusive and although our work began earlier this year in terms of forming the CMI initiative, it is an open process and we are eager to accept as many stakeholders as will come to our table. In conclusion this morning you may recall that Dr. Svarstad highlighted four key problems within the current CMI system and she said that these particular problems occurred at different points

along the process. NCPIE's CMI Implementation Committee will help us stay focused across the system, make sure we don't bark up the wrong tree and wisely direct our resources. And at the end of our panel, I'd be pleased to answer any questions you may have. Thank you.

CHAIRMAN SELIGMAN: Thank you very much. Our final speaker for this afternoon is Ray Bullman, who is the Executive Vice President of NCPIE. Mr. Bullman?

MR. BULLMAN: Good afternoon. My name is Ray Bullman. I'm Executive Vice President of the National Council on Patient Information and Education. My role today is to summarize the presentations you've just heard regarding NCPIE's CMI, Consumer Medicine Initiative, Consumer Medicine Information Initiative in relation to questions FDA posed for this public meeting. First, I would like to publicly thank the members of the CMI committees who have participated in planning the efforts you have just heard described.

I've been most impressed with the degree to which the members of our coalition have mutually focused on the goal of providing patients

with useful information about prescription medicines that they take. They have focused not only on the specific of the law -- the specifics of the law and the Keystone Criteria, but also on the spirit of providing patients with information that will help them use medicines safely and effectively. Providing patients who may not be able to use written information fully with additional sources of counseling information represents our commitment to providing usable as well as critically defined useful information. The FDA posed four questions regarding private sector efforts. First, what steps are the private sector taking to improve the usefulness of written information patients receive in order to meet the 2006 goals?

We have heard testimony from a number of CMI companies regarding their commitments and efforts in meeting the year 2006 goals throughout the day. The role of the NCPIE CMI initiative is to provide the steering and direction function needed to assure that we stay on course to meet the usefulness goals of 2006. This steering process is composed of three essential elements represented by our committees. The Criteria Committee will

provide specific and actionable information that the private sector can use faithfully -- to faithfully translate the Keystone conceptual criteria into useful consumer information.

The Education Committee will work to communicate these actionable standards and the Implementation Committee will work to provide the feedback necessary to determine if we are on course or if we need to redirect our efforts. With these three elements, we will provide a systematic approach to maintaining the quality assurance necessary to meet the 2006 goals.

Second, what barriers exist to meeting the goals and what plans exist to overcoming them? Achieving a 95 percent success rate in any system represents a very high standard. We can anticipate some barriers in achieving this goal but are likely to miss others. With our committee structure, we have developed a system for addressing and resolving problems. For example, we anticipate that we will face a barrier based on the logistics of distributing longer forms of written information. Much of the pharmacy information dissemination system is designed to distribute a single page of information as we've heard

throughout the day. Maintaining legibility and content standards, it may not be possible to keep all CMIs to a single page.

Solving this dilemma will be one of the primary roles of the Criteria Committee. As we work toward achieving the 2006 goals we may anticipate difficulties due to the lack of technology support in certain pharmacies. We may anticipate concerns about the application of the Keystone Criteria to certain medications. There may be measurement concerns and educational barriers. However, our plan calls for ongoing commitment to address these problems as they arise and to anticipate and avoid evolving barriers.

Third, what role should FDA take in assuring that the goals of the law and the Keystone Plan are met? FDA's primary role was to provide the oversight and evaluation necessary to determine if such goals are met. However, we also believe that FDA must provide a supportive role in meeting the year 2006 goals. We are pleased that FDA staff agreed to work with each of our committees to provide insight and direction. As our Criteria Committee moves forward, we need to make sure that the decisions we make regarding the application of

the Keystone Criteria are in content with the applications FDA will use in its evaluation. As our Education Committee moves forward in communicating the importance and the need for providing useful information, FDA has an important role in sharing its view as to how PL 104-180 will impact FDA actions if the Keystone goals are not met.

Finally, as our Implementation Committee moves forward, we need to assure that the methods we use to judge the success of our work is consistent with the approach planned by FDA. Thus, in every aspect of our efforts, we must encourage and rely on advice and direction from FDA. Finally, what are initiatives FDA should consider in providing patients with useful information?

One of the insights we are gaining from our discussions is that we must think about what is useful from the perspective of those who will use the information we provide. Unfortunately for many Americans, the ability to process written information is limited. That does not mean that they should not receive well-developed written information. Rather, it suggests that they may need additional interventions to fully utilize this

information. This will likely require additional oral counseling, audio-visual information or simplified written counseling sheets. We hope that the FDA will join us in undertaking this additional effort.

Secondly, in the long term, what is useful should be defined based on the impact of CMIs to effectively influence safer and effective medicine use. We believe that a research program could provide needed feedback on how to structure information so that it meets criteria and effect behavioral changes. This research approach would benefit both the CMI initiative and FDA's efforts at improving risk management communications. We hope that FDA will participate in such an effort. FDA has an important regulatory role. Their authority to require medication guides for selected medications is one aspect of this responsibility. However, for most prescription medicines, the long vision that the private sector should provide the primary mechanism for educating patients. We believe that FDA's proper role is to support these private sector efforts as envisioned by PL 104-180.

I thank you for the opportunity to present and I'd be happy to answer any questions.

Thank you very much.

CHAIRMAN SELIGMAN: Ray, thank you very much and thank you to all members of the panel. I guess let me start with a question to the panel at large. We've heard various presentations and comments today about the potential need for additional guidance from the FDA in this particular arena and I'm curious if FDA were to pursue such a route and produce additional guidance, what you all might think would be the appropriate content or the kinds of things you would like to see in such guidance that would improve the way consumer medication is either -- information is either distributed, scored, evaluated, whatever. Any thoughts or comments?

MS. WINCKLER: One thing that I think would be essential in that guidance is a clarification and we would think support for the idea that off-label uses could be included in the information but what's the format for that? Would they be designated as such, and also that there would be an allowance for some tailoring of the information so that if you know -- if the prescriber has indicated what the medication will be used for, that the pharmacist can put that on

the prescription label and then to use that to tailors the information that's provided. That's something that -- and I should say that this is from APHA's perspective that we would be looking for so that it would provide structure and yet that flexibility that's essential to make sure the information is useful for each patient.

CHAIRMAN SELIGMAN: So this would be something that's beyond what's already in the Keystone Criteria regarding off-label use where at least there is some opportunity to add additional information beyond what, you know, is in the PI.

MS. WINCKLER: Right, or at least confirming that -- as the Keystone Criteria at least confirming that off-label use would be appropriate to include in the information.

CHAIRMAN SELIGMAN: Any other comments from the panel? Questions or comments from the audience regarding the presentations? Everybody is tired.

MS. WINCKLER: Before anyone gets to the mike, I'll add just one other thing. Just on the idea of a guidance document, I think that it would be very helpful to this entire process.

MS. LIANTONIO: Carole Liantonio, an

independent consumer researcher. I guess I'm a little disappointed. It sounds like a lot of talk, a lot of planning and thinking that we're further along than that. It seemed like earlier today a lot more was covered that was more just about to happen. NCPIE, while I applaud that you are really behind the consumer and all for the benefit of consumers, it seems like it's taking a step back again.

Also I'm concerned that so many of your members are the people who are supplying the data systems. There are no health literacy experts. There are very few pharmaceutical companies on the committees. I think you need to have a broader base of input although I don't even know that that much input and thinking, rethinking is necessary at this point. I'm concerned that this might be another four or five-year process.

MR. BLAIR: Is it on? There we go. You know, this is a -- this is a marathon, it's not a sprint and we're meeting today. We would like to be farther along. Our goals were to have some -- we were hoping this meeting was going to happen in the fall, but because of the situation, it happened today. We are -- we have come a long way and one

thing we want to make sure that we do is one of the things that was spoke about earlier was when the Keystone Criteria was developed, there wasn't much of an implementation plan or how do we inspect to make sure this happens the way the Keystone Program was set forward.

We have that data. Now we need to go about it and implement it in a sensible manner. If you say we should have come farther, this is pretty much a new initiative starting in the last, what would you say, six months, Ray?

MR. BULLMAN: If I could, thank you for that comment, and can you hear me okay? With that comment, with my hearing that comment, the invitation is open for people like the person that just asked the question to be involved in this because a considerable challenge ahead for all of us involved in development of consumer medicine information is reaching high risk, hard to reach and sub-populations that are challenged, that have challenges with reading written information.

What we presented today was a process. It was not a specific plan. The next step for the organizations involved in the CMI initiative is to develop, to begin to put the finishing touches on

what is a skeletal plan that has been already developed and our Board of Directors meets on -- the NCPIE Board of Directors meets on September the 18th and the plan is that -- and the timing for that is such that the next step would be that the Board of Directors would be presented with a more comprehensive framework with accompanying budget and implementation steps for moving forward. Thank you.

CHAIRMAN SELIGMAN: Does that answer your question? Yes, Dr. Svarstad.

DR. SVARSTAD: Yes, Bonnie Svarstad. Two comments. One is that I share the previous speaker's concern about I think the weighting of participation of your committees. I guess my concern is of a conflict of interest. Those who are data based vendors now trying to define or redefine the criteria doesn't sound quite right to me. My concern really goes back to the Keystone Committee was made up of representatives from 34 organizations, as I recall. Was it 34 or 37, and what I heard is that you are proposing to re-evaluate or to repeat that process and I guess that would be a concern of mine. I think we'd be moving forward more quickly, it seems to me, if we looked

at those criteria and perhaps identified those that are the most important, as we were talking about this morning, or those that should be weighted more heavily or those that are the most misunderstood or the most ignored or something like that, but to completely restart the whole process of developing criteria, I think, would be a mistake. That's just a personal view.

The second thing, I think Susan Winckler, I really enjoyed your presentation. I think the idea of educational outreach is really essential, critical, to this whole process. My only suggestion here would be instead of focusing on consumers, I would focus on the pharmacists and the pharmacy managers. I think that your comment was something to the effect of that we have -- it's one thing to create useful information and it's another thing to use that information or you quoted someone there. And I would suggest that you forgot the intermediary there and that's the pharmacist.

In the process of collecting our data, I was personally shocked to find that 60 percent of the patients received absolutely no verbal counseling or oral counseling from the pharmacist. Now, I think that if you did research on this

behaviorally speaking, you would find that any time a pharmacist simply staples something to the bag or stuffs it in the bag and let's that medication be handed out by a clerk or a technician, you will not see the outcomes that you're looking for.

Someone this morning said, "You can lead a horse, but you can't get them to drink". Well, you certainly can get them to drink if you have a professional saying, "Here is a piece of information. It's very important. I'd like you to read it either now or when you get home and if you have questions, let me know", at least at level. So I'd really urge you to put top priority on the pharmacist. What are the professional standards here?

We've talked about criteria. What are the professional standards? When is it that the American Pharmacists Association, the American Society of Health System Pharmacists, National Association -- we need some professional standards here and I think that's -- FDA can issue a guideline or guidance, but the professional associations, I think, have a really critical role here to stand up, take leadership and for the first time say, "What are minimal professional standards

with regard to the distribution of written information to all clients, whether they're low literacy, high literacy or whatever"? I think the professional associations really need to stand up and take leadership and I'm delighted to see that you're starting to do that.

MS. WINCKLER: And if I may respond to the second question then I'll defer to Ray for the first question. I thank you for pointing that out because actually essential to what we're trying to do is to make sure that the pharmacist knows what should be done with that information and how to emphasize it, so thank you for bringing to light that perhaps that didn't come out in the testimony but I completely agree with what you've proposed. And it's always been a focus of APHA that when we talk about CMI, the content is very important but we can't just be throwing pieces of paper around. We have to have them presented in the right format, presenting, I guess, in the right environment and with the right set-up from the pharmacist so that it starts a conversation.

MR. BULLMAN: And Dr. Svarstad, the comment about the makeup of our committee structures certainly is well-taken. We want to

make sure that we engage or involve all of the relevant organizations. The groups that we brought to the initial set of meetings represented, if you were to look at the flow chart that Dr. Seligman presented earlier this morning, there was the whole systems process, from the vendor to the patient and what we tried to do for our core -- our core work in the initiative was to bring together representatives from each of those different boxes, as it were, and clearly that's skeletal and that will be built out.

It's not my impression, if it was represented, I think it's incorrect, that this -- the NCPIE CMI initiative is not about suggesting rebuilding or changing the eight Keystone Criteria.

I think the issue moving forward for those who are involved in the development and dissemination of information, is taking into consideration the criteria and the sub-criteria as you look across the wide spectrum of medications and how can the process address those criteria and sub-criteria so that they develop an information set that is consistent with the final assessment and it is also with certainty useful for patients.

DR. GOLDMAN: Dr. Steve Goldman, Steven

A. Goldman, Consulting Service, former medical doctor of MedWatch. I have a couple of general comments. The last questioner mentioned constituent that she said was not involved. I have one basic one. Where are the physicians in all of this? We were here in April for a three-day meeting on risk management and I believe there was one physician represented not even by a physician. Nobody has discussed the physician here through this entire day.

The second comment; you are concerned because only 50 percent of pharmacists will attach some kind of written material. How many written prescriptions are pharmacists filling during the shifts that they have at the pharmacy? Doctors are now given approximately seven or eight minutes to see patients and as a practicing physician, I can tell you the frustration of going over adverse events, going over what you're prescribing, asking the patient the following week to repeat what you've told them and realizing that most of the information didn't get through.

And I think there are some realities that we must acknowledge, that a one-shot educational program is not going to work. It's

going to have to be sustained. It's going to have to be useful information and I will play devil's advocate. I claim there's plenty of information available through the Internet and other means and modes available. Just take a vacation and come back for a week and see what piles up on your desk, in your e-mail, your voice mail, your fax machines and snail mail.

So I think it's not the lack of information, it's the utility of the information provided, the motivation of people to take a look at the information and the fact that it's not just the pharmacist's role, it's not just the consumer's role, it's also the prescriber's role and I am asking quite simply, where is the prescriber in all this?

MR. BULLMAN: I know that on the initial Keystone plan the AMA was represented. I believe the AMA decided or opted not to participate in this particular phase of the initiative. They are on our Board of Directors and that message will certainly be conveyed.

DR. GOLDMAN: If I may suggest, the AMA is not the only organization that represents physicians.

MR. BULLMAN: I understand that.

DR. GOLDMAN: And there are others. I'm simply again -- there's a whole list of MedWatch partners which happen to be physician groups who are already involved with the dissemination of information. They don't seem to be here.

MS. RUCKER: As part of the Education Committee outreach, we do expect to go out to not just pharmacists but all healthcare professionals. That is in our plan. We also feel that it's very important that there be consumer outreach, not just -- not to the Keystone Criteria if you will, but to the value of oral, written information as well as where other resources that consumers can go. And NCPIE for the past 20 years, what we have been trying to do is arm consumers, if you will, with questions to ask, how to dialogue with their healthcare professionals about appropriate use of their medicines and NCPIE will continue to do that.

DR. GOLDMAN: Just one last comment, if I may; I thank you. The question about medication errors, there was a presentation on that, if you take a look at the data that's come out of Jerry Phillip's (ph) shop and others, the leading cause

of medication error is not name confusion. It's not the things that are actually under-labeling although they are significant, it is lack of knowledge, lack of knowledge of medications, lack of knowledge of the populations in which they are to be utilized. Many of the initiatives being discussed today will be helpful but they are not going to solve the overall problem of medication error or proper usage, which goes back to the training of physicians, physician assistants, pharmacists, dentists and all other health professionals both in their training programs, post-graduate training programs, and ongoing continuing medical education and other education. That's also the link I would suggest needs to be addressed. Thank you.

MS. TABAK: I think the reason that the focus has been largely on pharmacists and pharmacy practice in this particular hearing and on the other committees that we've held, is that because the law, PL 104-180, requires the provision of useful information at the point of purchase with the prescriptions. That's not to say that physicians aren't an important link in developing useful information and a whole part of that

process, but I think that's why you'll see the focus is on the pharmacist is because that's what the law is talking about.

MS. PAUL: Kala Paul. Ellen, I have to thank you for that comment because obviously this is about written information. I think we can talk about all the other interventions but this is the one that we're considering and considering how advantageous it would be for the patient to have written information. And it was interesting that after the whole presentation today there were very few statements that really emphasized the idea of useful information that has to be usable information from two standpoints; one that it has to give patients something to do, something to recognize, some way to use, but also that it has to be understandable to them from a health literate standpoint.

In NCPIE, people from NCPIE mentioned this, but I do want to emphasize that while you can talk about the 93 million people who can't read above the fifth grade level and 50 percent of people who have some literacy difficulty in reading English, the idea of health literacy is somewhat different because even if someone can read and read

well, it doesn't not mean that they can understand medical terminology, medical words and it doesn't mean that they are going to be able to use what we consider usable or useful information if they can't understand it.

So I think in terms of the criteria that we're talking about that Dr. Svarstad talked about, the idea that a patient needs to be able to understand something that they can then take with them in using the medication, is extremely important.

Additionally, I just want to talk about something rapidly from my own experience. Getting a medication in which a patient leaflet was included in the packaging as opposed to getting a medication in which the patient information was a printout and stashed in the bag, two entirely different pieces of useful information, one I read because I'm interested, the other one I looked at and trashed. And part of the issue there is when it is presented to me as a unit and it comes and as soon as I open that medication, I find there is information for me, I can take it out and read it.

And we have talked to patients before, this is not new information. Patients who get this

kind of information have it in front of them, will read it. They feel empowered by it and if anything has the potential to add to all the other things that we're putting together to help alter patient behavior, which is indeed what we are trying to do, that kind of situation that's set up is one of the most powerful, if we again are talking about the provision of written information, not the entire spectrum of interventions.

CHAIRMAN SELIGMAN: Go ahead, yes.

MS. ALLINA: I just wanted to give anyone a chance to respond to that if they wanted to.

CHAIRMAN SELIGMAN: No, please go ahead.

MS. ALLINA: Amy Allina from the National Women's Health Network. Those of you who know my organization know that we've been involved in trying to get useful information to patients about medication since we were founded 27 years ago. And we were involved in the Keystone process and you know, I share some of the concerns that were brought up about consumer representation in the NCPIE process, but my comment really goes back to this morning's panel because after listening to

everything over the course of the day, I can't help but say that there's been an enormous amount of time by a huge number of people invested in this over 25 years, just over the time since Keystone and certainly if you include all the time people put into the Keystone process, it's pretty impressive.

But we're still in a situation where the information that's getting to consumers is either inaccurate or not useful, not comprehensible and that's in cases where it is getting to consumers and it seems clear to me that going back to this morning's panel, it's long past time for this -- the process of getting written information to patients to be made mandatory and to be overseen by the FDA. Thanks.

CHAIRMAN SELIGMAN: Thank you for your comment. Any other additional comments, questions, statements? All right, with that, then, I'm going to proceed then to concluding remarks and turn to Tom McGinnis, who -- those of us up here on the panel, at least one of those who has been around the longest on this particular issue and to give some of his reflections on today's proceedings.

MR. McGINNIS: Thank you. Today's

meeting is part of the ongoing process to get useful written information to consumers about their prescription drugs. It turned into a great day for FDA to hear about opportunities and discuss possible important next steps toward fulfilling consumers' need for useful written information. As Doctor Seligman mentioned earlier, one of Dr. McClellam's highest public health priorities is to make sure that consumers have easy access to reliable, understandable, and accurate information about the medications that they are being prescribed. We heard today a few things that we can take back to the Agency for action on some and discussions on others. First, we heard throughout the day, both panels this morning and this afternoon for a need for some type of guidance document or information document that FDA could to in providing links to pertinent information in the action plan toward prototype information, to off-label use information, to clarifying what the Agency would like to see even in the mandatory medication guides.

Second, we heard about the need for a possible mid-course review before we get to the year 2006 to see where we stand, what is being

done. We heard about two of the Agency's highest priority projects, the reformatting of professional labeling that may provide useful information to vendors about what the highest priority information is in the summary section of that labeling, and we've heard about the Agency's initiative to move forward in the paperless labeling area, getting to health professionals useful, up to date information that they could use in modifying information to consumers on a very timely basis.

We heard throughout the day for the first time in my recollection about unit of use packaging and the vehicle that it provides in the European community for dissemination of written information and in the United States for the dissemination of mandatory information, the medication guides and other patient information that the Agency has approved for manufacturers for use with their prescription drug advertising.

There are over 100 of those patient package inserts approved by the Agency. Finally, we heard about advances in new technologies and new softwares that we hadn't seen before providing information to patients, customization of information for patients about their medications to

allow them to use their medications more knowingly and more safely is doable with this new technology and could prove to be very useful instead of the one size fits all approach that we've been talking about.

As we have clearly heard today, we are not where we want to be in providing patients with useful information. However, both the Agency and its drug safety and risk management advisory committee are very impressed with the 90 percent distribution level that was achieved in our survey and we believe that the goals are reachable by 2006. That Advisory Committee has recommended that FDA work with all interested parties to achieve the goals over the next three years. And as you have heard from some of the presenters today, FDA has begun working with organizations and the Agency looks forward to taking further steps with interested parties to make sure the year 2006 goals are indeed met.

In conclusion, FDA is confident that the Action Plan goals can be met by 2006 if, as Linda Golodner, from the National Consumer's League, eloquently presented today, if a serious coordinated effort can occur to get the job done.

That means everybody working together. We need all the consumers involved in this organization. If consumers really want this, you need to get involved with this outside effort or set up an additional outside effort, the Agency will be glad to work with you to demand this information. With consumers demanding this information, with the Agency and other health professional groups pushing vendors and intermediaries to make this happen, that's probably the only way that this job is going to get done by the year 2006.

Thank you for participating.

CHAIRMAN SELIGMAN: Tom, thank you for your excellent summary and with that, I would like to again thank all of you for being here today and for the various panelists who have contributed to the process. The docket to this hearing will remain open until September the 2nd, so I encourage you, if you have written comments, to please submit them. We will look at them carefully. And again, thank you all and have a safe journey home.

(Whereupon, at 4:09 p.m. the above entitled matter concluded.)