

NONPRESCRIPTION DRUGS ADVISORY COMMITTEE

CENTER FOR DRUG EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

8:31 a.m.

Monday, July 14, 1997

Versailles Ballrooms III and IV  
Holiday Inn  
8120 Wisconsin Avenue

Bethesda, Maryland 20814

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NAHID MOKHTARI-REJALI, PH.D.

AL ROTHSCHILD, B.S.

## APPEARANCES (Continued)

## FOOD AND DRUG ADMINISTRATION STAFF: (Continued)

CHERYL TURNER, B.S., R.N.

MICHAEL WEINTRAUB, M.D.  
Director  
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## GUEST SPEAKERS:

WILLIAM W. BRADLEY  
Director of Technical Affairs  
Nonprescription Drug Manufacturers Association

STEPHEN GETTINGS, PH.D.  
Cosmetic, Toiletry, and Fragrance Association

JAMES LEYDEN, M.D.  
University of Pennsylvania School of Medicine

CHRISTINE H. MOORMAN  
Regulatory Affairs Manager  
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WILLIAM SOLLER, PH.D.  
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## ALSO PRESENT:

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## APPEARANCES (Continued)

ALSO PRESENT: (Continued)

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## C O N T E N T S

AGENDA ITEM	PAGE
CONFLICT OF INTEREST STATEMENT by Dr. Andrea Neal	9
OPENING COMMENTS by Dr. Michael Weintraub	10
FDA PRESENTATIONS:	
by Mr. Al Rothschild	12
by Mr. Cazemiro Martin	25
by Dr. Marina Chang	34
by Dr. Nahid Mokhtari-Rejali	36
by Ms. Debbie Lumpkins	39
by Ms. Cheryl Turner	42
NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION PRESENTATION:	
by Dr. R. William Soller	60
by Mr. William W. Bradley	77
by Ms. Christine H. Moorman	83
by Dr. R. William Soller	97
THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION PRESENTATION:	
by Dr. Stephen Gettings	108
by Dr. James Leyden	119
by Dr. Stephen Gettings	127
OPEN PUBLIC HEARING PRESENTATIONS:	
by Dr. Janet P. Engle	138
by Ms. Rose Ann Soloway	145
by Ms. Jann Keenan	151
by Ms. Rebecca Burkholder	156
by the American Optometric Association	160
by Mr. John Rector	164
by Ms. Susan Shellabarger	167
by Ms. Sandra Eskin	170

	10
by Dr. Clifford Whall	173
by Ms. Elaine Holland	179
by Ms. Delia O'Hara	182

## C O N T E N T S (Continued)

AGENDA ITEM	PAGE
CHARGE TO THE COMMITTEE by Dr. Debra L. Bowen	185
COMMITTEE DISCUSSION AND QUESTIONS	186

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

(8:31 a.m.)

1  
2  
3 DR. D'AGOSTINO: I'm Ralph D'Agostino. This is  
4 the meeting of the Nonprescription Drugs Advisory  
5 Committee. There are two FDA meetings going on in this  
6 hotel today. Our committee is the NDAC, the  
7 Nonprescription Drugs Advisory Committee, and our agenda  
8 today is on the proposed labeling requirements of the OTC  
9 drug products.

10 What I'd like to do is to begin the meeting by  
11 having the members of the committee and the FDA  
12 representatives at the table introduce themselves, and in  
13 doing so, we can check that the mikes are at the right  
14 volume. Kathleen, do you want to begin?

15 MS. HAMILTON: I'm Kathleen Hamilton. I'm the  
16 Chief of Staff to the California State Assembly Majority  
17 Leader.

18 DR. BLEWITT: George Blewitt, industry liaison  
19 representative.

20 DR. TONG: Good morning. I'm Ted Tong from the  
21 University of Arizona. I'm a professor of pharmacy and  
22 pharmacology and toxicology.

23 MS. SLINGLUFF: Beth Slingluff, nurse  
24 practitioner with Carondelet Occupational Health Services.

1 DR. JOHNSON: Cage Johnson, Professor of  
2 Medicine at the University of Southern California.

3 DR. NEAL: Andrea Neal, Executive Secretary to  
4 the Nonprescription Drugs Advisory Committee.

5 DR. D'AGOSTINO: Ralph D'Agostino, Boston  
6 University.

7 DR. BRASS: Eric Brass, Harbor-UCLA Medical  
8 Center.

9 MS. McGRATH: Patricia McGrath, University of  
10 Western Ontario.

11 DR. KODA-KIMBLE: Mary Anne Koda-Kimble,  
12 University of California at San Francisco.

13 DR. BERNSTEIN: Ilisa Bernstein in the Office  
14 of Policy at FDA.

15 DR. BOWEN: Debra Bowen, Division of Over-the-  
16 Counter Drugs, Director.

17 DR. WEINTRAUB: Mike Weintraub, FDA.

18 DR. D'AGOSTINO: Andrea Neal, the Executive  
19 Secretary, now will give the meeting statement.

20 DR. NEAL: The following announcement addresses  
21 the issue of conflict of interest with regard to this  
22 meeting and is made a part of the record to preclude even  
23 the appearance of such at this meeting.

24 Based on the submitted agenda for the meeting

1 and all financial interests reported by committee  
2 participants, it has been determined that since the issues  
3 to be discussed by the committee will not have a unique  
4 impact on any particular firm or product, but rather may  
5 have widespread implications to all over-the-counter drug  
6 products, in accordance with 18 U.S. 208(b)(3), general  
7 matters waivers have been granted to each member and  
8 consultant participating in today's meeting.

9 A copy of these waiver statements may be  
10 obtained by submitting a written request to FDA's Freedom  
11 of Information Office, room 12A-30 of the Parklawn  
12 Building.

13 In the event that the discussions involve any  
14 other products or firms not already on the agenda for which  
15 an FDA participant has a financial interest, the  
16 participants are aware of the need to exclude themselves  
17 from such involvement and their exclusion will be noted for  
18 the record.

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

23 DR. D'AGOSTINO: Thank you, Andrea.

24 Michael, do you want to begin the opening

1 comments?

2 DR. WEINTRAUB: Yes. I'd like to begin by  
3 welcoming the committee here this morning and all our  
4 guests as well.

5 It was really just about three and a quarter  
6 years ago that we first started with changing the label.  
7 Debbie and I and several people from the OTC Office in  
8 those days went down to NDMA and presented some thoughts  
9 that we had had about changing the label.

10 In the interim, we had had many meetings of  
11 this committee where we've discussed the label and some of  
12 our ideas. We had a part 15 hearing which many of you  
13 attended, and that was really a very exciting and very  
14 helpful event. It resulted in the publication of a Federal  
15 Register document on February 27th of this year.

16 For such a complex procedure, it has moved  
17 relatively well, given that this is the government and we  
18 have to achieve a certain amount of internal agreement  
19 before we can move on to further things.

20 However, the Federal Register document owes  
21 much of its life to Ilisa Bernstein and her staff. It is  
22 partly due also to Debbie Bowen and her staff in OTC Drugs.  
23 It is partly due to the NDMA and CFTA and their willingness  
24 to go along with it and to participate in the process

1 leading towards its approval.

2 Today we are going to carry on with this  
3 process and do it in an open and public discussion. I hope  
4 we will not have too much confrontation, but we are willing  
5 to even have some confrontation and some discussion of this  
6 very important topic. So, I look forward to the discussion  
7 today myself, but it is part of the process to bring things  
8 to the public, to bring things to an open setting, and we  
9 are going to continue with that process today.

10 DR. D'AGOSTINO: We are going to begin the  
11 actual presentations with the FDA presentations. Now,  
12 there are a number of speakers. I've been asked if it  
13 would be possible to probably hold the questions or any of  
14 the detailed questions till after all the speakers have  
15 made their presentation. Presumably some of the questions  
16 that you may want to address to the early speakers will be  
17 answered by the later speakers. So, why don't we see if we  
18 can do that? If there are points of clarification, as  
19 always please do feel free to ask questions, but if there  
20 are questions in terms of the structure of the label and  
21 things of that nature, we can hold them off till the end.

22 We're going to begin with Al Rothschild and  
23 Cazemiro Martin and then Dr. Chang, Dr. Rejali, Debbie  
24 Lumpkins, and Cheryl Turner. What I'd suggest is that you

1 make your announcement of your name so that the transcriber  
2 can get it and also make your presentation. I won't keep  
3 interrupting in the middle for introductions. Thank you.

4 Now, Al, do you want to begin?

5 MR. ROTHSCHILD: Thank you very much. My name  
6 is Al Rothschild.

7 I noticed this morning that some of you were  
8 reading the newspapers, and in all the newspapers this  
9 morning on the front page there was this story of this man  
10 who was arrested. When he was brought to court, the judge  
11 looked at the arresting officer and said, you know, what is  
12 the story here? The arresting officer said, Your Honor,  
13 this man was fishing under a sign that clearly read  
14 "Private Property. No Fishing Allowed."

15 The judge looked at the defendant and said,  
16 what have you got to say for yourself? The defendant  
17 looked at the judge and said, Your Honor, I don't want to  
18 call the arresting officer a liar. It's true I was fishing  
19 under a sign, but the sign that I was fishing under said,  
20 "Private Property? No. Fishing Allowed."

21 (Laughter.)

22 MR. ROTHSCHILD: It's amazing how many people  
23 can misinterpret not only the spoken word but also the  
24 written word.

1           The February 27th proposal is intended to  
2 assure that all consumers will understand the intent of the  
3 information on the drug label so that consumers will be  
4 able to use OTC drug products more safely and effectively.  
5 The preamble of the proposal emphasizes this objective in  
6 numerous places, that the intent of the proposal is to  
7 enable consumers to better read and understand the OTC drug  
8 product label.

9           In a number of places in the proposal, the  
10 agency asks for help and suggestions in how to regulate  
11 labeling, thereby underpinning the labeling initiative as a  
12 joint effort between government and the public. Indeed,  
13 later in the day, you, the advisory committee, will be  
14 asked for specific recommendations and to submit comments  
15 on their proposal.

16           As stated in the preamble of the proposal, we  
17 believe that the labeling initiative is especially  
18 important to the American public at this time because OTC  
19 drugs are mostly used without medical supervision.

20           In recent years more potent OTC drugs have been  
21 switched from Rx to OTC. This trend of switching from Rx  
22 to OTC is expected to increase in the future as the safety  
23 profiles of many drug products become more established.

24           Consumers are becoming more actively involved

1 in their own health care and now practice self-diagnosis  
2 and self-medication with OTC drugs. Today 60 to 95 percent  
3 of all illnesses are initially treated with some form of  
4 self-care, including self-medication with OTC drugs.

5 Costs of hospital charges, health care provider  
6 fees, costs for prescription medication, and other health  
7 care related services are rising faster than the associated  
8 costs of self-medication with OTC drugs. 60 percent of the  
9 medications purchased by consumers in the U.S. are OTCs and  
10 these purchases account for less than 2 percent of the U.S.  
11 health care dollar, making it likely that the use of OTC  
12 drugs will increase as a low cost alternative to health  
13 care.

14 The elderly comprise close to 20 percent of the  
15 population and are expected to consume as much as 50  
16 percent of all medications by the year 2000.

17 For all these reasons, it is increasingly  
18 important that OTC drug labeling provide consumers with  
19 information that is readable, understandable, and contains  
20 the necessary information to ensure safe and effective use  
21 of the OTC drug product. To assure that such labeling  
22 accompanies all OTC drug products is the objective of this  
23 proposal.

24 The proposal was published on February 27th and

1 the comment period is still running, so there's still  
2 opportunity to comment on the proposal.

3 The proposal would establish a standard  
4 labeling format for all OTC drugs. However, the proposal  
5 would not apply to the format and content of the principal  
6 display panel. The proposal would also not apply to  
7 homeopathic drugs.

8 Currently the content and format of OTC drug  
9 product labeling varies depending on the drug product. As  
10 a result, consumers often have difficulty finding, reading,  
11 and understanding the information consistent with the safe  
12 use of the product, and especially in comparing one OTC  
13 drug product to another OTC drug product.

14 The agency has solicited and received comments  
15 from the industry which it used to develop the proposed  
16 standardized format that we believe will facilitate the  
17 reading and understanding of the information presented in  
18 the OTC drug product label.

19 The agency is proposing that the outside  
20 container or wrapper of the retail package, or the  
21 immediate container, if there is no outside container or  
22 wrapper, contain the label information required in the  
23 final OTC drug monograph or in the approved marketing  
24 application in the order listed with the appropriate

1 headings and subheadings identified in the proposed  
2 rulemaking.

3 The agency is proposing five types of labeling  
4 changes for OTC drug products.

5 One, to require that OTC product labels contain  
6 standardized headings and subheadings in a standardized  
7 order, as well as standardized graphical features.

8 Two, to permit manufacturers, packers, and  
9 distributors to delete connecting terms that are currently  
10 required in OTC drug product labeling. They say a picture  
11 is worth a thousand words, and later this morning we will  
12 show you some examples of OTC drug labels with connecting  
13 terms deleted.

14 Number three, the proposal would expand the  
15 list of interchangeable terms, and again later in the  
16 morning we will show you examples of labels taking  
17 advantage of the use of interchangeable terms to save  
18 space.

19 Four, the proposal would amend the currently  
20 required specific warning language regarding pregnancy and  
21 nursing and overdose and accidental ingestion.

22 Finally, the proposal would preempt state and  
23 local authorities from establishing a different format and  
24 content requirement from what would be required by the

1 proposed regulations. After this then, all OTC drugs  
2 throughout the United States would have very similar labels  
3 and the consumer would know exactly where to go for  
4 information on the label.

5 I will address only that part of the proposal  
6 that would require that the OTC drug product label contain  
7 standardized headings and subheadings in a standardized  
8 order.

9 The proposal would require that the letter  
10 height and type size shall be no smaller than 6 point type.  
11 You will be asked for a recommendation relating to the  
12 print size for information on that label, and I thought  
13 that I should summarize some background information from  
14 the preamble of the proposal regarding print size that you  
15 may find useful.

16 Type size is one of the major elements that  
17 affect the legibility of OTC drug product labels. A recent  
18 study examined the legibility of type size in persons 60  
19 years and older. The subjects were tested using three  
20 marketed OTC analgesics. The research has found that a  
21 significant number of the elderly population could not  
22 adequately see the print on certain OTC product labels due  
23 in part to the type size.

24 Another study evaluated the visual acuity

1 needed to read 25 marketed OTC product labels. The office  
2 found that the majority of labels required a visual acuity  
3 much greater than what is considered normal.

4 Many individuals, especially the elderly, are  
5 concerned that they are unable to read labels with small  
6 print. For these people, small print may result in  
7 improper dosing and thus may result in unsafe or  
8 ineffective use of the OTC drug product.

9 The agency received a petition requesting that  
10 the agency adopt regulatory standards for optimum size and  
11 style of print used for OTC drug product labeling. The  
12 petition opined that standards are needed to maximize  
13 readability of the print for persons with deteriorating  
14 vision and because most people, especially the elderly, are  
15 unable to read the small print that currently appears on  
16 some OTC product labeling.

17 On March 6, 1991, the agency published a notice  
18 to seek comment on the feasibility of regulatory standards  
19 for print size and style of OTC drug product labeling. We  
20 received 57 comments on the notice. About half of the  
21 comments were from consumers and favored larger and more  
22 readable print.

23 Also at about that time, the NDMA established a  
24 special task force on label readability and had distributed

1 guidelines to its members as part of a voluntary program to  
2 enhance readability of OTC drug product labeling by  
3 addressing improvements in print size and other factors.  
4 The NDMA guidelines were amended in 1995 to recommend 6  
5 point type with 4.5 type as an absolute minimum in very  
6 small packages where space does not allow 6 point type.

7           One comment submitted an investigative survey  
8 of consumers' ability to read labeling printed with the  
9 minimum size, and that comment -- I'm sorry -- that is,  
10 that size was the size recommended by the NDMA guidelines.  
11 The comment stated that 49 percent of the adults who  
12 currently purchase OTC medications are not able to read  
13 labels with 4.5 point size. People over 51 have the most  
14 trouble reading labels, with only 32 percent able to read  
15 4.5 type size. 37 percent of the people under 51 were not  
16 able to read the labels, that is, with 4.5 type size.

17           One comment recommended 12 point size for  
18 elderly people. This comment recognized that such a large  
19 print is not possible for many OTC drug product labels and  
20 urged the agency to consider a sliding scale of type face  
21 sizes based on the size of the product package.

22           I'll talk more about the proposed labeling  
23 requirements using the skeleton that is now on the slide.  
24 Again, the skeleton is in the format of the proposed

1 labeling.

2           As I've indicated earlier, the point size would  
3 have to be a minimum of 6 point size and the proposal would  
4 require that the headings be bolded and be a mixture of  
5 capital letters and non-capital letters because the agency  
6 found that it was easier to read a mixture of both capital  
7 letters and non-capital letters than all caps or all non-  
8 caps.

9           The first section is the active ingredient  
10 section, and the dosage unit would have to be identified.  
11 In this case it's a tablet, and opposite that, the purpose.  
12 The active ingredients would be listed under that with the  
13 amount of active ingredient in the tablet. Then opposite  
14 that under purpose would be the pharmacological category or  
15 the principal intended use of the product.

16           The proposal requires that there be a thin line  
17 after each section to separate the sections so that the  
18 consumer could focus their eyes directly on the section  
19 that they're interested in. And then the next section  
20 again would have to be bolded and a mixture of letters.

21           And the next section that would follow would be  
22 the use section with the indications preceded by bullets.  
23 The proposal does not require the icons used for the  
24 bullets. Following the use section, again a thin line.

1                   The next section would be the warnings section,  
2                   and the first warnings that are required to appear under  
3                   the warnings section are those warnings that are unique to  
4                   the product. So, if this was an aspirin product, the first  
5                   warning would be a Reye's syndrome warning. If an alcohol  
6                   warning was necessary, then there would have to be a  
7                   heading alcohol warning and it would be the first one that  
8                   follows.

9                   The next set of warnings are the "do not use"  
10                  warnings, and these are the absolute contraindications. Do  
11                  not use unless prior diagnosis of, such as an example,  
12                  asthma or under any circumstances if you are currently  
13                  taking a certain product.

14                  The next section of the warnings is "ask a  
15                  doctor before use" section which would be related to those  
16                  warnings that would be consistent with "unless directed by  
17                  a doctor," "without first consulting your doctor," or  
18                  "except under the advice and supervision of a doctor."

19                  The first group of warnings under that is the  
20                  "if you have," and those would be the kinds of situations  
21                  where there are preexisting conditions such as high blood  
22                  pressure or heart disease.

23                  The next group of warnings under "ask a doctor"  
24                  is the "if you are" warnings or "if you" warnings which

1 relate to drug or food interaction warnings. Again, the  
2 warnings are bulleted. Each item is bulleted or is  
3 required to be bulleted so that the consumer can glance  
4 down and be attracted to those warnings.

5           The next warning is the "when using this  
6 product" warning, and that relates to side effects,  
7 substances, or activities to avoid.

8           The warning after that, "stop using this  
9 product if," is signs of toxicity or serious reactions. If  
10 there is something listed there, then following that there  
11 would have to be another warning which is: "Ask a doctor.  
12 These may be signs of a serious condition." That phrase  
13 would have to be included.

14           After that warning, there may be other warnings  
15 that should be added, and these would be listed right in  
16 the space after the "stop using this product." Those would  
17 be warnings, as an example, for external use only.

18           The next group of warnings are the pregnancy  
19 and breast-feeding warning and the accidental overdose  
20 warning. You'll notice here that there's no reference to  
21 the poison control centers, and that's something that we'll  
22 also be talking about with you later on today.

23           That's it for the warnings. So, after all the  
24 warnings are completed, then another thin line to separate

1 it.

2 The next group is the "directions". And the  
3 directions, again, are bulleted.

4 Then after the directions is "other  
5 information" which may be other information that's required  
6 by the monograph or the marketing application information  
7 or other information that's optional. As an example, it  
8 might be other ingredients or inactive ingredients that  
9 would be there.

10 The proposal would also require that the  
11 warnings section not be separated, that is, it be on one  
12 panel so that the consumer does not have to search around  
13 the label to find the rest of the warnings if it is  
14 separated.

15 Also the agency recognizes that this format may  
16 not fit all OTC products and that there should be  
17 exemptions for certain products. So, the proposed  
18 regulation would provide for an exemption for products  
19 where this labeling is inapplicable or impractical to  
20 implement or to use on an OTC product.

21 If you were reading the paper this morning, you  
22 also may have read the story of this man who went to a  
23 doctor's office and he went to see Dr. Brown and went to  
24 the receptionist and said, I want to see Dr. Brown. The

1 receptionist said, take this towel, go into room A, take  
2 off all of your clothes, and put on the towel and go into  
3 room B.

4 So, the man compliantly went into room A, took  
5 off all his clothes, put on the towel, opened the door to  
6 room B, and he saw 10 other men all sitting there wearing  
7 nothing but towels.

8 There was only one seat available next to a  
9 disgruntled person, and he sat down next to him. And as he  
10 sat down, the man said to him, this is ridiculous. I'm  
11 here for a sprained knee. I have to take off all my  
12 clothes and sit here waiting for the doctor. The other man  
13 said, what are you complaining about? I'm here to deliver  
14 a telegram.

15 (Laughter.)

16 MR. ROTHSCHILD: The point of the story is if  
17 there's a message to be delivered, you have to speak up.  
18 The comment period on this proposal is still open. Now is  
19 the time to speak up. The agency is receptive to receiving  
20 comments and changing the proposal if it will make it  
21 better, if it will make the label better. So, now is the  
22 time to take the opportunity and to comment on the proposal  
23 and I urge you to do that.

24 The next speaker is Cazemiro Martin and he will

1 tell you about the comments that came from those people who  
2 were not in Dr. Brown's office. They did submit their  
3 comments and they get their message through.

4 Thank you very much.

5 DR. D'AGOSTINO: Thank you, Al.

6 MR. MARTIN: Thank you, Al.

7 My name is Cazemiro Martin and I'm from the  
8 Food and Drug Administration.

9 In the proposed OTC labeling requirement  
10 document published in the Federal Register of February 27,  
11 1997, interested persons were given until June 27, 1997 to  
12 respond to comments regarding the proposal. In response to  
13 the proposal, FDA received requests from the  
14 Nonprescription Drug Manufacturers Association and the  
15 Cosmetic, Toiletry, and Fragrance Association to extend the  
16 comment period to permit industry and other interested  
17 parties additional time to assess and respond to the  
18 proposed OTC labeling requirements.

19 Based on the far-reaching effect the proposal  
20 will have on OTC drug labeling and the reasons provided by  
21 the two manufacturer associations, the agency concluded  
22 that an extension of the comment period was appropriate.

23 In the Federal Register of June 19, 1997, FDA  
24 published a notice that provided an extension of the

1 comment period to October 6, 1997 to respond to the  
2 proposed OTC labeling requirements.

3 At this time within the comment period, we have  
4 received 362 comments in response to the proposal. I want  
5 to give you a very brief sampling of the comments we have  
6 received in response to the specific labeling issues.

7 Most of the comments received so far within the  
8 comment period strongly recommend that the agency revise  
9 the phrase "ask a doctor before use" by replacing the word  
10 "doctor" with the term "health care provider" or adding the  
11 word "pharmacist" or "prescribing provider" such as "nurse  
12 practitioner" wherever a doctor in the phrase stands alone.  
13 Of the 362 comments received, 285 comments specifically  
14 addressed this issue.

15 The comments are from national and regional  
16 professional health care associations, academia, and health  
17 care professionals, including pharmacists, nurses, pharmacy  
18 students, physicians' assistants, and other health care  
19 providers.

20 The comments point out that asking people to  
21 consult only a doctor gives the public impression that only  
22 a doctor can answer questions regarding OTC medications.  
23 According to the comments, the addition of other health  
24 care providers on all OTC drug labeling would help bring to

1 the attention of the consumer the important role the  
2 pharmacist and other health care providers can play in  
3 their OTC drug selection.

4 Many comments stated that pharmacists and other  
5 health care providers are highly trained and accessible  
6 professionals who are available to consumers to provide  
7 information regarding the benefits and possible risks,  
8 including potential side effects and drug interactions,  
9 associated with various OTC drug products.

10 In addition, health care providers can also  
11 determine when self-care is not indicated and refer the  
12 patient to a physician.

13 Another commented stated that in a time when  
14 everyone is trying to reduce health care costs, patients  
15 are self-medicating more and using more nonprescription  
16 drug products. According to the comment, because of the  
17 availability of a large number of OTC drug products,  
18 patients are often confused. Not only can the labels be  
19 confusing, but the product line extensions that contain  
20 different ingredients from the original product can cause  
21 the unknowing patient to take the incorrect drug.

22 The comments maintain that pharmacists are  
23 educated about OTC drug products and are qualified to give  
24 essential and accurate information. The comments asked why

1 not include the phrase "ask your doctor or pharmacist" on  
2 all OTC drug labeling.

3 Because one of the questions before this  
4 committee is concerned with this issue, let me take this  
5 opportunity to briefly give you some background concerning  
6 how we arrived at the reference to health professional in  
7 the pregnancy and breast-feeding warning currently required  
8 in the labeling of OTC systemic drug products.

9 In the Federal Register of December 3, 1982,  
10 the agency published a final rule that amended the general  
11 drug labeling provisions to include a warning concerning  
12 the use of OTC systemic drug products for pregnant and  
13 nursing women. In the preamble of this final rule, the  
14 agency discussed a number of comments requesting that the  
15 general warnings specify a physician or a pharmacist as the  
16 professional for whom a pregnant or nursing woman should  
17 seek advice on the use of OTC drugs.

18 Several of the comments to that rulemaking  
19 requested that the agency adopt the warning, "if pregnant  
20 or nursing a baby, consult your physician or pharmacist  
21 before using this product."

22 Some comments argued that a pharmacist should  
23 be specified because a pharmacist is readily available to  
24 consumers at the time of most OTC drug purchases and is

1 particularly knowledgeable concerning these products.

2 Other comments argued that the physician, as  
3 the primary provider of medical care for pregnant and  
4 nursing women, should be the only professional specified.

5 Another comment stated that the word  
6 "professional" was subject to varying interpretations by  
7 consumers and pointed out that the consumers might construe  
8 the broad term "professional advice" to include persons who  
9 might not be familiar with the objectives of the warning.

10 The agency concluded that the warning should be  
11 changed to advise pregnant and nursing women to contact a  
12 health professional for advice regarding OTC drug usage.  
13 While a physician or a pharmacist would probably be the  
14 most likely health professionals to be consulted because of  
15 their availability and recognized expertise, the agency  
16 indicated that it did not believe that the warning should  
17 specify one or both of these professionals only. The  
18 agency pointed out that many professional groups such as  
19 nurses, nurse practitioners, certified nurse midwives, and  
20 physicians' assistants are also sources of sound  
21 information on OTC drugs.

22 The agency also recognized that a woman who is  
23 considering taking an OTC drug is in the best position to  
24 choose the health professional to help her assess the risk

1 and benefits of using the drug. Thus, the warnings should  
2 not limit her sources of information.

3 I hope this brief review of how we arrived at  
4 the current pregnancy and breast-feeding warning will help  
5 you this afternoon when discussing question number 3.

6 Now, let me continue with the comments received  
7 in response to the current labeling proposal.

8 18 of the 362 comments received in response to  
9 the proposal addressed the issue of print size. Most of  
10 the comments agreed that the current print size is too  
11 small and that increasing the print size of the required  
12 labeling information to 6.0 or larger would enable  
13 consumers, particularly the elderly, to more easily read  
14 the critical information included in the label. Many of  
15 the comments indicated that current print size requires the  
16 use of a magnifying glass to read all the directions and  
17 warnings included in the label.

18 One comment noted that although proposed  
19 graphic format appears to make the drug labeling  
20 information easier to read, unless the 10 point size is  
21 used, the new format will not improve the readability of  
22 the label.

23 On the other hand, one comment from a  
24 manufacturer recommended that 4.5 point size should be

1 acceptable for a medication which is clearly not intended  
2 for use by the elderly, for instance, acne medication.

3           Seven comments recommended that inactive  
4 ingredients be included in the label. The comments  
5 strongly urged the agency to include all ingredients,  
6 including inactive ingredients, in the label. The comments  
7 noted that consumers who have allergies to color additives,  
8 preservatives, or numerous other chemicals need to have  
9 this information identified in the label. One comment  
10 stated that millions of Americans are allergic to or  
11 intolerant of a number of inactive ingredients, including  
12 lactose, various dyes, corn starch, and other chemicals  
13 commonly found in OTC medications. According to the  
14 comment, it is imperative that inactive ingredient  
15 information be listed on the label in order to avoid life-  
16 threatening anaphylaxis reaction due to exposure to certain  
17 inactive ingredients.

18           Nine of the 362 comments strongly urged the  
19 agency not to delete the reference to poison control  
20 centers in the accidental overdose ingestion warning as  
21 discussed in the proposal. Seven of these nine comments  
22 are from regional poison control centers throughout the  
23 United States.

24           The comments indicated that other medical

1 professionals are all too often understandably lacking in  
2 the knowledge about what to do in the event of overdose.  
3 According to many comments, advising consumers to get  
4 medical help right away is likely to encourage consumers to  
5 proceed immediately to an emergency department without  
6 assessing whether the overdose is medically significant.  
7 The comments pointed out that poison control centers can  
8 save consumers hundreds of dollars in health care costs by  
9 treating their exposures at home without an unnecessary  
10 trip to the emergency room or doctor's office.

11           The comments maintained that a poison control  
12 center, if called first, can advise the caller and if  
13 necessary put the caller in touch with a 911 provider. The  
14 poison control center can also contact the hospital to let  
15 them know the patient is coming in and what the appropriate  
16 treatment recommendation should be. The comments added  
17 that most of the time patients calling poison control  
18 centers can be safely instructed in a proper treatment at  
19 home.

20           The comments went on to indicate that it is  
21 common knowledge that many medical professionals, including  
22 emergency department staff, have limited knowledge about  
23 toxicology and call the poison control centers for advice  
24 on management of their patients.

1           The comments also noted that although poison  
2 control centers may not be located in every state, some  
3 centers serve more than one state and are readily available  
4 to consumers.

5           The remaining comments were nonspecific, yet  
6 strongly supported the agency's initiative to improve the  
7 information on the labeling of OTC drug products. One  
8 comment stated that this is a resounding yes vote for the  
9 new suggested label for OTC drug products. Most of the  
10 comments congratulated the agency on the proposed format  
11 and for taking the initiative to make these very necessary  
12 changes.

13           Other comments addressed concerns about the  
14 implication of these labeling requirements on homeopathic  
15 drugs.

16           Several comments recommended that expiration  
17 dating should be clearly visible and printed in ink.

18           Other comments insisted that package inserts be  
19 mandatory if a manufacturer is unable to meet the minimum  
20 print size because of package size restrictions.

21           Finally, several comments recommended that the  
22 proposed rule include a field test requirement for new OTC  
23 drug labels. The comment stated that the field test would  
24 assist in the development of criteria that define good OTC

1 drug labeling and confirm with representative consumer  
2 groups that the new labels are readable, understandable,  
3 and cause the desired drug use behavior.

4 This concludes the summary of the comments  
5 received as of this date. It should be noted that we still  
6 have approximately two and a half months left in the  
7 comment period and that we expect a large majority of the  
8 anticipated comments to be submitted on behalf of the  
9 industry and its associations.

10 Thank you.

11 DR. D'AGOSTINO: Thank you.

12 MR. MARTIN: Now if there are no questions, it  
13 is my pleasure to introduce to you Marina Chang who will be  
14 showing you a label of a currently marketed OTC drug  
15 product. Marina?

16 DR. D'AGOSTINO: This material has been passed  
17 out to the panel. Is that right?

18 DR. CHANG: Good morning. My name is Marina  
19 Chang.

20 As you have just heard, Al spoke about the  
21 background for the OTC labeling proposal which was  
22 published on February 27, 1997. He mentioned that the  
23 intention of this labeling proposal is to ensure that all  
24 consumers are better able to read and understand the OTC

1 labeling product. The proposal also established a  
2 standardized labeling format for all OTC drugs.

3 Cazemiro followed and gave us a very good  
4 summary of all the comments we have received related to the  
5 proposed labeling.

6 Now we would like to show you some samples of  
7 how this proposal might work with some actual labels.

8 Here is an example of the labels of a currently  
9 marketed combination OTC product. It's ibuprofen and  
10 pseudoephedrine tablets approved under an NDA process.  
11 Only the brand name has been changed.

12 As you can see, all information is presented in  
13 a text format, in this case in a double column format. The  
14 same label can be presented in a single format. The format  
15 depends on graphic presentation and the availability of  
16 space.

17 Now I'm going to show you the same product  
18 label which you have just seen with the content arranged in  
19 the proposed labeling format. Let us focus and compare the  
20 warnings section of these two labels. For a currently  
21 product, the regulation requires an indications and  
22 directions and warnings section on the label. In this  
23 label, the warnings section is separated by indications and  
24 directions.

1           In reviewing the NDA for this product, our  
2 agency required that the aspirin sensitive warning  
3 statement be placed first because this product contains an  
4 active ingredient, ibuprofen, which shares the same  
5 property as aspirin.

6           Now, look at the proposed label. The warnings  
7 are all placed in the same section, and the aspirin  
8 sensitive warning remains foremost. The directions section  
9 has moved to follow warnings, and the indications section  
10 remains at the beginning of the label. But the heading  
11 "directions" has been changed to "uses," a more consumer  
12 friendly term.

13           Now, let us look specifically at the warnings  
14 section in the proposed labeling format. The contents are  
15 grouped into subsections with very defined headings. The  
16 consumer can readily find out under what circumstances the  
17 product should not be used or whether to ask a doctor  
18 before using the product or when to stop using the product,  
19 so on and so forth.

20           Now I want to show you the same two labels you  
21 have just seen in 6 point type to illustrate how the  
22 proposed label utilizes white space and bullets to promote  
23 easier reading.

24           As Al mentioned earlier, a picture is worth a

1 thousand words. Which labeling format do you prefer?

2 Now I'd like to introduce Nahid Mokhtari-  
3 Rejali. She will show you the label for a topical product.  
4 Nahid.

5 DR. MOKHTARI-REJALI: Good morning. My name is  
6 Nahid Mokhtari-Rejali. I'm a new member of the OTC  
7 Division.

8 What I would like to do for the five minutes  
9 that I have with you is to share an example of current  
10 labeling on one of the topical acne products and compare it  
11 with the proposed rule, the way that it's going to be in  
12 the future.

13 What you see is the actual print size of the  
14 two labels. The left is the current existing labeling and  
15 the right is the proposed labeling. I would like to refer  
16 the members of the committee that there is a three-page  
17 handout. If you can look at the colorful version of this  
18 labeling, it probably would be more useful. I'm going to  
19 be more emphasizing the warnings and directions section.

20 But comparing the existing labeling with the  
21 current one, you would see on the left-hand side -- in the  
22 new proposed labeling the first category is the active  
23 ingredients and the purpose. This section of the current  
24 labeling actually does not address any of this information.

1 The active ingredients is on the side panel. It is not  
2 even on the front panel. The purpose you can see is  
3 somewhere -- it should be around here. So, it's kind of  
4 hard to get the information.

5 The next section is the use which you have  
6 under the indication in here. It's more precise, accurate  
7 and in bulleted format to get the information that is  
8 needed.

9 Next in here -- would you please move to the  
10 next slide? Actually I have enlarged the section, and I  
11 need the new one on the right screen please.

12 Comparing what we have already with what we  
13 propose, there are many differences in here, but I would  
14 like to emphasize the interchangeable words that I have  
15 underlined in the two overheads. Immediately right after  
16 "directed by a doctor" -- actually there are  
17 interchangeable words. You may use "directed." No.  
18 Actually you can say "unless told to do so," but I think I  
19 have actually missed this part. "Directed by a doctor" is  
20 supposed to be -- in here -- is in here. It saves more  
21 spacing here.

22 "Excessive" versus "too much" and "consult and  
23 contact a doctor." "Ask a doctor." There are similar  
24 other differences.

1                   Actually as you see, "do not use" is started in  
2 the beginning, which is kind of hard to get it in here.  
3 "Do not get into eyes," or "avoid contact with eyes," which  
4 is actually kind of more concise and saving the space.

5                   "For external use only" is in the beginning  
6 which in the new standard format it usually comes here.

7                   As mentioned, the first speaker, the proposed  
8 rule regarding the warnings statement, what the agency has  
9 proposed is to have special language for the warnings  
10 statement, specifically "keep out of reach of children" and  
11 specifically for the topical product, which is "is not  
12 intended for oral use" to be added. "If swallowed, get  
13 help right away."

14                   As you noticed, actually the order of the  
15 different categories differ from one to another. For the  
16 directions, it was kind of less complicated. I just struck  
17 out the lines that have been deleted in the new format.  
18 May I have the overhead on the right please? Yes.

19                   Some of the interchangeable words, "cleanse"  
20 versus "clean" or "medication" versus "drug" and some have  
21 been actually just deleted.

22                   After "because" the beginning of here, actually  
23 everything comes almost the same, but not in bulleted  
24 format.

1           So, as you see, the new format would provide a  
2 more concise and easier understanding of getting the  
3 information to the consumer, and we would like to have your  
4 comments regarding the new proposal. Thank you.

5           Now I would like to introduce the next speaker,  
6 Debbie Lumpkins, who is going to be talking about aspirin.  
7 Thank you.

8           MS. LUMPKINS: Good morning. This morning I  
9 will be showing you some sample labels for an OTC analgesic  
10 product containing aspirin. These labels are based on  
11 labeling proposed by the agency for these products in its  
12 tentative final monograph, or TFM, for OTC internal  
13 analgesic antipruritic drug products. As I show you these,  
14 please keep in mind that the wording used in the samples  
15 are based on a proposal and may be subject to change.

16           This label includes all the wording proposed by  
17 the agency in the TFM. It also has the Reye's syndrome  
18 warning that's currently required for all aspirin  
19 containing drug products and it also has the alcohol  
20 warning that is included in the labeling of many OTC  
21 analgesics.

22           As you can see, the proposed labeling contains  
23 a great deal of information. I really don't expect that  
24 you'll be able to read this, but this gives you a sense of

1     how much a label for such products would be required to  
2     contain.

3             One aspect of the current labeling that I would  
4     like to highlight for you is -- of the current proposal is  
5     the highlighting -- the connecting terms. The proposal  
6     includes 13 connecting terms. Manufacturers may delete  
7     these terms from product labeling, provided the meaning  
8     established by regulation or an applicable monograph is not  
9     altered. These terms are "and," "as may occur with,"  
10    "associated with," "consult a doctor," "discontinue use,"  
11    "due to," "if this occurs," or "occurring," "such as,"  
12    "while taking this product," "within," and "unless directed  
13    by a doctor."

14            The next sample shows the text that can be  
15    deleted from the previous example either because it is a  
16    connecting term or it is covered by headings and  
17    subheadings already included in the proposal. I don't know  
18    if you can see this. It's still pretty hard to read.  
19    "Unless directed by a doctor," or "as directed by a  
20    doctor," or "consult a doctor" appears many times in the  
21    labeling.

22            Also highlighted is the longer form of the  
23    pregnancy/breast-feeding warning and the overdose warning.

24            The last sample is in the new format and has

1 had the redundant connecting terms removed. In addition,  
2 the warnings proposed by the TFM are arranged under the  
3 subheadings of "do not use," "ask a doctor before use if  
4 you have," or "if you are," and "stop using this product  
5 if."

6 As Al pointed out today, there is a section  
7 that allows for additional warnings that are product-  
8 specific. In this label the Reye's syndrome warning, as it  
9 is currently required to do, appears under the major  
10 heading "warnings."

11 The alcohol proposal may also be included in  
12 this section.

13 Also included in this last example is this  
14 streamlined pregnancy/nursing warning and the overdose  
15 warning.

16 As the sample shows, the largest impact of the  
17 proposed labeling format on the labeling of these products  
18 would be in the presentation of the warnings. In this last  
19 sample, important information relating to the safe use of  
20 this product is highlighted by an increased amount of  
21 surrounding space.

22 Next Cheryl Turner will show you how the  
23 proposed labeling format works for an antacid product.

24 Thank you very much.

1 MS. TURNER: Hello. Thank you, Debbie. I'm  
2 Cheryl Turner and I'm with the Division of Over-the-Counter  
3 Drug Products.

4 I will be showing two antacid labels. First I  
5 want to tell you that, as my colleagues before me spoke,  
6 these are sample labels. These are not labels that are  
7 required to be done in this format.

8 I have two labels today that I'm going to be  
9 showing you of an antacid product. The antacid is a final  
10 rulemaking which is one of our much older rulemakings. It  
11 was finalized on June 4, 1994, and at that time I guess we  
12 were not as stringent as we are now with the directions and  
13 warnings, and it has very few warnings and directions in  
14 this rulemaking.

15 The first label I copied off -- I will show you  
16 in just a second. The first label was copied word for word  
17 off an existing product that is actually marketed at this  
18 time, and the second label that I will show you is a label  
19 that I drafted in the proposed format.

20 Could you show the first label please?

21 I do want to point out that these labels -- I  
22 think they are in 14 point. These are not 6 point labels.  
23 I have given copies of the 6 point labels to the -- the  
24 panel members do have copies of each label in 6 point. So,

1 you can realize the 6 point you could probably not read  
2 that and I did want you to be able to read this label.

3 As you notice, everything is run on. There's  
4 not a lot of information. This is the old label, and this  
5 is not a lot of information to put on the product. I  
6 understand that, but it's all run-on. It's kind of hard to  
7 pull out the warnings and the directions statements.

8 I do want to point out here that it does  
9 mention -- this is a magnesium and alumina oral suspension  
10 product, an antacid product. It does say 5 milliliters, a  
11 teaspoon, which is the unit dose on this product. It  
12 contains magnesium hydroxide and aluminum hydroxide. You  
13 do see that there.

14 At the very bottom you'll see dietetically  
15 insignificant. It mentions the amount of sodium, but it  
16 does not mention it in milligrams. It mentions it in  
17 milliequivalents which I had a difficult time in figuring  
18 out. I had to do a lot of calculations, and I'm sure  
19 consumers cannot figure out how to interpret  
20 milliequivalents.

21 It does not list the specific separate amounts  
22 of magnesium, although it does have a warning here that  
23 mentions about not using it if you have kidney disease  
24 except under advice and supervision of a physician. That's

1 to indicate that if you have kidney disease, you may not  
2 want to take this product.

3           Could you show the second one please? All  
4 right.

5           As I said, this is a blown-up label, and this  
6 is in the new format. You do see the first change here is  
7 that alumina and magnesium are put in alphabetized order.  
8 It used to be magnesium and alumina. You do see here the  
9 unit dose, and each 5 milliliters equals one teaspoon.  
10 That is our unit dose and we listed active ingredients in  
11 alphabetical order. Prior to this format, they were done  
12 in order of the highest amount would go first.

13           This is the new information that I'd like to  
14 emphasize to you in this label, and this is an example of a  
15 requirement. In the new format, it's proposed that you  
16 have a separate section that will list dietary information.

17           As hopefully most of you are aware, we had a  
18 rulemaking publish on April 22, 1996. There was a proposed  
19 rulemaking for calcium, magnesium, and potassium. That was  
20 a proposed rulemaking and there was a final rulemaking for  
21 sodium which also published that day. The rulemakings will  
22 both be finalized and be effective on the same date at this  
23 time. Because of the need for testing and new labels  
24 costs, we've decided that would be reasonable.

1                   But there are going to be new requirements that  
2 you will have to list -- depending on the product, if it's  
3 high enough -- sodium, calcium, potassium, magnesium. I  
4 hope I didn't forget anything here. You will have to list  
5 the amounts depending if it meets the requirement for that  
6 product. Such products that maybe need to list this  
7 information would be certain analgesics, antacids, and  
8 laxatives and maybe some other products. They're orally  
9 ingested products that we're talking about here.

10                   The option which was mentioned in the proposal,  
11 although I think dietary information is probably the best  
12 place to put it, you could also put it down as other  
13 information when you list amount of electrolytes, minerals.  
14 It's to be listed in milligrams.

15                   Here you see this, and this is necessary in  
16 this new label. The magnesium content would have to be  
17 listed because it is rather high in this product, and it  
18 was not listed in the other product. You also see here  
19 that the sodium content would have to be listed.

20                   Other than that, this label hasn't really  
21 changed very much. You do see that we do have the first  
22 rather important warning here which is do not take antacids  
23 with any other prescription drugs, and that is the first  
24 warning that we've listed here.

1           We also still have the kidney disease warning  
2 and we also have added -- this was not on the old warning  
3 -- "or if you are on a magnesium restricted diet." That's  
4 required in the new proposal.

5           In conclusion, I would like all of you to bear  
6 in mind that the labeling you have seen today is not a  
7 format you would have to follow exactly because these are  
8 samples. But as I say, these are examples of ways new  
9 labeling could be proposed. Obviously the design, format,  
10 and placement of the required labeling information varies  
11 considerably among different OTC products. As a result, we  
12 feel that consumers have difficulty reading and  
13 understanding this information. We believe presenting this  
14 information in a new standardized format will help  
15 consumers be able to read better and understand the OTC  
16 labeling of these products and apply it to safe and  
17 effective use of the drug products.

18           Again, I would like to remind you that the  
19 proposal is still a proposal. It is not the final rule as  
20 yet and that you do have until October 27, 1997. It ends  
21 the comment period.

22           Thank you again for listening to our samples  
23 and our discussion today, and I'd like to turn this meeting  
24 over to the Chair and possibly this will be a good time for

1 questions. Thank you.

2 DR. D'AGOSTINO: Thank you very much and thank  
3 all of the FDA staff for the fine review and presentation.

4 I would like to entertain questions now, but  
5 before doing so, given that there were so many FDA  
6 presentations, does anybody from the FDA at the table --  
7 and Dr. Katz has joined us -- want to make a comment?  
8 Debra?

9 DR. BOWEN: Yes. I'd just like to make the  
10 comment that we have a few mockups of actual sizes of  
11 packages and the old label, the new labeling. We'd like to  
12 pass them around to you.

13 DR. D'AGOSTINO: Thank you.

14 Michael?

15 DR. WEINTRAUB: Yes, I would like to make one  
16 comment.

17 As you can see from the FDA presentations,  
18 we've done a lot of thinking about this, but still we know  
19 that the proposal is not perfect in every way. That's one  
20 of the reasons for having this meeting, is to find out what  
21 imperfections there are, what changes need to be made,  
22 particularly from your standpoint and also from the  
23 standpoint of the other speakers here today. It's a very  
24 important aspect of this whole process, is to find out

1 where we may have missed things.

2 I don't want to present things to you that you  
3 can't say no about. You should all be able to say no about  
4 some aspect of this.

5 DR. D'AGOSTINO: Debra?

6 DR. BOWEN: Just one other clarification. The  
7 comment period closes October 6, 1997.

8 DR. D'AGOSTINO: Eric, why don't you start?

9 DR. BRASS: I have several comments and  
10 questions about the proposal, but I think even before I  
11 start, I have to say I'm kind of uncomfortable asking the  
12 questions because I don't think I'm the target for the  
13 label. What does or doesn't make sense to me, I'm not sure  
14 is relevant to the discussion.

15 While I was impressed by some of the data that  
16 was presented that indicates the ineffectualness of  
17 existing labels, I don't see much offset, other than common  
18 sense, that this is an improvement, and I do think it's an  
19 improvement. But I'm concerned that when I give my  
20 subjective reaction to things, that it's not particularly  
21 the best subjective reaction.

22 The first is -- and again, this product  
23 illustrates it and it was shown -- that you've tried to  
24 demonstrate that the size of the two are in fact a

1 reasonable match. But there's certain information off the  
2 original label that no longer appears, and I'm talking  
3 specifically about the storage directions, the 800 numbers,  
4 and the manufacturer's name and address which have now been  
5 lost off the label. So, I think in terms of size  
6 comparison, I think we're apple-ing and orange-ing on some  
7 of these comparisons to do that.

8           Could you just clarify? What's the existing  
9 recommendation on inactive ingredients? Is there going to  
10 be a requirement? Is there a requirement under the current  
11 proposal?

12           DR. BOWEN: There is not a requirement in the  
13 current proposal. There is not a requirement to list those  
14 inactives currently.

15           DR. BRASS: Given the concerns expressed during  
16 the comment period, do we have an estimate on the number of  
17 individuals or percentage of the population that's impacted  
18 by inactive ingredient reactions?

19           DR. BOWEN: I don't think we have --

20           DR. BRASS: Because again, in the context of  
21 providing the information to the consumers, that would seem  
22 to be an obvious hole and the question is what's the  
23 magnitude of the impact.

24           An idiosyncratic reaction. I've always reacted

1 to the warning about driving with a chuckle. The specific  
2 warning says something like use caution when driving a  
3 motor vehicle. I've always thought that was a good general  
4 policy. It had nothing to do with the medication. I'm  
5 wondering if that warning actually conveys anything of  
6 relevance to a consumer about what the nature of the risk  
7 in driving with the product actually is and whether that is  
8 an effective warning in that syntax at all.

9 DR. WEINTRAUB: Yes. The warning, as it's now  
10 stated, may not be particularly helpful to any individual,  
11 and that brings up an important generic question. We take  
12 a lot of guff from some of our colleagues in the FDA that  
13 we just say these things and we don't tell people what they  
14 mean and how they will know they are going to happen and  
15 what is the result. We just say don't do this if you're  
16 not -- don't walk on girders at 25-story buildings when you  
17 take this medication. We don't say why. You might fall  
18 off. You might get dizzy. So, that's a generic problem  
19 with OTC warnings.

20 In fact, that warning may not tell anybody to  
21 do more than take the normal precautions in driving which  
22 would be meaningless. You're right.

23 DR. BRASS: And then the last comment I have  
24 now has to do with under the warnings for the "stop using

1 this product warnings," there's a list of stop using this  
2 product, and at the bottom it says "ask a doctor." That  
3 contrasts with the "before use" where it says "ask a doctor  
4 before use if you," which links the act of asking the  
5 doctor to a very specific temporal relationship and is very  
6 explicit. I'm concerned that the "ask a doctor" after the  
7 "stop using this product" isn't clear exactly when you are  
8 suggesting a health professional be contacted.

9 DR. D'AGOSTINO: Other comments, questions?

10 MS. HAMILTON: Well, maybe I'll save my general  
11 comments for the close of our discussion, but I do have a  
12 couple of questions. The various presentations provide  
13 information on who cannot read a 4.5 point type size. I'm  
14 wondering if anyone has information on who can read 6 point  
15 type. That's not intended to suggest the 6 point type  
16 isn't a vast improvement over the smaller type. There's an  
17 invitation to read it just by virtue of its increased size,  
18 but I can't read either one of them. So, I'm wondering if  
19 anyone has information on who we gain by increasing the  
20 type point size.

21 DR. D'AGOSTINO: Does anybody have an answer to  
22 that?

23 I was concerned that I would lose my job at the  
24 house of reading the labels and so forth, but I think I

1 still will qualify with the 6. My wife can't read it but I  
2 can.

3 DR. WEINTRAUB: We had a presentation at the  
4 part 15 hearing, and unfortunately I don't remember the  
5 exact figures. But I do think it does move the population  
6 to a greater -- it sort of widens the role of people who  
7 can read 6 point type, but it doesn't take into account  
8 everybody.

9 DR. D'AGOSTINO: I think with the clutter  
10 removed also that even the size with less clutter helps.

11 DR. WEINTRAUB: Yes, the clutter and the  
12 background and the contrast and all kinds of things that  
13 the manufacturers have been very, very sharp about and,  
14 because of the law in California, have studied a good deal.

15 MS. HAMILTON: I have an additional observation  
16 regarding the way the proposed label uses language to  
17 describe the active ingredient and then to juxtapose that  
18 with the purpose. As I looked at various sample labels,  
19 two things occur to me.

20 In several of the examples that we've been  
21 presented, the active ingredient is juxtaposed with a  
22 purpose that appears to me to just further describe the  
23 sort of property of the pharmacy product such as  
24 antihistamine. As a consumer, to me that's still a

1 technical, pharmacology term. It doesn't tell me what  
2 symptom the product is intended to address.

3           If I understand the reason, which I think is a  
4 good one, to provide that information, I think it's  
5 intended to reduce over-medication by using products  
6 together. If you say to a consumer, the purpose of this  
7 particular ingredient is an antihistamine rather than the  
8 purpose of this particular active ingredient is to reduce  
9 sneezing and other allergy symptoms, that's a much more  
10 useful way to present that information that gets at the  
11 actual intended purpose.

12           I notice on the ibuprofen, the Comed,  
13 description, it's actually done in an improved way. The  
14 label comparison that we've been presented with today  
15 describes the purpose for ibuprofen as pain relief and  
16 fever reducer. That to me is much more useful than, for  
17 instance, analgesic or something.

18           I find that the various samples aren't  
19 consistent that way, so I want to make a suggestion that we  
20 provide symptomatic information there rather than a further  
21 description of the product.

22           One other general comment. I'm concerned.  
23 Actually I was a little bit confused, but it seemed to me  
24 that there wasn't the same level, which I know is typical

1 in these proceedings, of consumer organizations', senior  
2 organizations', health care educator organizations'  
3 participation in the comment period to date. I want to  
4 suggest that the FDA make a particular effort to solicit  
5 comment from consumer groups, health educators, senior  
6 organizations in the remaining comment period, especially  
7 with the model labels. I think that's a good way to  
8 present the information. I was concerned that only nine  
9 individual consumers and not a single major consumer  
10 association appeared to submit comment.

11 Thank you.

12 DR. D'AGOSTINO: Mary Anne?

13 DR. KODA-KIMBLE: I wanted to ask if any  
14 consideration had been given to using universal signs, for  
15 example, red for stop, yellow for warning, or colors? Are  
16 there any guidelines on colors for the labels?

17 DR. BERNSTEIN: I guess I could answer that.

18 We did consider the use of icons and different  
19 other kind of graphical features, but what we found so far  
20 in the literature is that everything can be interpreted so  
21 many different ways, we weren't exactly sure of which  
22 particular icon or graphical feature would be understood by  
23 a majority of the consumers.

24 As for color, we were pretty much silent on

1 that except for the fact that the labels have to have a  
2 clear contrast and leave it up to manufacturers to  
3 introduce the color.

4 DR. D'AGOSTINO: Any other comments or  
5 questions? Cage?

6 DR. JOHNSON: Well, as we've discussed before  
7 in these meetings, I think the proposed format is much more  
8 readable than it was in the past. The 6 point type, even  
9 with my continuous curve bifocal, is right at the limit --

10 (Laughter.)

11 DR. JOHNSON: -- of reading. Since 20 percent  
12 of over-the-counter products are purchased by the elderly,  
13 I think the 6 point type has to be looked at a little bit  
14 more strongly.

15 The other specific comment I would have, in  
16 addition to the ones that Eric made, would be where it says  
17 "warnings," which is centered in the label, to me that's a  
18 little too far to the right and doesn't immediately  
19 correlate with the rest of the label.

20 And third, since the magnesium, sodium, and  
21 other mineral content is given, why isn't the aluminum  
22 content given? Admittedly aluminum toxicity is very rare  
23 and probably only relevant to chronic renal disease. Is  
24 there some specific reason why the aluminum was deleted?

1 DR. WEINTRAUB: No, there's no specific reason,  
2 no definitive reason, but it's so rare that the drug would  
3 contain aluminum that we didn't put it in. However,  
4 sodium, potassium, and magnesium are much more important.

5 DR. D'AGOSTINO: Beth?

6 MS. SLINGLUFF: First off, I'd like to  
7 congratulate the agency because I think we've all come a  
8 long way in looking at labels in the last three or four  
9 years that I've certainly been on the committee.

10 I have a rather recurring refrain that probably  
11 the other committee members are getting a little tired of  
12 hearing. The Federal Register refers to requiring that  
13 labels be able to be read and understood by the majority of  
14 the population. We have consistently seen labels presented  
15 to us that clearly require a higher level of literacy and  
16 education than most of the American population actually  
17 has.

18 Have the current sample labels been tested  
19 against literacy levels or reading levels in any way?

20 DR. WEINTRAUB: No, they really have not.  
21 However, we are taking certain steps to improve the  
22 readability and the understandability, which is more  
23 important in this case, of the labels. So, we are trying  
24 to tease the words about and change things to make them

1 more understandable.

2           You'd be surprised the kinds of words that were  
3 in there. They took a Ph.D. really to understand them.

4           MS. SLINGLUFF: One final thing. I hesitate  
5 when I say this because I realize the conflict I present  
6 here. As a nurse practitioner, I absolutely support the  
7 idea that a doctor is not the only health care professional  
8 that someone may need to consult either before use, during  
9 use, or if they have a problem. Obviously the word  
10 "doctor" is more easily recognized. It's shorter, takes up  
11 less space than health care professional. I nevertheless  
12 think that taking the space on the label to use the term  
13 health care professional is absolutely necessary for the  
14 consumer's safety as a whole.

15           DR. D'AGOSTINO: Thank you, Beth.

16           Ted?

17           DR. TONG: I have three questions.

18           The first one, I think FDA staff can help me.  
19 The content of alcohol and sugar, where will that appear on  
20 the label? I may have missed it. I heard lactose -- in  
21 materials that are alcohol-free or content of alcohol or  
22 sugar-free.

23           DR. BOWEN: Where the content of alcohol will  
24 appear is likely to be in the other information section.

1 In terms of lactose or sugars, if those are inactive  
2 ingredients, it will appear wherever the inactive  
3 ingredients appear.

4 DR. TONG: Now, Dr. Weintraub mentioned  
5 aluminum and the rare occasion when that's a problem. How  
6 aware is the consumer about calcium and magnesium? Are  
7 these two pieces of information really directed at the  
8 health care provider in giving advice? I'm not certain  
9 consumers really know the role of calcium or magnesium in  
10 over-the-counter.

11 DR. WEINTRAUB: Yes, that's a good point, but  
12 we feel that if a patient is told to watch out for the  
13 calcium content of his diet and if he had a renal stone and  
14 you sit down and talk to him about all the different  
15 things, they will become more knowledgeable about, for  
16 example, the calcium content, or if they're on a potassium  
17 restricted diet. So, I think it's intended both for the  
18 health care professional, but more importantly for the  
19 aware consumer, for somebody who has been taught, has heard  
20 the words before.

21 DR. TONG: Finally, the question about the  
22 public comment process. Could someone again from FDA  
23 explain to me? We have this extension to October. Will  
24 this committee then have an opportunity to hear the

1 comments and the summary of the comments like we heard this  
2 morning, which I thought was extremely valuable?

3 The next thing is what happens to these  
4 comments? We then reflect on those comments and make  
5 decisions or advice to you?

6 DR. BOWEN: Actually we set up this meeting  
7 because we thought the comment period would be closed by  
8 the time we held it, but it turns out it's somewhat in the  
9 middle. We had not intended to come back to the committee  
10 with the additional comments. Those comments will be  
11 summarized in the final rule and will be responded to.

12 We're actually trying to collect comments from  
13 you today too, in response both to the 300-plus comments  
14 that we've already received and your additional comments.

15 DR. TONG: If the committee felt that we'd like  
16 to hear --

17 DR. BOWEN: Yes, we would accommodate that.

18 DR. TONG: Thank you.

19 DR. D'AGOSTINO: Any other comments? One more,  
20 Cage?

21 DR. JOHNSON: I'll give up the aluminum, but  
22 the lactose intolerance is a lot more common. So, I would  
23 like to make another plea to include the so-called inactive  
24 ingredients.

1 DR. D'AGOSTINO: Very good.

2 This is probably a good time for a break. Why  
3 don't we come back at 10:15. Please come back right at  
4 10:15 and we'll hear the next presentation.

5 (Recess.)

6 DR. D'AGOSTINO: I'd like to begin the meeting  
7 again.

8 We are now going to have a presentation from  
9 the Nonprescription Drug Manufacturers Association. Dr.  
10 Bill Soller will begin the presentation and introduce the  
11 other speakers. Bill?

12 DR. SOLLER: Good morning, Mr. Chairman,  
13 members of the committee. My name is Dr. Bill Soller. I'm  
14 Senior Vice President and Director of Science and  
15 Technology for the Nonprescription Drug Manufacturers  
16 Association, NDMA.

17 NDMA is a 116-year-old trade organization  
18 representing the manufacturers and distributors of  
19 nonprescription medicines. By sales, our members represent  
20 over 95 percent of the OTC, or nonprescription, drug  
21 marketplace.

22 You have in front of you a blue handout that  
23 we've given you, and just to give you a little bit of  
24 orientation, the first section shows two prototype labels,

1 some changes to the prototype very similar to what we  
2 proposed in 1995 with some minor changes, and then FDA's  
3 proposal. Then you'll go to section II and you'll see that  
4 the first slide is up and you can walk along with us as we  
5 go through the presentation.

6 In addition -- and I'll be referring to them --  
7 at the back of the folder are the NDMA Voluntary Codes and  
8 Guidelines, and I'll make brief reference to them at that  
9 time.

10 I'd like to start my presentation, if I may, by  
11 just referencing, A, there have been a lot of comments  
12 during the break that talked about inactive ingredients,  
13 and I'd just like to sort of lay that to rest and then go  
14 on with the main presentation, if I could.

15 There is an NDMA voluntary program. It's page  
16 11 of the Voluntary Guidelines that provide for inactive  
17 ingredient labeling of OTC drugs, and that is a regular  
18 practice that is seen.

19 You'll also see on the first model prototype in  
20 section I, at the bottom "inactive ingredients" -- that's  
21 the NDMA proposal -- as well as "other ingredients" that  
22 are proposed in prototype B.

23 So, from the standpoint of a voluntary program,  
24 even though there are these legal nuances, given that the

1 practice out there is that inactive ingredients are there,  
2 I think that that probably answers the question. Ted, I  
3 see you nodding, and I think that helps.

4 Well, let me go on. Joining me up here will be  
5 Bill Bradley, Director of Technical Affairs for NDMA, and  
6 Chris Moorman, Regulatory Affairs Manager, P&G. We also  
7 have in the audience as resources on economics, labeling,  
8 and packaging Bob Bartizek and Dave Jespersen.

9 Our comments are in four parts. I'm going to  
10 start with a brief discussion of our commitment to label  
11 readability over the years, get into a brief discussion of  
12 what the type size dilemma is, and then our major  
13 presentation is section III on questions to the committee,  
14 and I'll return with a brief summary.

15 We have a mutual goal with FDA: comprehensive  
16 labeling for OTC drugs, as well as consumer friendly  
17 labeling. FDA wants it, we want it. It's good for  
18 consumers.

19 Goal 1 is accomplished. OTC labels have all  
20 the information needed for safe and effective use of the  
21 product by the consumer.

22 Goal 2 is in progress towards a solution, but  
23 as we go through today, you'll see that there are some  
24 competing endpoints for comprehensive labeling and consumer

1 friendly packaging given the practicalities of the  
2 marketplace.

3 Phase I, label readability, as we call it,  
4 started by FDA with the OTC review in 1972. That was an  
5 ingredient-by-ingredient review of safety and efficacy of  
6 all OTC products currently marketed at that time. It  
7 created all the needed information for safe and effective  
8 use of the product by the consumer. If we look back over  
9 these past 25 years, there's clearly a remarkable safety  
10 record from that experience supporting the current  
11 labeling.

12 Phase II is what we at least at NDMA fondly  
13 call the NDMA phase, but it was really in conjunction with  
14 the State of California in 1990 and highlighted in 1991 by  
15 our Voluntary Guidelines. I'd just like to take a brief  
16 side trip through our Voluntary Guidelines to show you on  
17 page 4, if you'll turn to them -- and I'll be referencing  
18 this a little bit later. That is the start of our  
19 guidelines on OTC labeling and label readability. As you  
20 look through those pages in that handout -- this is the  
21 blue handout in the back. I'm sorry. I realize your back  
22 is to me as I'm talking. But you'll see the 17 or so  
23 factors related to label readability, and I'll address it.  
24 These guidelines, as I say, being in effect since 1991.

1                   But importantly at that time, we had the vision  
2                   to seek to foster continuous improvement in OTC label  
3                   readability to enhance the responsible use of  
4                   nonprescription medicines in self-care settings so that all  
5                   constituencies share in this commitment and contribute to  
6                   practical and workable solutions to the benefit of the  
7                   consumer. The result is, when looking at those guidelines,  
8                   that all the technical factors for improved readability are  
9                   identified, and in the first two years of that program, we  
10                  changed over 37,000 linear miles of labeling.

11                  Phase III is today. What we hope is for an FDA  
12                  and NDMA partnership type of dialogue. In 1995, November  
13                  14th, we submitted our detailed proposal to FDA on label  
14                  format, very similar to what you see in the prototype A in  
15                  section I.

16                  On February 27, 1997, FDA proposed its scheme  
17                  for the label, and we are now in the process doing surveys  
18                  to seek to identify problem areas, economic impact,  
19                  environmental impact, as well as potential solutions to the  
20                  problems that we're identifying.

21                  So, we are here today, July 1997, looking at  
22                  four selected questions, and of course, as was amply  
23                  mentioned over and over again, comments are due October  
24                  6th.

1                   So, in a great sense, what we present to you  
2 today and I think what you'll be hearing from others is a  
3 progress report, is a work in progress as we continually  
4 find new things that impact this rule and try to find ways  
5 of how to deal with them.

6                   I'd like to take sort of a side trip here on  
7 the principles and technical factors of readability. They  
8 are well known and two facets of this I'd like to touch on  
9 and that is the readability literature, as well as our  
10 voluntary readability guidelines.

11                   On the left-hand side of slide 9, you'll see  
12 it's headed up "readability literature." This comes from  
13 such books as Doak, Doak and Root, which is essentially the  
14 biblical reference. I'm holding it up here, and it is one  
15 that is used by readability experts. There are a number of  
16 others, and there's a host of literature.

17                   There are a number of basic principles from  
18 using the active voice to using common words, using the  
19 least number of syllables -- I think the interchangeable  
20 terms -- placing the information and the context before new  
21 information, and using organizers -- and this is a word of  
22 art -- to "chunk" information, that is, the headings and  
23 subheadings, using a consistent sequence of information to  
24 help the reader follow the flow of information,

1       typographical cues such as highlighting, bullets, color,  
2       and reducing clutter.

3                     Dr. Brass, I was taken by your comments in  
4       terms of your subjective view. It is true for me. When we  
5       get into a labeling discussion, everybody has an opinion on  
6       the label, but it is also true that as you look at the  
7       readability literature, that these kinds of principles  
8       overall are understood to be ways to present information in  
9       the written form. We've taken these particular principles  
10      and we have applied them through those 17 facets of the  
11      label readability guidelines that I showed you earlier from  
12      design down to color.

13                    I'd also say that in terms of thinking about  
14      what we're going to say about the organization of this --  
15      and Dr. Brass this also addresses a little bit of what you  
16      were saying earlier, and that is it's important to step  
17      back and think from the standpoint of medical and consumer  
18      expert and readability expert how you're going to organize  
19      that because it's not necessarily a consumer preference,  
20      not thinking of all the ramifications that can develop the  
21      best label, and we hope to show you that today.

22                    So, by way of interim summary, taking all those  
23      principles together and the technical factors, we proposed  
24      to FDA a standard order, uniform headings and warning

1 subheadings, expanded use of interchangeable terms,  
2 bulleted lists, and no use of all caps, upper and lower  
3 case, and a few other things. We think because of these  
4 principles being well established, it really was not a  
5 surprise that FDA came to similar conclusions.

6 So, as a result of all of this attention over  
7 the last 25 years, we have OTCs that have an excellent  
8 safety record. There is not a public health crisis related  
9 to the readability of OTC labels, and we agree with much  
10 that FDA has proposed with some refinements, as you'll see  
11 today.

12 I'd like to turn now to the second part of the  
13 talk and just discuss briefly the type size dilemma,  
14 specifically as it would relate to definition, impact, and  
15 reasons. I touched on this a little bit earlier. The need  
16 for comprehensive information balanced against the  
17 practicalities of the marketplace; in simple terms, trying  
18 to put comprehensive text on limited label space, the type  
19 size dilemma.

20 Here's an example of a pediatric Sudafed nasal  
21 decongestant done with all the bells and whistles with  
22 FDA's proposals, without the refinements that we're  
23 considering. You can see there's a nice fit when you look  
24 at 6 point Helvetica with bold and 1 point leading. That's

1 one seventy-seconds of an extra space between the line, one  
2 seventy-seconds of an inch. So, here on many of the  
3 products, we do see a fit with FDA's proposal.

4 Next slide, and this is not upside down because  
5 we're looking at the lower label here, but this is a fold-  
6 out of a blister pack. If you were to do the same put-up  
7 that I showed you before for pseudoephedrine for the adult  
8 product, you would see that it does fit within this  
9 section.

10 However, when you add guaifenesin, which isn't  
11 a particularly complicated ingredient from the standpoint  
12 of labeling, you see that you get this kind of overlap when  
13 you do the 6 point Helvetica and 1 point leading.

14 When you go to unit-dose packaging, things get  
15 much, much worse.

16 So, that's the dilemma in pictorial form.  
17 Chris Moorman will come back and show you some of the  
18 things that we're trying to do to resolve this. But we've  
19 done a survey of our members, and we've found that the  
20 proposed rule, as proposed, doesn't fit just over 30  
21 percent of the national brands and about 95 percent of the  
22 store brands or house brands. Some of the examples here  
23 I've shown up here are some of these specially shaped  
24 triangular bottles, the convenience sizes, the rolls, the

1 tubes, not shown here, and again bottles without cartons,  
2 and even the small cartons of the analgesics, for example,  
3 that are just slightly larger than the convenience sizes.  
4 These are some of the products that we're talking about  
5 being affected by the proposed rule.

6           The reasons for this are the realities of the  
7 marketplace. We have environmental concerns with fewer  
8 outer cartons. Those companies are responding to those  
9 environmental concerns and moving to that type of  
10 packaging.

11           There are also economic motives to provide  
12 price differentials. Think of the difference between the  
13 national brands and the store brands.

14           Legislated limitations on packaging, the  
15 California slack fill law that prevents deceptive packaging  
16 practices, and that would be the equivalent of taking a  
17 very small tens and putting it in a large box and making it  
18 look as if it contains more tablets. There are laws  
19 against that that limit how we change packaging.

20           There are consumer preferences for the smaller  
21 packages, the convenience sizes, the travel sizes.

22           And we have special packaging configurations in  
23 certain product categories.

24           These realities, balanced against the proposal

1 that creates a longer label -- in many instances, we're  
2 seeing about a 20 percent increase in the label length,  
3 just because of the outline form, plus the 6 point type  
4 size proposal, the 1 point leading, and some suboptimal  
5 consolidation of warnings that we'll get into a little bit  
6 later -- all lead to the reasons behind this type size  
7 dilemma.

8 I'd like to turn to the third portion here and  
9 questions to the committee. I'm going to touch on the  
10 first two areas very quickly, A and B, in two slides, and  
11 then we will go into a more detailed discussion of the type  
12 size considerations. Bill Bradley and Chris Moorman will  
13 join me for those.

14 You've been asked to look at four questions:  
15 type size, "ask a doctor," the overdose warning, and  
16 cation. We're going to be focusing on type size first.

17 But I'd like to point out to you that there are  
18 many other associated issues. On the left-hand side, are a  
19 number of issues that deal with formatting questions, from  
20 active verbs, to category exemptions, to the inner  
21 container. There's a proposal for the 6 point type on the  
22 inner container, and as a broad proposal, we are seeing  
23 that as largely unworkable as it relates to the inner  
24 container. But what we will be talking about is the outer

1 container today in terms of the survey results that I  
2 showed earlier and in terms of the actual stats or the  
3 label mockups that Chris Moorman will be showing. Product  
4 attribute information, repackaging.

5 Then there are a host of larger policy issues,  
6 economic, environmental impact, implementation time, slack  
7 fill laws, as I mentioned, small business impact.

8 So, you've been asked to focus on four selected  
9 areas, and in reality as we're looking at this, this really  
10 represents a very small piece of the pie here and many of  
11 these things are interrelated in whatever will be the final  
12 resolution of this.

13 So, now, let's turn to type size considerations  
14 in more detail. Our thought, in trying to put this  
15 presentation together, was that it was important to convey  
16 some of the reasons that we have for how the information  
17 ought to be constructed from the flow of information and  
18 then how you optimally consolidate because ultimately, if  
19 you can handle this, you can contribute to optimizing type  
20 size. So, I'll handle these one at a time, and then Bill  
21 Bradley will come up to talk about visual acuity and Chris  
22 Moorman about practical applications.

23 So, how to construct the flow of information.  
24 Two major points here on major headings and warning

1 subheadings. First, let's look at the major headings and a  
2 couple of comments.

3           This is what FDA has proposed: active  
4 ingredient, purpose, use, warnings, directions, other  
5 information, inactive ingredients, or other ingredients.  
6 And there are advantages to this. We support this. The  
7 uniform outline provides basically an index for the  
8 consumer. With time, the consumer gains familiarity, is  
9 educated about this, and has information that is easier to  
10 find. It makes sense.

11           Let's look more specifically at active  
12 ingredient and purpose first. We think that this  
13 information is important to be uniform, location, easily  
14 accessible, for easy identification and comparison of  
15 products when counseling occurs, as needed, with health  
16 professionals, for example, in a retail establishment with  
17 the pharmacy or over the telephone with a triage nurse --  
18 it's Nurse McDonald in our pediatric practice -- or in an  
19 overdose situation that might also occur over the telephone  
20 with the poison control centers.

21           It's also important during self-selection by  
22 the consumer. I think, Dr. Brass, this is where I was  
23 referencing one of the medical reasons behind this that a  
24 consumer might not necessarily, in looking at a label,

1 understand the subjective connect here. But it is  
2 important to avoid the use of two products at the same time  
3 with the active ingredient. We think over time with the  
4 placement of actives and purpose first, followed by uses,  
5 that an educational process will occur, and overall this  
6 will be value added for how the products are marketed and  
7 used by consumers.

8           Now, again, we're still in the flow of  
9 information under major headings and warnings before  
10 directions. Very simply stated, we think it's more  
11 important that an individual know when not to use the  
12 product -- do not use if you're taking an MAOI inhibitor --  
13 before they consider dosing directions.

14           Now, I'm moving from the major headings and  
15 their order to warning subheadings, and we're looking only  
16 at the warning section now. I'll talk about our objective  
17 and then the order of those subheadings.

18           We would like to create a medically rational  
19 flow of information in an easy to use format that chunks  
20 information, that word of art, with easy to understand  
21 subheadings.

22           What we have on the left-hand side here is the  
23 conceptual order of information and then the warning  
24 subheadings on the right side. You'll note on the top,

1 absolute contraindications, which would be do not use if  
2 you're taking an MAO inhibitor, for example; conditional  
3 contraindications for concurrent diseases that might  
4 require a physician diagnosis; or conditional  
5 contraindications where a health professional might consult  
6 on pregnancy/breast-feeding, drug-drug interactions, or the  
7 alcohol-drug interaction; and then in-use precautions to  
8 discuss emergent side effects when using this product, then  
9 discussing drowsiness or something like that associated  
10 with an antihistamine; or other in-use precautions as to  
11 when to stop use because of certain emergent conditions;  
12 and then finally, what we in the industry have called the  
13 poison control center or the overdose warning.

14           Now, moving from the flow of information --  
15 we've looked at the major headings and the warning  
16 subheadings in terms of how that flows together -- how do  
17 we optimally consolidate the text? What I'd like to do is  
18 to focus on the warnings here, and there is some difference  
19 in how this is constructed between FDA and NDMA's proposal.

20           On the left-hand side, just in brief form, as  
21 we look at that proposal, we see a nonuniform format.  
22 There is a paragraph text, followed by bulleted lists,  
23 followed by paragraph text. That does mix conditional  
24 contraindications before absolute contraindications in some

1 instances, and it also creates a bulleted list that  
2 actually precedes one of the subheadings. Dr. Brass, I  
3 don't mean to pick on you, but this is another one of the  
4 points that you brought up and we will address it.

5 In addition, "health professional" was deleted  
6 from some of the warnings.

7 On the other hand, we're suggesting six  
8 subheadings or seven, roughly in that area, a medically  
9 rational flow of information from absolute  
10 contraindications to in-use precautions within the  
11 warnings, and using a bulleted list always after the  
12 pertinent header, and maintaining the health professional  
13 as a relevant source of drug information. And this will  
14 help the formatting situation and consolidation, as you'll  
15 see.

16 So, this looks a little bit more complicated  
17 than it is. Just to focus on a couple of points on the  
18 slide, first if you look at the overhead projector, you'll  
19 see that in the top we have the specialty warnings, and  
20 then the subheadings with the bulleted lists, and then the  
21 pregnancy/nursing warning. We're only talking about the  
22 warnings here. What we're talking about is taking these  
23 specialty warnings and this paragraph information and  
24 moving it over into the health professional subheading as

1 well as, in some cases, "ask a doctor before use if you  
2 have."

3           Now, what I'd like to do is to just kind of  
4 increase the focus here and look just at the conditional  
5 subheading, "ask a doctor before use" as proposed by FDA  
6 here for the drug-drug interactions and the  
7 pregnancy/nursing warning. Again, we're suggesting "ask a  
8 health professional before use if you are pregnant or  
9 breast-feeding" -- that gives this a special bullet for  
10 that warning -- and then "taking sedatives or  
11 tranquilizers." It does not remove "doctor" from the  
12 label. "Doctor" would be there for "ask a doctor before  
13 use if you have diabetes, heart disease, thyroid disease"  
14 for a nasal decongestant as a partial list.

15           This use of health professional is consistent  
16 with longstanding FDA policy. It's unclear to us in the  
17 proposal why only "doctor" was proposed for warning  
18 subheadings. It is counter to the 25-year regulatory  
19 history of the OTC review where FDA has repeatedly  
20 addressed this particular issue and netted out that "health  
21 professional" should appear on the label. It's consistent  
22 with established policy. That's why we think it should be  
23 maintained, and in addition, it includes all the relevant  
24 sources of drug information, nurses, nurse practitioner,

1 pharmacist, dentists, and so on, conforms to today's  
2 practice of self-care. We use the telephone. We contact  
3 poison control centers. We contact the pediatrician's  
4 office and speak with the nurse and get drug information.  
5 And it gives the pregnancy warning more prominence.

6 Adding "or pharmacist" would exclude other key  
7 professionals as relevant sources of drug information, and  
8 if you say no, we can have "or pharmacist and others," then  
9 obviously the list would get too long and we'd say, where  
10 do you stop?

11 Now, this is your point, Dr. Brass. Keep  
12 bulleted lists after subheadings. Again, this is a partial  
13 list of the warnings subheadings. Here we have the in-use  
14 precautions when using the product. We would suggest that,  
15 yes, "stop using this product if" is important with the  
16 emergent signs, but then the readability experts that we  
17 have consulted with have said all the other subheadings  
18 start with a subheading followed by a list, and when you  
19 get down to this one, it's confusing because there's no  
20 list after it. So, we would suggest -- and we've come up  
21 at least at this time -- with "stop use and ask a doctor  
22 if." It's short, it's sweet, and it gets to the emergent  
23 signs and symptoms immediately.

24 So, by way of interim summary, consistent flow

1 of information contributes to potentially better  
2 comprehension, a consistent look to the warning label, a  
3 cleaner look to the label, space savings.

4 Consolidation of warnings maintains the non-  
5 physician health professional as relevant sources of drug  
6 information, and it also contributes to space savings, all  
7 with the idea of optimizing type size.

8 So, as I turn the podium over to Bill Bradley  
9 and to Chris Moorman, I would like to just ask you to keep  
10 in mind that type size alone is not the sole issue. There  
11 are a host of different factors that interplay. We think  
12 that the strategy ought to be to drive us to optimization  
13 but not perfection, as we look at how to best address some  
14 of these problems.

15 Bill Bradley?

16 MR. BRADLEY: One of the things that we need to  
17 do when we are addressing the type size dilemma, as Dr.  
18 Soller has described, is to remind ourselves of the basic  
19 things involved with visual acuity. What does visual  
20 acuity actually mean? How is this measured? And how does  
21 this relate to type size?

22 So, I'm going to give a brief review. You  
23 probably are all aware of this, but just to remind you some  
24 of the things, these are technical things, not debatable

1 but actually definitive about visual acuity.

2           The definition of visual acuity is the ability  
3 of the eye to resolve detail. That's very simple. This  
4 visual acuity is usually expressed -- and this gets a  
5 little more complicated -- as the reciprocal of the minimum  
6 separation of two lines just resolvable as separate, and  
7 this is expressed in minutes of an arc.

8           You can see this diagram at the bottom. This  
9 letter E subtends a certain arc as measured from the eye,  
10 and that arc would get greater as the E moves closer to the  
11 eye or as the E would get larger. So, this is sort of a  
12 visual of what it means in measuring visual acuity related  
13 to the subtended arc.

14           The ability to resolve two lines 1 minute of an  
15 arc apart would be called 1 to 1, or as commonly used  
16 20/20. The eye chart that you recall being tested with for  
17 distance vision is usually put at 20 feet away.

18           The letter E is often used because the E has  
19 each of its five elements at the right size subtending 1  
20 minute of an arc. You have the three legs of the E and the  
21 two spaces. If each one of those is 1 minute of an arc,  
22 the whole letter subtends 5 minutes of an arc, and that  
23 would be, if you could just make that out, a measure of  
24 20/20 vision.

1                   We've given you an eye chart which you might  
2                   want to refer to. This is for close-up vision and this  
3                   particular eye chart -- and you have it in actual size --  
4                   is designed to be used at a distance of 40 centimeters, or  
5                   about 16 inches. You'll notice that the printed lines for  
6                   different visual acuities are proportional. The 20/40 line  
7                   is twice the size of the 20/20 line. The 20/100 line is  
8                   five times the size of 20/20 and so forth.

9                   The 20/20 line, if you hold this 16 inches from  
10                  your eye, the letters on that line subtend 5 minutes of an  
11                  arc.

12                  You can measure the size of the letters, and  
13                  let me just give you a quick example of what you can do.  
14                  Here's the eye chart that you have. We've also provided a  
15                  measuring device. This is the measuring device. There are  
16                  several scales. There's a centimeter scale, an inch scale.  
17                  There's a pica scale. If you turn it over here, over on  
18                  the right-hand side, there's a point scale. One point, as  
19                  used in discussing type size is one seventy-second of an  
20                  inch, and that's what that right-hand scale is.

21                  If you wanted to measure something with this,  
22                  you can do it two ways if you're interested in points. One  
23                  is to use that scale. Perhaps an easier way to get an  
24                  approximate measure would be to put these heavy lines or

1 these variable width lines that are the designated number  
2 of points wide. If you take the 20/50 line, for example,  
3 and put these lines over, you'll see that the 4 point line  
4 just about obscures that 20/50 line on the eye chart. So,  
5 that means that line is approximately 4 points high when  
6 expressed as a type size.

7 Now, from the definition of visual acuity and  
8 the size of the letters on the eye chart, it can be seen  
9 that a person with 20/50 vision -- that is, the letters on  
10 20/50 vision are two and a half times the height of the one  
11 on 20/20 -- can resolve letters at a height of about 1 and  
12 a half millimeters, or the equivalent of about 4 and a  
13 quarter points.

14 Perhaps the best known study of visual acuity,  
15 because we're all interested, well, what visual acuity does  
16 the population have, is the Framingham eye study. This is  
17 part of the overall Framingham health studies that I'm sure  
18 you're all familiar with. This measured visual acuity best  
19 eye corrected in several age groups, starting with age 56  
20 and going up from there. In this group, overall 38.9  
21 percent had 20/20 vision or better. That should say "or  
22 better" not "better than." Age 65 to 74, on the other  
23 hand, only 3.8 percent had 20/20 vision or better.

24 Now, let's go up to 20/50 vision. The picture

1 changes. Overall 98.5 percent had 20/50 vision or better,  
2 and going to the age 65 to 74, 98.6 had 20/50 vision or  
3 better.

4 This table is a summary of the Framingham eye  
5 study results by age group and visual acuity.

6 The ability to read smaller type sizes has been  
7 confirmed by at least two authors. Smith found that 98  
8 percent of test subjects could read the equivalent of 4.5  
9 point type at a distance of 13 inches. And Holt found that  
10 the majority of the 25 OTC labels he studied required 20/50  
11 vision to read.

12 Now, let's talk a little bit about light. As  
13 we age, there is an increased need for illumination due to  
14 reduced pupil size and/or media opacities. You've all  
15 heard, or maybe you've done it, you've seen a child reading  
16 in what appears to be the dark and said, turn on more  
17 light. You can't read with that amount of light. In fact,  
18 the child can. It's just that the adult needs more light  
19 than the child.

20 Visual acuity in the elderly is often confused  
21 with the need for more light. For example, a 55-year-old  
22 needs twice as much light as a 20-year-old to read a given  
23 type size of print.

24 Inability to read a given print size may be the

1 need for more light.

2           Now, about type size. Type size alone, as Dr.  
3 Soller mentioned, cannot assure easy readability. This was  
4 quickly discovered by NDMA in our work which started in  
5 1990 on label readability which lead to our label  
6 readability guidelines. Some of the other factors: type  
7 style, contrast, language itself, layout and format, the  
8 sharpness of the printing, the line length, bulleting,  
9 chunking, headings, et cetera. These all work together to  
10 affect readability.

11           So, just to summarize this part of the  
12 presentation, the 6 point proposal seems arbitrary. The  
13 vast majority of the population can read less than 6 point  
14 type.

15           Now, let me just explain one thing about that.  
16 We learned a lot in our dealing with the State of  
17 California with improving readability of labels.

18           Small print initially puts one off, and you can  
19 look at something in small type and say, I can't read that  
20 and you don't try. But yet, if you try, you find that  
21 indeed you can.

22           Other consumer products permit less than 6  
23 point type, dietary supplements, for example, folic acid,  
24 iron, and so forth. And the definitions that we've

1 reviewed support this.

2 Now I'm going to turn this over to Chris  
3 Moorman who is going to discuss the practical applications  
4 of the proposed rule.

5 MS. MOORMAN: Thank you, Bill.

6 Now, this is where hopefully we'll get a lot  
7 more interesting and a lot more believable in terms of many  
8 of the things that we're going to talk about.

9 The rule, as you've heard over and over,  
10 published in February, and one of the first things that we  
11 did through the NDMA was to survey the membership to find  
12 out exactly what's going to work, where we're going to have  
13 problems, and how things will go forward. As such, what we  
14 found is that about 66 percent of the branded or national  
15 SKUs could fit this rule.

16 Now, what a SKU is, just for the record, that  
17 stands for shelf keeping unit. Shelf keeping unit is the  
18 size. There's a 20-count package of tablets. There's a  
19 40-count. It may come in a liquid, 4 ounces, 6 ounces, 8  
20 ounces, whatever the case may be. Each one of those is  
21 considered a shelf keeping unit. We account for all of  
22 that because each one of those packages will be impacted by  
23 this rule.

24 Secondly, we also have some survey results from

1 the store brands or house brands. Again, at this point in  
2 time, they felt that only about 5 percent of those products  
3 were going to fit the rule.

4 This obviously creates some problems. So, I  
5 will show you some of this information. I'll go on and  
6 talk about these solutions that Dr. Soller has mentioned.  
7 I'll tell you what the results are of trying a lot of these  
8 kinds of things and I'll come back and give you a couple of  
9 advantages that we see to this rule.

10 Now, just real quickly to reiterate what the  
11 rule specifically requires from a formatting and graphical  
12 presentation standpoint. 6 point type, Helvetica font, 1  
13 point of leading. Again, that is the spacing between  
14 lines. The 2 M spacing between bullets. That is, if you  
15 take the capital letter M, put two of them side by side, it  
16 creates a square. That is defined as this 2 M spacing that  
17 the rule asks for between bulleted information if you place  
18 that information on the same line.

19 Of course, the headers, subheaders. They want  
20 the headers bolded or highlighted in some fashion, a line  
21 between the sections, and then the specified order with the  
22 actives, purpose, et cetera.

23 Just to comment on the point around the dietary  
24 supplements before as was mentioned. If that information

1 were to be placed after the word "active" before the word  
2 "use," this could sort of create a little bit of a  
3 disconnect perhaps for the consumer because the word  
4 "purpose," while it may be more pharmacologically oriented,  
5 immediately precedes "uses" which hopefully will be in the  
6 simplest language for the consumer to then truly understand  
7 what the intent of the product is all about.

8           So, now, these are a couple of examples that  
9 will show how the rule does fit. This happens to be a  
10 product that comes in a bag, and it's 25 cough drops. At  
11 the top is the area that would be available to print the  
12 copy. The screen, of course, is not the best, and let me  
13 point out that even the copies that you have available in  
14 your books again is not necessarily the quality that you  
15 would see on the actual printed package, that it really is  
16 enhanced even further.

17           But in any case, the rule fits for this  
18 product. That's a bag product.

19           The next one we have is a carton product, and  
20 in this case what's kind of interesting to note is that the  
21 copy on the left panel here is all on one panel, but the  
22 bottom of the label in this case stops right here because  
23 the rest of this copy will overflow. It will overrun it.  
24 Following the rule of the 6 point, 1 point leading creates

1 a bit of a problem.

2 The other thing that the agency is asking for  
3 is that all of the copy be placed on one panel. Again, it  
4 may not necessarily be practical to do that. So, what the  
5 company did in this case is they utilized more than one  
6 panel. So, now they used the left panel, and particularly  
7 over here on the far right side, they've continued the  
8 copy. And the rule does fit. So, this is the way many  
9 products are already set up.

10 So, now let's go on with more one more examples  
11 where three panels are already being used to provide the  
12 required copy, but again it fits the rule. It starts on  
13 the left, continuation down this panel here, and then on  
14 the far right, again you wind up with the remaining amount  
15 of copy that's needed. In this case the inactives are what  
16 are on the right.

17 So, as you can see, that's just a quick  
18 sampling of where the rule does fit and that's how we got  
19 to that roughly 66 percent of the national brands would  
20 make it.

21 Now, here's where things get a little bit more  
22 interesting. As we've talked, we do have this type size  
23 dilemma and we're trying to find ways to make this work.  
24 Some of the things that we are suggesting as ways to help

1 to optimize the label overall are really three-fold.

2           The first thing is to take away the requirement  
3 in the rule, not necessarily that we wouldn't do these  
4 things, but again the requirement for the 2 M spacing  
5 between the bulleted information. The key is maintain  
6 adequate space so that the consumer can pick the  
7 information out and read it.

8           The second point is regarding the leading.  
9 Basically you might just say we want to get the lead out.  
10 But the real point is that we want to have appropriate  
11 spacing between the lines of copy such that it does not  
12 compromise readability. Specifically the descenders from  
13 the line above do not touch the ascenders from the line  
14 below. If that occurs, the copy will remain readable.

15           Then the last point on this first one is about  
16 sans serif type. Sans serif type is that type which has no  
17 extra curlicues on it. It is fairly simple, straight-  
18 looking kind of type. Again, the literacy experts also  
19 tell us that when you have smaller type, it is very good  
20 and really important to use sans serif type. There is  
21 nothing magical about Helvetica over some other types of  
22 sans serif type.

23           So, if those three points are taken into  
24 account first, then what we would try to do is to optimize

1 the point size based on the available label space that we  
2 have to use. Again, we definitely do not want to go below  
3 the 4.5 point type size.

4           Lastly, as Dr. Soller has also talked about, he  
5 referenced you to the readability guidelines that those  
6 principles always be maintained. There are about 17  
7 different points to what it really takes to graphically  
8 present copy in a readable format.

9           So, seeing is believing. I've created a slide  
10 using partial labeling information. It's a four-way  
11 cough/cold product. On the left you see us following the  
12 rule as it is written where we're using that 2 M spacing  
13 between bullets, the 1 point leading, 6 point in Helvetica.

14           Underneath that you notice it says 6 on 7.  
15 This is to let you know that as some of the examples you  
16 will see later, sometimes people refer to point  
17 size/leading in a relationship. They'll talk about 6 on 7,  
18 5 on 6, whatever the case is. The first number means point  
19 size. The second means leading. If there's a difference  
20 of 1 between the two numbers, that would indicate that  
21 you're using 1 point of leading.

22           Now, that same, exact copy is presented on the  
23 right, and with this we have taken the stepwise approach to  
24 minimizing some of the constraints that we feel are not

1 necessarily critical to maintaining readability. We have  
2 the actives, of course, the uses, and then you get into the  
3 warnings, and it probably becomes a little bit more obvious  
4 in the warnings how the copy fits together by using the  
5 consolidation of the warnings as well as taking away some  
6 of the other constraints around leading and bullets.

7           It shows that there is about a 20 percent  
8 savings in terms of the amount of space needed to provide  
9 that label copy, and that becomes pretty critical for some  
10 package configurations and formats.

11           Now, here are a couple of examples that the  
12 companies have tried to show just what this looks like. We  
13 have on the right in this case, the labeling laid out as  
14 would be required by the rule with the 6 on 7. If you take  
15 that copy and if you were to try to put it on the space on  
16 the carton itself, it would overflow, overrun that  
17 available space.

18           But if the company, as with what they've done  
19 -- they have taken the point size down just a little bit.  
20 Excuse me. They have taken leading down a little bit and  
21 kept the point size at 6 and the copy fits. I don't think  
22 that there is much compromise at all in the actual  
23 readability of the label on the package versus what's up  
24 here on the right because there is a lot of white space,

1 and in fact a lot of dead space that sort of could even  
2 detract to some extent from the readability.

3 Now, in this example, what we've got, I've got  
4 two things to show you here. First of all, with the  
5 Benadryl label, if you look at the top one, 5 point type  
6 size with 1 point leading is what we'd like to focus on  
7 first. The copy is laid out and it manages to fit in the  
8 space provided. It was okay, but it maintained that 1  
9 point leading.

10 Now, again, our idea is to optimize point size.  
11 We don't want to compromise on point size unnecessarily as  
12 long as we can still maintain good readability.

13 So, now if you put that second one up where  
14 we're using 5.2 type and now we have a half point leading.  
15 I think if you take a look at those side by side, you would  
16 probably tend to agree that perhaps that bottom one with  
17 the slightly larger point size is even a little bit better,  
18 but definitely no worse by far. So, the issue of leading  
19 is not a major issue in terms of readability, and that's  
20 the key I want you to understand here.

21 Now, we've got a number of other examples where  
22 we continue to try this, how well our suggestions to  
23 resolve the type size work with both consolidation of  
24 warnings, and not everyone has incorporated that. But more

1     importantly, we've looked at the factors around leading in  
2     particular.

3                     In this particular example, the first one of  
4     these is that the company said, okay, we took a look at the  
5     rule and the rule showed some examples of where the  
6     headers, the stop using this product, the directions, the  
7     actives, those pieces were in 8 point type and not always a  
8     good thing. It creates some space problems, is not  
9     necessarily needed. While they did 6 on 7 for the rest of  
10    the copy, the dotted line above the BFI is really the upper  
11    printable label space. So, a major problem.

12                    So, if we take a look at what they've done  
13    here, the only thing that they've done on this is they've  
14    taken the point size down a half, down to 5.5. They're  
15    using leading that is solid, or 5.5 on 5.5. So, no extra  
16    leading is used here. Again, the copy fits and I think  
17    again it maintains good readability which is critical.

18                    Now, in the case of this package, a carton,  
19    they need to use two panels to provide the copy. The  
20    active ingredients start in this panel here, which is fine.  
21    You get to the uses. You go through the warnings. Now,  
22    obviously, the copy doesn't fit the rest of it with the  
23    directions, and while inactives are not here in this case,  
24    they probably would fit if the company were to do it.

1 Again, these are mockups, so we're not necessarily using  
2 all of the rules 100 percent.

3 But in any case the copy is 5 and three-  
4 quarters with a quarter point of leading. Again, hopefully  
5 you're getting the picture that leading is not necessarily  
6 a make or break by any means for readability.

7 Here's an example again where we're using one  
8 panel to provide all the required copy. But as you can see  
9 on the left, it overruns the bottom of the carton, and in  
10 fact you can't really use that bottom flap of the carton  
11 either. So, you've got a pretty significant amount of copy  
12 overrun. With this it was a 6 on 7.

13 But if we go to the next one, we're using 6  
14 point on, I think, 6 point again. They've expanded it,  
15 though, to go across two panels. Now, again, that goes  
16 against one of the principles in the rule, but if the idea  
17 is to make this readable for the consumer, do you want  
18 giant packages with one long carton which isn't going to be  
19 feasible for a lot of other reasons, or is it logical to  
20 then consider moving from one panel to the next to continue  
21 reading the copy?

22 This is an example of a principle we haven't  
23 really addressed yet, and that is in the readability  
24 guidelines, it talks about not using less than 6 point type

1 for reverse copy. Now, the term "reverse" has a real  
2 technical meaning, but in practical terms what it means is  
3 that when you're printing light copy on a dark background,  
4 it may be white type or it could truly be a reverse. But  
5 in any case the quality in your book is much better than  
6 the screen here.

7 But the copy starts on the right because this  
8 is a triangular-shaped bottle, and so the two panels would  
9 be next to each other. The copy flows down through here.  
10 In this case the copy does not have to be split. The  
11 warnings are not split, which in some cases could be  
12 problematic, but the point is that we would not go below 6  
13 in order to provide good readability with this type of  
14 print.

15 The last example that I have is -- and this is  
16 not upside down. This is the three-pack roll of Roloids.  
17 With this I call your attention to the left first where  
18 they've provided all the copy that is actually required  
19 from the rule and then tried to fit it into the space over  
20 here on the carton itself.

21 Now, there is an area up here that you go,  
22 well, gee, there's blank space and there's this little half  
23 moon down here. This is a carton that has what's called a  
24 hang tag. So, it's on the shelf. It's hanging, and that

1 area needs to be maintained in order to present it  
2 appropriately on the store shelf, and so consequently,  
3 you're left with less space to provide the printed copy.  
4 So, therefore, they've actually used a double column  
5 format. They've got the actives and the purpose across  
6 from each other which the rule asks for.

7           And then we go to uses, warnings, and  
8 directions. Now, here while the warnings are on one panel,  
9 if you will, they've been split between the columns, again  
10 because there's no choice of how to provide that copy in  
11 one spot.

12           Now, what I'd like to comment on here is that  
13 we've got kind of a unique situation that we're up against.  
14 While we can find all kinds of ways to make this rule work  
15 and going from the monograph copy to the format in the rule  
16 is not necessarily the major problem. There are a few  
17 questionable areas. Sometimes you have to pick where  
18 should it go in terms of some of these headers, but the  
19 more interesting thing is that you've got products that  
20 come in many forms, et cetera. So, let me just pull out my  
21 toys here to try to make my point for you.

22           You take this Roloids copy and all of that copy  
23 has to be presented on a bottle. This is the package that  
24 sits on the store shelf. So, you've got the back panel

1 label, which is fine. That's a pretty good size. I'm sure  
2 this will fit even the 6 on 7 kind of an approach.

3 Well, now we offer the product in fewer  
4 tablets. It's still in a bottle. You've still got this  
5 wraparound label. I don't know whether the copy will  
6 literally fit with 6 on 7 following the principles of the  
7 rule. It may. That's fairly good size, but as I'm sure  
8 you can imagine, there are smaller packages at times.

9 Here's the format of the package that is up  
10 there, in essence. I didn't pull the hang tag out of the  
11 back, but the white space on the back would be the hang tag  
12 area. So, now, you've got a product that's offered in a  
13 carton like that, and then you've got these little rolls  
14 that you can pick up at the front counter or the checkout  
15 counter on your way out and they've got labeling on the  
16 back.

17 So, the dilemma on one hand that we're faced  
18 with is not only finding a way to make the copy readable,  
19 but finding a way to also fit it on various package  
20 configurations. That's why we're asking to look at some of  
21 the positives about some of the flexibility that we're  
22 trying to accommodate because we want this rule to work.  
23 As a couple of you have already commented, yes, the new  
24 format is a major improvement for the consumer. So, we're

1 looking for some balance of what's going to work for the  
2 consumer, what's going to work for us without increasing  
3 costs inappropriately.

4           So, I think we'll summarize with -- well, I  
5 pretty much talked about this a number of times, but I just  
6 put that in there again to reiterate our points about the  
7 suggested solutions to the type size.

8           But you take a look at what it has done for us  
9 and the advantages. Going back to survey 1, I told you 66  
10 percent of the national brands would work with the rule as  
11 it is proposed.

12           With this strategy that I've just shown you  
13 numerous examples, we're in the process of still collecting  
14 that data. So, I left it blank in hopes of having more  
15 information to provide you, but what I can tell you is at  
16 least based on Friday's results, we had heard from 17  
17 companies and at this point about 90 percent of the  
18 national brands would fit the rule with the strategy that  
19 we have discussed here. We do not have data yet on the  
20 store brands, so I can't even give you a perspective on  
21 that at this point.

22           So, in summary and in closing for my part, the  
23 two key points. One is that more SKUs could comply with  
24 the rule. As I said, 92 percent is what the number is now,

1 but that's not a final number by any means, and I would  
2 hope that it would go up but I can't guarantee it because  
3 there are a lot of package configurations that still have  
4 to try this.

5           Then secondly -- and you've heard a mention  
6 about the petition process -- this would minimize the  
7 number of petitions that companies would have to go through  
8 and place that burden on the agency to review and come to a  
9 position on. At this point we had an estimate from our  
10 first survey that at least over 12,000, 13,000 petitions  
11 would be filed to try to find a way to meet the rule even  
12 if it's by a petition. With this strategy, we're down to  
13 2,200 for the national brands, but by no means are we  
14 finished with this yet.

15           Just to make a further comment about this, we  
16 need more work yet, but if the agency holds to forcing us  
17 to maintain all the copy on one panel or they don't want  
18 the warnings separated and there are problems with that,  
19 that number of petitions, even with the strategy that we've  
20 talked about, unfortunately could increase and I don't  
21 think any of us wants that.

22           So, we're looking for ways to try to make this  
23 work.

24           Thank you very much.

1 DR. SOLLER: Thank you, Chris. Thank you,  
2 Bill.

3 In closing, I'd like to just touch on the  
4 overdose warning and cation labeling and then give a brief  
5 summary comment.

6 First, in terms of the poison control center  
7 warning or the overdose warning -- those terms have been  
8 used synonymously by industry -- poison control centers are  
9 important sources of drug information. It's unclear why  
10 FDA proposed to omit poison control centers except perhaps  
11 to create a shorter copy.

12 Our recommendation would be to try and keep  
13 poison control center in the overdose warning while  
14 shortening the warning, and we don't have specific language  
15 to show to you but it is something that we're working on.  
16 The point being, keep poison control centers in as relevant  
17 sources of drug information.

18 In terms of the cation labeling, we've provided  
19 previously to FDA detailed comments on the labeling of  
20 sodium, magnesium, potassium, and calcium. We don't have a  
21 final position in the context of the proposed labeling rule  
22 for format and content changes. However, we have a couple  
23 of general comments.

24 The first is if you were to look at a calcium

1     antacid table that I'm holding up here, you can see that  
2     there is both nutritional labeling as well as general  
3     labeling. I'm not sure but I think I heard earlier that  
4     there would be some consideration for those products that  
5     have dual labeling as an OTC and a dietary supplement.

6             Our particular view would be, in terms of the  
7     quantitative disclosure of how much calcium or whatever is  
8     there, that dietary information and nutritional facts  
9     should not be redundant on the label space, that if it's  
10    there as a dietary supplement, keep it within that  
11    particular section of the label.

12            Second, we do have valuable label space. The  
13    question is when and how. It's important to look at the  
14    category of products, and we're in the process of doing  
15    that. We start adding more warning subheadings because the  
16    danger over time is obviously once you get a very clean  
17    format, you start having a process of accretion and now you  
18    get a very complex label 5, 10 years down the line and we  
19    want to be very jealous about that kind of label expansion.

20            So, I would say that it's important to think in  
21    terms of whether that cation content might not more  
22    appropriately, for example, be within the warnings tied to  
23    that warning for a renal patient and magnesium. There's a  
24    warning there already. But if, as Dr. Weintraub had

1 mentioned earlier, it's important for those patients and  
2 the physician is telling them to look out for the products,  
3 then telling them to look out for that warning and having  
4 that information all together might be the best way to go.  
5 Again, we're looking at this. We don't have a final  
6 opinion, just some thoughts to put into your discussion.

7           This was touched on by Chris and maybe you can  
8 take it out of the sleeve. I added this in by way of a  
9 comment that, Kathleen, you had in terms of where you would  
10 put the dietary information, and it would not necessarily  
11 be in this label mockup because I pulled this from some of  
12 the extra slides that we had. But fitting it in after  
13 "purposes" before "uses" would clearly go counter to the  
14 rationale of why active ingredient and purpose and this  
15 whole use section is important for the ultimate education  
16 of the consumer.

17           So, my first reaction -- and again this is a  
18 work in progress, but from what I saw, my first reaction is  
19 that the placement for dietary information there would not  
20 be perhaps optimal.

21           Now, to summarize what we have been saying  
22 today, I'd like to touch on consumer factors, public health  
23 factors, and then some of the market realities.

24 Comprehensive label information for safe and effective use

1 is something that the consumer needs. It is something that  
2 we want. Consumer friendly labels. Consumers want it.  
3 FDA, industry also want that. It's important to keep in  
4 mind that the majority can read less than 6 point type, and  
5 again as we think about this, it's important to consider  
6 that consumers also want affordable medications with the  
7 appropriate price differentials.

8 From a public health standpoint, there are a  
9 number of government initiatives to enhance communication  
10 at all levels. NIH has programs and other agencies also  
11 have programs. In this particular instance, we're not  
12 dealing with a public health crisis associated with OTC  
13 readability. There's no lack of information for the  
14 consumer and there's an excellent OTC experience record.

15 From a reality standpoint in terms of the  
16 marketplace, the proposal, as Chris mentioned is not a fit  
17 for 30 percent of the brand and 95 percent of the store  
18 brands. We know from our early survey that we can bring  
19 the 30 percent figure for the national brands down into a  
20 much lower figure by using the strategy that we've worked  
21 up and that Chris articulated.

22 We also have slack fill laws. These are the  
23 deceptive packaging laws that I had mentioned earlier that  
24 prevent increasing package size as a simple solution to

1 this. It's not a simple solution.

2 Packaging changes mean substantially added  
3 cost, and if they deal with the inner container as well,  
4 then I can tell you the whole issue of stability testing in  
5 terms of the length of time to actually comply, as well as  
6 the cost, has not even been factored in.

7 Now, I would be the last I think to bring  
8 economic issues up to this particular committee, but you  
9 were given the proposal and there was an economic analysis  
10 in that proposal. I'll have a very brief comment here to  
11 let you know that that proposed economic analysis is  
12 faulty. In fact, the analysis that we have done is \$175  
13 million for a two-year implementation time. That can be  
14 reduced to about half of that with a three-year  
15 implementation time. That does not include scrap and it  
16 also does not include packaging changes because if there  
17 are substantial packaging changes, putting stability issues  
18 aside, then we're talking something in the neighborhood of  
19 \$400 million to \$500 million, about a half a billion  
20 dollars, for what we're talking about today.

21 You've also perhaps seen some of the  
22 technological advances. I think the Aleve label had an  
23 accordion label, and then there are some other labels that  
24 have an inner label with an over one that slides across it

1 and there's a little cut-out that you can read. These  
2 technological advances simply are not in a place where we  
3 can put them into widespread use, particularly on packages  
4 without secondary packaging or secondary cartons. We're  
5 not at a point where we can take the technological advances  
6 and then just put in expansive labeling information.

7           Finally, as I said earlier, timing is an issue.  
8 We need at least three years, given what we're talking  
9 about. If we're into packaging changes, we may be into a  
10 very different time frame.

11           So, by way of summary, remembering our mutual  
12 goal, we hope that you keep in mind that most national  
13 brand SKUs will be in greater than or equal to 6 point  
14 type. This is the other side of that 30 percent figure,  
15 the 70 percent figure.

16           Store brands. We're in the process of trying  
17 to get information and we are getting information from  
18 them.

19           Remembering also what Chris said about the  
20 petitions for exemption. Potentially they're in the  
21 thousands. Actually potentially they're in the tens of  
22 thousands, and that is not something that we want. It's  
23 not something that could be handled easily from a resource  
24 standpoint either within the industry or FDA.

1                   We need to be able to use less than 6 point  
2 type, down to 4.5 point type. We think there is a  
3 reasonable approach, a reasonable strategy to achieve this.

4                   We need similar treatment for OTCs as for other  
5 FDA and other regulated products such as the Nutritional  
6 Labeling Education Act requirements for dietary supplements  
7 that allow dietary supplements such as folic acid or iron  
8 or calcium to use down to 4.5 point type.

9                   The vast majority of consumers can read these  
10 smaller type sizes, as Bill Bradley pointed out.

11                   Ultimately when we get through all of these  
12 with these formatting changes, with the outline changes,  
13 the bulleted points, and so on, ultimately all the labels  
14 will be improved for better readability.

15                   So, in closing, we have this vision. We hope  
16 that you can embrace it too and that you do for continuous  
17 improvements to OTC label readability for the responsible  
18 use of OTCs, enhancing that responsible use in self-care  
19 settings, and that you share in the commitment and  
20 contribute to practical and workable solutions for the  
21 benefit of the consumer.

22                   We look forward to working with the agency and  
23 with the committee and other constituencies as we work  
24 through these particular issues.

1                   Thank you very much, Mr. Chairman, members of  
2 the committee.

3                   DR. D'AGOSTINO: Thank you very much for that  
4 fine presentation, Dr. Soller, Mr. Bradley and Ms. Moorman.

5                   Many of these issues will obviously be the  
6 items of our discussion this afternoon, but why don't we  
7 see if we can get 10 minutes or so of questions if there's  
8 something burning on these particular presentations. Eric?

9                   DR. BRASS: First, a clarification. The  
10 proposal is that only the warnings cannot be split amongst  
11 panels. Is that correct?

12                   DR. WEINTRAUB: I think so. I think that's  
13 true.

14                   DR. BRASS: And second, I'd be curious if  
15 somebody would like to comment on the database for the  
16 readability. In the information provided in the Federal  
17 Register preamble, it was suggested that only 48 percent of  
18 consumers could read a 4.5 point label. Yet, Dr. Bradley's  
19 data would have suggested that 98 percent have 20/50 vision  
20 and should be able to read 4.5 and Dr. Soller used the word  
21 "majority" to describe a target of readability. I'm having  
22 trouble reconciling those to give an estimate as to what  
23 percent of the population can or can't read a given level.

24                   DR. SOLLER: Let me make a comment on that, if

1 I can, Dr. Brass. My comment was purely compatible with  
2 Mr. Bradley's comments, so we can put that one aside, as  
3 you might imagine.

4 There was a label readability study that was  
5 done by the National Consumers League I think referenced in  
6 the Federal Register, and I thought I saw a bulleted point  
7 earlier this morning. That particular study was done at  
8 the time that we were coming out with our label readability  
9 guidelines and looked at some labels that had black on red  
10 and some other types of type style configurations.

11 What you're seeing from Chris Moorman in terms  
12 of how to optimize type style and looking at less than 6  
13 point type, for example, includes as part of our strategy  
14 the use of dark on a lighter background when you get below  
15 6 point type, for example.

16 DR. BERNSTEIN: For the proposal, we did an  
17 extensive review of the literature and what we found was  
18 there wasn't a lot out there. There were two other times  
19 when the agency had issued a Federal Register notice asking  
20 for data on that particular question, and again we didn't  
21 get very much. What you saw was in reply to one of the  
22 Federal Register notice, some of the studies that we  
23 received. So, there really isn't a lot out there. What Al  
24 Rothschild presented was just the little bit that we had.

1           In terms of the data that Bill Bradley  
2 presented, we haven't seen that. I think that's the first  
3 time we've seen that. I guess I have some questions as to  
4 what he was actually presenting in terms of the 95 percent  
5 can resolve the letters.

6           DR. D'AGOSTINO: Mary Anne, do you have a  
7 comment on that?

8           DR. KODA-KIMBLE: Well, I think it is true that  
9 4.5 is not 4.5 is not 4.5. It depends upon what the  
10 character is, how close the letters are to each other,  
11 formatting, contrast, all of those things. I think all of  
12 us have had the experience of reading the same type size  
13 and some of it looks blurry and some of it doesn't. So, I  
14 think this is really more than a point size issue.

15           Since it's on the top of my mind and since it  
16 was raised in this particular presentation, I do think it  
17 is important to somehow retain a phone number to a poison  
18 center. I even like that icon where there's a phone there  
19 because no matter what happens, this stuff is going to be  
20 small, it's going to be condensed, we are going to achieve  
21 some increased readability, but in an emergency, when  
22 somebody really needs to contact somebody, it would be nice  
23 to be able to find that piece of information quite quickly.  
24 I think in that particular instance, an icon and a phone

1 number would be useful.

2           The other issue is that in many of the  
3 presentations I have heard in other hearings, the FDA and  
4 the industry have used poison control center data as post-  
5 marketing surveillance, safety issues, that sort of thing.  
6 So, to the extent we can consolidate that kind of  
7 reporting, I think it would be useful to all of us in the  
8 future.

9           DR. D'AGOSTINO: Thank you.

10           On this side, Kathleen?

11           MS. HAMILTON: I want to second what Mary Anne  
12 said about a 4.5 isn't necessarily a 4.5 and to thank the  
13 presenters for demonstrating that there's some shape that  
14 can be given to smaller type face that still makes the  
15 information presented readable, more readable certainly  
16 than it is currently.

17           I just had a brief comment on the slack fill  
18 issue and would like to suggest that the extent to which  
19 information is at least as valuable as product, that the  
20 extent to which increased package size might be indicated  
21 at some point in order to provide the complement of  
22 information that consumers need, I'd like to suggest that  
23 that's a legitimate use of an increased package size and  
24 would be happy to work with the association to clarify a

1 definition of slack. It doesn't apply when we're talking  
2 about critically needed information.

3 DR. D'AGOSTINO: Thank you.

4 DR. SOLLER: Obviously an implementation time  
5 issue once you're working through those kinds of things.

6 DR. D'AGOSTINO: Other comments or questions?

7 (No response.)

8 DR. D'AGOSTINO: We are now going to turn to  
9 the Cosmetic, Toiletry, and Fragrance Association. Dr.  
10 Steve Gettings will begin the presentation.

11 Let me make one comment before that. This  
12 afternoon after lunch we're going to have the open public  
13 hearing. There are available outside at the desk, at the  
14 table, the agendas. I'd ask everyone who is going to make  
15 a presentation this afternoon to please get the agenda and  
16 note where you are because we'll follow that. I just want  
17 to make that comment now so I don't forget it before the  
18 lunch break.

19 Now, Dr. Gettings?

20 DR. GETTINGS: Good morning, Mr. Chairman,  
21 members of the advisory committee, and representatives of  
22 FDA. My name is Steve Gettings. I'm with the Cosmetic,  
23 Toiletry, and Fragrance Association.

24 CTFA is a national trade association

1 representing the cosmetic, toiletry, and fragrance industry  
2 in the United States. CTFA represents over 500 companies  
3 involved in the personal care products industry, and CTFA's  
4 active members manufacture and distribute the vast majority  
5 of personal care products marketed in the United States.

6 Why we are here today I hope will become clear  
7 as my presentation develops.

8 Later on I'll be introducing Dr. Jim Leyden.  
9 He's a practicing dermatologist and also a teacher and  
10 researcher at the University of Pennsylvania School of  
11 Medicine.

12 First of all, let me say up front that we share  
13 FDA's goals and that we appreciate that the proposal as  
14 written represents a considerable amount of effort on  
15 behalf of FDA, in particular Mike Weintraub, Debbie Bowen,  
16 and Ilisa Bernstein and the rest of FDA's staff. Without  
17 question, we support the efforts to ensure that our  
18 customers are able to select products which are best suited  
19 to their needs and to ensure that they're able to use those  
20 products safely.

21 We're not here to advocate any position today  
22 because clearly the proposal is a work in progress. We've  
23 heard that phrase bandied around a lot this morning, and  
24 that is evidenced by some of the comments made by FDA and

1 the fact that FDA itself is continuing to conduct further  
2 research on consumer label comprehension.

3 For our part, we're still trying to understand  
4 the ramifications of the current proposal, irrespective of  
5 how it might change given the results of FDA's new  
6 research, as it affects the broad range of product  
7 categories manufactured by our members. Our concern is  
8 that the products manufactured by our members continue to  
9 be readily available to consumers through a variety of  
10 different channels after implementation of FDA's proposal.

11 You've heard some specific issues raised by  
12 NDMA. What I'd like to do is outline some of the  
13 complexities which distinguish our products from other OTC  
14 drugs and why some of the implications of FDA's proposal  
15 may be different for our manufacturers than those  
16 represented by NDMA.

17 I'd like to start by defining three categories  
18 of product. First of all, an area you may not be as  
19 familiar with as some others I'll get into. Let me give  
20 you the definition of what a cosmetic is. It's an article  
21 or "articles intended to be rubbed, poured, sprinkled, or  
22 spayed on, introduced to, or otherwise applied to the human  
23 body or any part thereof for cleansing, beautifying,  
24 promoting attractiveness, or altering the appearance."

1                   Those later adjectives, "cleansing,"  
2    "beautifying," "promoting attractiveness," are not  
3    typically attributes you'd associate with an OTC drug  
4    product.

5                   I'll now turn to the definition of a drug.  
6    "Articles intended for use in the diagnosis, cure,  
7    mitigation, treatment, or prevention of disease in man or  
8    other animals; and articles, other than food, intended to  
9    affect the structure or any function of the body of man or  
10   other animals."

11                  I give you these definitions. It may be old  
12    hat to some of you, but I think it is important to just set  
13    the stage for some of those distinctions I want to make  
14    later on.

15                  We turn now to the third category which is the  
16    primary reason why I'm here today representing the  
17    manufacturers of cosmetic drugs. First of all, let me say  
18    this is not a new term. It's not something that I've just  
19    invented for the purpose of this presentation. It's a  
20    legal term of art.

21                  Essentially products which come within the  
22    cosmetic and drug definitions, as I've just outlined, are  
23    regulated and must be labeled as both cosmetics and drugs.

24                  For example, skin care products such as

1 moisturizers are examples of typical cosmetic products.  
2 Adding a sunscreen active and making an SPF protection  
3 claim, i.e., a drug claim, makes the product both a  
4 cosmetic and a drug.

5           Certain products that are often thought of as  
6 cosmetics, the converse of this argument, for example,  
7 antiperspirants and sunscreens, are in fact drugs. These  
8 products become cosmetics only if cosmetic claims are made  
9 for them, in this case a deodorant attribute or a  
10 moisturizing effect, for example, in the case of  
11 antiperspirants or sunscreens.

12           Just to emphasize the subtlety of these  
13 distinctions, in many countries, most notably in the  
14 European Union, some cosmetic drug products, for example,  
15 antiperspirants, products for the care of the teeth and  
16 mouth, sunscreens and traditional cosmetic products with  
17 sunscreens are considered only as cosmetics.

18           If we go to the next overhead, these are some  
19 examples of cosmetic drug products: antiperspirants,  
20 deodorants, antidandruff shampoos, antimicrobial soaps,  
21 traditional cosmetics with sunscreens such as skin  
22 care/treatment products, foundations, and lipsticks. This  
23 is not an exhaustive list. It serves mainly to illustrate  
24 what it is we're talking about. Both antiperspirants and

1 deodorants and antidandruff shampoos serve as examples of  
2 drug products which have become cosmetic drugs because of  
3 cosmetic claims, for deodorant effects in one instance,  
4 cleansing effects, i.e., shampoo, in another.

5 In the final category there, traditional  
6 cosmetics with sunscreens, cosmetics provide an aesthetic  
7 vehicle for drug delivery, and because these products are  
8 marketed with drug claims, they also become cosmetic drugs.

9 Just to emphasize what it is I'm talking about  
10 in the variety of products, let me show you a few slides  
11 which have examples of those products. Here we have some  
12 examples of some antiperspirant deodorants.

13 The next slide we have some examples of  
14 antidandruff shampoos.

15 I think already just with two slides, we begin  
16 to realize that these are the kinds of products that we see  
17 every day, we use every day in our bathrooms. We also see  
18 there's a variety of different kinds of product size,  
19 packaging, and also a different type of packaging geared  
20 toward the kind of outlet that these products are sold.

21 What we've seen so far is some products which  
22 you might expect to see either in your grocery store or in  
23 a drugstore. But also it's important to remember we have  
24 products like these. These are moisturizers with

1 sunscreens that will typically be found in a department  
2 store. So, again it emphasizes the fact of lots of  
3 different products, different product sizes for different  
4 retail outlets.

5           Finally, this final category again illustrates  
6 what it is I'm talking about. We have several different  
7 kinds of products. Here on the left we have a cosmetic  
8 product, a typical moisturizer that contains a sunscreen  
9 ingredient and makes a sun protection claim and makes it a  
10 cosmetic drug.

11           I think the next product is in the same  
12 category.

13           The green container in the middle contains a  
14 product which is essentially a sunscreen. It's a drug  
15 product but because it makes moisturizing claims, which is  
16 a cosmetic claim, is a cosmetic drug product, and so on.

17           If I could turn off the slides and go back to  
18 the overheads, let's now focus on the basis of FDA's  
19 concern. I think one of the earlier speakers today really  
20 described this very precisely. It's to help the consumer  
21 to select the right product to meet his or her needs, to  
22 ensure that customers use these products effectively and  
23 safely and will reduce the numbers of adverse drug  
24 experiences, a very key baseline to this whole proposal.

1           Clearly labeled products are essential to  
2 meeting these objectives. Clearly labeled products are  
3 something that all manufacturers of consumer products  
4 should be concerned about.

5           Before we look more closely at some  
6 ramifications of the FDA proposal. I thought it was worth  
7 examining the current labeling scheme for OTC drugs,  
8 cosmetics, and cosmetic drugs because the distinctions are  
9 important, particularly as it applies to cosmetic drugs  
10 where, remember, we have to take into account the  
11 requirements for both kinds of products.

12           OTC drugs. We have mandatory labeling of  
13 active ingredients. We have NDMA supported voluntary  
14 labeling of inactive ingredients. We also have mandatory  
15 warning requirements, and the example I'm using here is the  
16 ones that are governed by individual OTC monographs.

17           If we go to the next slide, we look at  
18 cosmetics. You may be surprised to learn, some of you at  
19 least, that we have mandatory ingredient labeling for  
20 cosmetics for inactive ingredients.

21           Then we have a significant benefit.  
22 Essentially listing all the inactive ingredients on the  
23 cosmetic product enables a consumer to be able to identify  
24 an ingredient or those ingredients which he or she may be

1 sensitized to.

2           Earlier on we heard from one of the members of  
3 the panel who expressed concern that not only is there  
4 important information with respect to ingredients on these  
5 products, but also there's other important consumer  
6 information that's not required by any government agency,  
7 and he used the example of 1-800 numbers. The examples I'm  
8 using there is information which is important to the  
9 consumer not only in terms of identifying which ingredients  
10 he or she needs to avoid, but also if he or she has a  
11 particular dermatological condition or type of skin, he or  
12 she may need to be able to identify those products which  
13 are, for example, non-comedogenic or PABA-free, oil-free.

14           This is important because even those consumers  
15 who are under the direction of a dermatologist,  
16 dermatologists give general advice. They don't give  
17 specific advice. So, it's important that a consumer be  
18 able to actually determine useful information from a  
19 product himself or herself.

20           In sum, the labels on cosmetic products contain  
21 a lot of essential information. Let me just emphasize a  
22 little bit exactly what I mean by that.

23           This label is a mockup of the label on this  
24 product. It's a Chanel moisturizing product. It has a

1 sunscreen in it and makes a sunscreen claim, so it's a  
2 cosmetic drug. As you see, it's a nice, very attractively  
3 packaged product that's available in department stores. On  
4 the back of this product, we have a list of inactive and  
5 active ingredients.

6           You may not realize just exactly how many  
7 inactive ingredients a typical cosmetic product contains.  
8 This product is a simple moisturizer. It contains over 60  
9 inactive ingredients. What that means is if we're trying  
10 to comply with the proposal as currently written, we can't  
11 get all the information, i.e., all the inactive  
12 ingredients, on one panel. You can see we're having  
13 difficulty getting all this information actually on one  
14 slide.

15           If we split this information and put it on more  
16 than one panel, we have some concerns that a consumer may  
17 try to identify a particular ingredient that he or she may  
18 be allergic to and just looks at one panel. If they do  
19 that, they could be missing some very important  
20 information, something which they are allergic to, because  
21 of the proposal as written.

22           If we go to the next overhead, this really  
23 summarizes the problems we have with cosmetic drugs because  
24 we have to comply with both drug requirements and cosmetic

1 requirements. In effect, we have mandatory ingredient  
2 labeling of active and inactive ingredients. One of the  
3 important distinctions I think between cosmetic drug  
4 products and other OTC drug products is the sheer number of  
5 inactive ingredients in cosmetic drug products. I don't  
6 think you're going to see that number of inactives in a  
7 typical OTC product.

8 We again have mandatory warning requirements,  
9 and again we have important consumer information that we  
10 have to convey.

11 To summarize then, attempting to place all  
12 these requirements for a cosmetic and an OTC drug on the  
13 same limited available space becomes a complex problem, one  
14 for which a one-size-fits-all approach which treats  
15 cosmetic drugs and other OTC drugs alike may not be either  
16 optimal or workable.

17 If I can go to the next overhead, in the  
18 foregoing overheads, I tried to outline how manufacturers  
19 of cosmetic drugs and other OTC products currently help  
20 consumers select the right product to meet their needs and  
21 to ensure the safe use of those products. In doing so,  
22 I've tried to identify some important distinguishing  
23 features, the main one being that with cosmetic drug  
24 products, we have to comply with both regulations.

1           I'd like now to focus on these most important  
2 fundamental distinction, and that is most cosmetic drug  
3 categories have no dosage limitation. Most cosmetic drug  
4 categories have no dosage limitation because these products  
5 have a particularly wide margin of safety.

6           Further, there are no common active ingredients  
7 between product categories. Again, that's a consideration  
8 in terms of being able to use more than one product  
9 simultaneously. You can get up in the morning. You can  
10 wash your hair with your antidandruff shampoo. You can use  
11 an anti-acne product. You can clean your teeth. You can  
12 wear an antiperspirant and you can wear a moisturizer with  
13 an SPF sunscreen in it. You can then go to the beach later  
14 in the day and use another sunscreen. The only time that  
15 you have any commonality of active ingredients are in the  
16 latter two categories, and that actually is a benefit. One  
17 of the problems with sunscreens is people don't wear enough  
18 sunscreens, a very important consideration.

19           What I'd like to do now is introduce Dr. Jim  
20 Leyden. Some of you know Jim. Dr. Leyden is an expert in  
21 the field of dermatology and, as I pointed out earlier,  
22 conducts research at the University of Pennsylvania,  
23 teaches at the University of Pennsylvania School of  
24 Medicine. He's also a practicing dermatologist, sees

1 patients every day who either use these products or to whom  
2 he recommends the use of these products. Jim.

3 DR. LEYDEN: Thank you, Steve.

4 When he says I'm a practicing dermatologist, he  
5 means I'm still trying to get better at what I'm doing,  
6 which I've been doing for 30 years.

7 First, let me begin by telling you why I'm  
8 here. I am a dermatologist at the University of  
9 Pennsylvania. I've had a long, long interest in the OTC  
10 drug process, starting with those halcyon days of the early  
11 1970s which was supposed to be a two-year review of the  
12 efficacy of OTC drugs. It ended up being I think 10 years.  
13 I spent many, many days with many, many panels, sometimes  
14 at their request, sometimes at industry's request as a  
15 consultant, and sometimes as a consultant for the agency.

16 I've opposed industry requests or proposals in  
17 the past as well as being in favor of them.

18 Approximately 10 days ago or so, the CTFA  
19 contacted me and made me aware of this proposal which, of  
20 course, I did not have a clue about its existence, and  
21 raised some of the issues that Dr. Gettings just raised. I  
22 was clearly concerned about some of the things that were in  
23 the proposal, particularly as they relate to acne products  
24 in general, and then the so-called cosmetic drug category

1     which you just heard some of.  So, I did volunteer to be  
2     here.

3                     If it's of any interest to you, nobody is  
4     paying me.  I'm not receiving an honorarium even though I  
5     obviously have served as a consultant to many companies and  
6     been involved in sponsored research over the years.

7                     I've read this proposal and I heard the  
8     presentation this morning, and I think there are many  
9     issues, particularly with respect to systemic drugs, that  
10    obviously seem worth fine tuning.  It seems to me this is  
11    an extremely complex set of issues.  I guess nobody is  
12    against better labels or labels that are more  
13    understandable.

14                    My concern, as I say, is mainly in the area of  
15    acne, at least from what I know so far, and then in the  
16    area of cosmetic drugs.  I have some copies of the  
17    presentation here this morning.  If any of you want to read  
18    more about acne, I just published a review of the treatment  
19    of acne in the New England Journal of Medicine at their  
20    request in the April issue, and some of the directions fly  
21    in the face of what I said in that article.  So, I'd just  
22    like to point that out.

23                    First of all, I think there's an overemphasis  
24    on the cleansing.  Underlining the word "cleansing" and

1 using the word "thoroughly" leaves individuals who read  
2 that to believe that that's helpful. It is not helpful.  
3 In fact, the evidence is overwhelming that that is  
4 counterproductive in many cases. It can actually make the  
5 disease worse. The major issue with topical drugs is local  
6 irritation, not systemic issues such as exists with oral  
7 drugs. So, emphasizing that, I would plead with you to  
8 please don't do that.

9 To eliminate the suggestion that adult acne is  
10 not really somewhat different than teenage I think is  
11 oversimplification, and many of the cosmetic drug products,  
12 are designed, formulated to be used by a different kind of  
13 person who often has a different kind of skin and can  
14 benefit from the cosmetic properties of the moisturizing  
15 properties of many of those. Younger teenagers with very  
16 oily skin and an actually a somewhat different disease  
17 benefit from a different type of vehicle.

18 To expunge the continued daily using to help  
19 prevent new lesions, new pimples, is a terrible mistake.  
20 It's the only way I can say it. During the process of the  
21 OTC efficacy review process, we all agreed -- there were  
22 several panels that got involved. The process was fairly  
23 long. All of us who have been involved in acne research  
24 and trying to lead to better treatments know that these

1 drugs work best to help prevent new lesions, and the best  
2 benefit that an OTC user of an acne product can get is from  
3 using it in a way to help prevent new lesions.

4           The other thing I would comment on is that in  
5 the warnings section, there is a suggestion that only one  
6 acne medicine should be used. Currently that flies in the  
7 face of what many, if not most, teenagers are doing. Many  
8 of them are using cleansing pads that have salicylic acid  
9 which affects one aspect of acne, the abnormal desquamation  
10 of follicular epithelium, and they're also using benzoyl  
11 peroxide which works by suppressing the overgrowth of the  
12 organism *P. acnes* which generates inflammation. And some  
13 of them are using astringents, some of which are regulated  
14 cosmetic drugs. So, there are many, many individuals  
15 already doing that.

16           In fact, one company is suggesting a program of  
17 gentle, underlining the word "gentle," cleansing and the  
18 use of salicylic acid once a day and benzoyl peroxide an  
19 additional time during the day. In their advertising, they  
20 indicate that this kind of approach is supported and  
21 endorsed by the American Academy of Dermatology because we  
22 feel that attacking multiple aspects of the disease  
23 simultaneously is better than treating one aspect only,  
24 that that's a much more rational and we think effective

1 approach.

2 So, those are some of my points on acne.

3 Then getting into the drug cosmetic category  
4 where I think again acne comes up, there are formulations  
5 often in small units for individuals who have occasional  
6 breaking out with their period, for example, or not a  
7 constant process like teenagers with more pronounced acne  
8 vulgaris. The formulations are designed to be compatible  
9 with using other things such as makeup, for example, in the  
10 morning. They really have benefit in many cases in terms  
11 of helping to neutralize some of the local irritation that  
12 can occur in more sensitive people.

13 But I think the most important area is those  
14 products with sunscreens. If there's one thing dermatology  
15 and dermatologists have been in favor of in the last 10, 12  
16 years it has been urging cosmetic companies to do what  
17 they've done. When they first started, they barely had any  
18 UV protection in them at all, and all of us encouraged them  
19 and eventually they did increase the level of protection.  
20 These products have gotten better with time. As has become  
21 apparent, full spectrum coverage is ideal not only for  
22 cancer protection but also for premature aging.

23 Industry has learned to take formerly  
24 objectionable materials such as titanium and zinc oxide and

1 make them available in formulations that can be used,  
2 elegant formulations that can be used with benefit. With  
3 the recent approval by the FDA of avobenzone, a material  
4 that extends coverage into long wavelength or so-called  
5 UVA-1, I'm sure that these products will start to have that  
6 ingredient, or at least I hope they will start to have that  
7 ingredient, in them and further enhance the protection  
8 against UV.

9           These kinds of products are used by people who  
10 often get significant exposure, sometimes without knowing  
11 they're going to get it. It's different than knowing  
12 you're going out to play golf or go to the beach. It's a  
13 lovely day. You decide to go out and sit outside at lunch.  
14 We hang a sign outside our lab at my hospital when people  
15 go out in the spring and it says, "Do you have your  
16 sunscreen on?" Because usually most of those people do  
17 not.

18           People walk for exercise. They don't  
19 necessarily think of it as sun exposure, but it can be  
20 significant sun exposure; likewise watching children play,  
21 et cetera.

22           I think lip balms with sunscreens, which the  
23 personal care product companies and cosmetic companies have  
24 introduced, have been a major, major health benefit.

1           I do see, particularly with that size unit and  
2 with many of the products -- I looked at a couple that my  
3 wife uses. They come in very small jars or small tubes  
4 sold by cosmetic companies because she prefers those  
5 formulations. Obviously, with the small units it's a big  
6 problem when you have 60 inactive ingredients, and we  
7 dermatologists think those ingredients should be listed, as  
8 I'll comment on in a second. Where are you going to put  
9 all that information?

10           Other potential issues that I think you should  
11 consider is there is other information that is currently  
12 highlighted which might be crowded out along with some of  
13 the other things like who to call or what 800 number to  
14 call if you want more information. Dermatologists give out  
15 advice to individuals who are acne prone to look for  
16 cosmetics, moisturizers with or without -- usually we  
17 advise with sunscreens in them unless a person works  
18 indoors all day and never sees the outdoors. If they're  
19 acne prone, we tell them to look for the words oil-free,  
20 non-comedogenic. If they have an allergy to sulfonamides,  
21 we tell them to look for PABA-free. If they're allergic --  
22 we've proven their allergic to fragrances -- we tell them  
23 to look for fragrance-free. So, that kind of information  
24 needs to be, in my opinion at least, very available on

1 these kinds of drug cosmetic products.

2           Then finally, with all this discussion about  
3 size, I'm a little bit concerned about what could happen in  
4 terms of those people who are truly allergic, when we  
5 identify someone who is allergic to one of the excipients  
6 in that long list that you saw, and we tell them to avoid  
7 certain preservatives or we tell them to avoid cetyl  
8 alcohol or ethylenediamine, for example. And they get a  
9 product and they see active ingredients and instructions  
10 and warnings, and then because of the size of the product,  
11 all the other ingredients are on some other panel which  
12 they may or may not look for because they may assume that  
13 they have read the ingredients on that other panel.

14           So, I think the potential for separating this  
15 long list, which people who are allergic are perfectly  
16 prepared to read no matter how small the print is -- they  
17 know what they're to avoid, and they spend a lot of time  
18 scrutinizing very, very carefully what's in their cosmetics  
19 when they are attracted to a new product category.

20           So, in sum, those are some of the issues that I  
21 thought were important to at least publicly say somewhere.  
22 I think this whole issue seems to me to be very, very  
23 complex, and I hope when you're considering this and giving  
24 advice to the FDA, you'll remember this category of topical

1 drugs and topical cosmetic drugs and some of these issues.

2 Thank you.

3 DR. GETTINGS: Thanks, Jim, for coming in and  
4 offering your perspective.

5 Although there are differences between  
6 different cosmetic drug categories and we want to explore  
7 those differences between now and October in terms of what  
8 the terms of this proposal will mean in terms of attempting  
9 to comply with the proposal for different categories, there  
10 are certain factors which are common to most, if not all,  
11 cosmetic drug products.

12 The first one I want to point out is  
13 preventative care. Many of these products, sunscreens  
14 being the most obvious example, have a preventative  
15 function, in this case the prevention of sunburn and skin  
16 cancer. You may feel that we're focusing to a large extent  
17 on sunscreens in this presentation, and to a certain extent  
18 that's true but only because sunscreens illustrate most, if  
19 not all, the factors which distinguish cosmetic drugs from  
20 other OTC products.

21 It's important to remember that selection of  
22 these products and compliance, i.e., the fact that  
23 consumers use them, is driven to a large extent by the  
24 cosmetic attributes, the aesthetics of the products, not

1 necessarily just the fact that they contain a drug active.  
2 This is particularly true for cosmetic products containing  
3 sunscreens, but equally true for anti-acne products,  
4 antidandruff shampoos, and antimicrobial soaps, to name but  
5 a few others.

6           Secondly, as I think I alluded to earlier,  
7 cosmetic drug products like cosmetics are sold in a diverse  
8 variety of retail environments: direct sales -- I'm  
9 talking about the Avon representative -- in drugstores,  
10 grocery stores, departmental stores -- I showed you the  
11 product earlier. We're talking Macy's and Nordstrom's and  
12 Bloomingdale's. It's not a commercial by the way.

13           If you want to continue to keep these products  
14 as widely available as they are now, manufacturers need  
15 flexibility to be able to package and label these products  
16 in order to meet the particular demands of those various  
17 retail environments.

18           Thirdly, problems with compliance. We heard  
19 earlier from Chris about problems with compliance just in  
20 terms of getting the information on the packages. As we  
21 heard from her, it's not just an issue of package size.  
22 It's also an issue of package shape. All these factors  
23 combine to give us an available label space in which we  
24 have to try and fit all the information we want to convey.

1           I think the problems with compliance are  
2 exemplified by cosmetic drugs because, as we saw from the  
3 slides, we do have a variety of different product sizes,  
4 many of which are convenient to the consumer. If we're  
5 removing those convenient products, obviously that's a  
6 detriment to the consumer.

7           Finally, let me finish by identifying some  
8 potential down sides of FDA's proposal. We'd all like to  
9 see improved labeling that consumers can fully understand,  
10 but sometimes the best intentions can have unintended  
11 consequences.

12           From talking to some of our manufacturers,  
13 we're concerned that because of the difficulties and  
14 expense of complying with the proposal, there's the  
15 potential to limit the variety and availability of existing  
16 products, as we've heard, with proven health benefit.

17           There's also a disincentive to develop new  
18 products.

19           Again, we share the same concerns about  
20 improving the safety and efficacy of OTC drugs, including  
21 cosmetic drugs, but we need to acknowledge that any  
22 improvements could come with attendant costs.

23           One potential problem that we have identified  
24 is that because companies, in order to be as competitive as

1 possible, have developed uniform packaging to be able to  
2 sell products overseas, limiting the flexibility in the way  
3 manufacturers provide essential information on product  
4 labels can only lead to duplication of packaging for  
5 overseas markets. This is going to lead to increased  
6 production costs, inevitably increased cost to the  
7 consumer, and that can obviously have a detrimental effect  
8 on people buying important products.

9           Thirdly, I think someone again on the advisory  
10 committee talked about the effect on the environment.  
11 Because of the small package size of many cosmetic drugs,  
12 in order to comply with the proposal as written,  
13 manufacturers, in the absence of any kind of regulatory  
14 small package exemption, are going to have to either  
15 increase package size or perhaps more likely with some  
16 products move to the increase of secondary packaging. This  
17 is obviously going to have a negative impact on the  
18 environment. There's going to be an increased impact on  
19 landfill size. This will undo a lot of work done by the  
20 cosmetic industry in particular to reduce the amount of  
21 packaging on our products.

22           Finally then to summarize, we do support FDA's  
23 goals for improved labeling. There are obviously some  
24 issues that need to be addressed, and we hope to work with

1 NDMA and FDA to address them. We've heard earlier about  
2 some of them, type size in particular, but other technical  
3 improvements.

4 We want to enable customers to be able to  
5 select and use our products effectively and safely, but we  
6 must be able to maintain flexibility in labeling in order  
7 that we can bring the wide variety of these products  
8 through a variety of different channels. Many of the  
9 package sizes sold in a variety of different retail outlets  
10 are small. As a result, a small package exemption is going  
11 to be essential for cosmetic drug products.

12 Finally, I hope I might actually convey some of  
13 the idea of the numbers and variety of cosmetic drugs in  
14 the marketplace.

15 As I said at the beginning, this is a work in  
16 progress. We're still learning which products are affected  
17 and to what extent. It may be that some cosmetic drug  
18 products are able to incorporate FDA's proposal in their  
19 labeling. For others compliance is clearly going to be a  
20 problem, to say the least.

21 One thing that may be worth considering is  
22 making the new label format -- and I'm talking about format  
23 -- voluntary for cosmetic drugs.

24 In conclusion, we look forward to submitting

1 comments in October, at which time we hope the results of  
2 FDA's consumer perception studies are available and by  
3 which time we will have resolved some of the issues which  
4 affect our products.

5 In the interim, we look forward to working with  
6 FDA and addressing some of the specific issues of how our  
7 manufacturers can best meet the concerns that FDA has.

8 Thank you for your attention. I'd be happy to  
9 answer any questions.

10 DR. D'AGOSTINO: Thank you, Dr. Gettings, and  
11 thank also Dr. Leyden for his presentation.

12 Are there any questions from the advisory  
13 committee members? Cage?

14 DR. JOHNSON: Thank you.

15 With respect to the comment about foreign  
16 marketing, could you expand a little bit? Do you use the  
17 same package when you market in foreign countries, and what  
18 are the requirements for foreign companies marketing here  
19 in the United States with respect to labeling?

20 DR. GETTINGS: Manufacturers are moving towards  
21 trying to develop a so-called global package. What that  
22 means is they can sell the same product with the same  
23 packaging both in the U.S. and overseas.

24 Because there are different requirements for

1 these kinds of cosmetic drug products -- and I think early  
2 on in my presentation I pointed out that in the European  
3 Union, many of these products are treated as cosmetics. In  
4 Canada, on the other side of the coin, many of these  
5 products are treated as drugs. Each country is going to  
6 have its specific requirements for labeling whether it be  
7 for cosmetics or drugs.

8 My point is in order to be able to maintain  
9 competitiveness and to be able to develop that global  
10 label, manufacturers need to have flexibility to be able to  
11 meet the requirements of the overseas markets and the U.S.  
12 market. If those requirements are too stringent in the  
13 U.S. and there's no room, for instance, to be able to put  
14 dual labeling for Canadian markets, then obviously that's  
15 going to have a negative impact on competitiveness. As I  
16 pointed out, it's going to be increased costs, which  
17 inevitably are going to be passed on to the consumer. It  
18 has a negative impact on the use of these products.

19 DR. D'AGOSTINO: Other comments or questions?

20 (No response.)

21 DR. D'AGOSTINO: If I understand the morning,  
22 we have before us proposals for comprehensive standardized  
23 labeling for the safe and effective use.

24 We heard about readability and

1 understandability.

2           The types of comments that I think that the  
3 advisory committee will be thinking about is that we heard  
4 comments from the NDMA that the type size and leading have  
5 created problems and 30 percent of the brands won't be able  
6 to accommodate it, 95 percent of the house brands won't be  
7 able to accommodate the requirements. If one gives a bit  
8 on the type size, the leading, and the use of multiple  
9 panels, it increases dramatically, at least for the  
10 national brands.

11           We also had discussions about the "ask the  
12 doctor" and how that fits in with the health professionals,  
13 "before use," the placement of the warnings.

14           It appears that the poison control center has  
15 been raised a couple of times, that we probably should  
16 suggest putting it back in or should be suggested.

17           Certainly things like the 800 number and the  
18 literacy have been questions that have come up that I don't  
19 think we feel comfortable with, at least again the way the  
20 panel is raising questions.

21           Then lastly we heard, overlapping with the  
22 NDMA's considerations, concerns with the cosmetics that the  
23 listing of the inactive ingredients, the doses, the size of  
24 the containers, the economic aspects could have a major

1 effect if the new regulations or the new suggestions are  
2 turned into regulations.

3 This gives us an awful lot to think about later  
4 on this afternoon. We do certainly have our questions  
5 brought out I think in good focus and some other issues,  
6 and we'll find out later on how much of those other issues  
7 we need to discuss.

8 Right now I think it's time for a break.  
9 Debra, I'm sorry.

10 DR. BOWEN: Yes. I need to have a  
11 clarification from NDMA about the brands versus the SKUs  
12 because the discussion earlier was whether or not a certain  
13 percentage of the brands are affected or if it's the shelf  
14 keeping units that we're talking about here. Could you  
15 clarify that for the committee as well?

16 DR. SOLLER: I'm Bill Soller with NDMA, and  
17 what I think you're referring to is some of the shorthand  
18 we used in our slides where we said brands and store  
19 brands. We're talking SKUs. So, that's numbers of  
20 products.

21 DR. BOWEN: Yes. So, I think what went into  
22 the record was brands, and I think it's the numbers of  
23 shelf keeping units.

24 DR. D'AGOSTINO: Exactly. I believe so. I

1 took it as brands.

2 Any other comments?

3 (No response.)

4 DR. D'AGOSTINO: It's about 5 after now.

5 Please let me ask the people who are going to ask  
6 presentations this afternoon to sit to the front and be  
7 prepared to get up when you are on the list. We will  
8 follow that list.

9 Why don't we take our lunch break until 1:15,  
10 as scheduled.

11 (Whereupon, at 12:07 p.m., the committee was  
12 recessed, to reconvene at 1:15 p.m., this same day.)

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AFTERNOON SESSION

(1:15 p.m.)

DR. D'AGOSTINO: It's just about 1:15 and I think we want to get organized so we can move on.

We have 11 groups and individuals who have identified themselves and would like to make presentations during the open public hearing session.

I'm going to follow the agenda. For those of you who have not picked it up yet, on page 3 of the agenda that you could get outside, third page, it's a list of the speakers for the open public hearing, and we will follow that list.

I will also ask individual speakers to stay within the time that has been allocated. For making your presentation or your statement, you're welcome to use either the podium behind me or any of the mikes that are on

1 the floor, whichever you find more convenient. If you do  
2 have materials to pass out, please as you begin, pass them  
3 out quickly.

4 Because sometimes people do change the  
5 individual speakers, before you present your material, I  
6 would like you to state your name, your affiliation and who  
7 you are representing at this particular meeting.

8 The first one will be Janet Engle from the  
9 American Pharmaceutical Association. Just let me read the  
10 list of different groups. The American Association for  
11 Poison Control Centers will be next, the Keenan Group Low  
12 Literacy Specialists next, the National Consumers League,  
13 the American Optometric Association, the National Community  
14 Pharmacists Association, the American Academy of Nurse  
15 Practitioners, the WCE Clinical Evaluations, the American  
16 Association of Retired Persons, the American Dental  
17 Association, and the American Academy of Pediatrics.  
18 Hopefully you are all here and let's begin now with Dr.  
19 Janet Engle from the American Pharmaceutical Association.

20 DR. ENGLE: Good afternoon. Thank you for  
21 affording me the opportunity to speak to the  
22 Nonprescription Drug Advisory Panel today. My name is  
23 Janet Engle and I am a pharmacist. I serve as the  
24 Associate Dean for Academic Affairs and Clinical Associate

1 Professor of Pharmacy Practice at the University of  
2 Illinois at Chicago.

3 In addition, I serve on the Board of Trustees  
4 of the American Pharmaceutical Association, the national  
5 professional society of pharmacists.

6 I am speaking on behalf of the APHA which did  
7 pay for my travel expenses to participate here today. I do  
8 not hold any financial interests in any manufacturer of  
9 nonprescription drugs.

10 What I'd like to do is outline my points  
11 briefly and then I'll be happy to respond to any questions  
12 or comments from members of the advisory panel.

13 The first thing I'd like to do is share some  
14 data with you. I'd like to briefly summarize a few key  
15 points from a study that will appear in the  
16 September/October issue of the Journal of the American  
17 Pharmaceutical Association. This study by Dr. Sujit  
18 Sansgiry and others evaluated 100 nationally available  
19 analgesic and cough/cold medications for the congruence of  
20 their labeling with NDMA voluntary guidelines. I'd like to  
21 share some of their results.

22 They found that 22 percent of the product  
23 packaging used used less than 6 point type. 6 point type  
24 requires 20/40 visual acuity according to a Canadian study.

1 NDMA has recommended 6 point type, with exceptions  
2 permitted, for smaller packages.

3 Another finding. As package size increased,  
4 the font size used for the product name also increased.  
5 However, the font size for warnings remained constant.  
6 I'll make some observations here. Given that manufacturers  
7 are already varying font size with container size, it  
8 certainly seems feasible and helpful to take very seriously  
9 the proposal described in the Federal Register to add more  
10 information or increase the font size of warnings as the  
11 container increases in size.

12 Another finding of the study regarding  
13 warnings. 63 percent of the labels used no bold print even  
14 though NDMA recommends the use of bold print.

15 30 percent of the labels used all capital  
16 lettering for about half of the text of warnings. Again,  
17 NDMA recommends the use against all capital letters.

18 Finally, 49 percent used hyphens although the  
19 NDMA recommendations are not congruent with that.

20 So, I just thought I'd share some of that data  
21 from the study that is about to be published.

22 It's extremely important that consumers have  
23 access to consistent, comprehensive, and comprehensible  
24 information on OTC drug products that they're either using

1 or evaluating for potential purchase and use. However, it  
2 is not feasible for the label of the OTC drug products  
3 alone to carry the burden of supplying all this  
4 information. Only the most important information regarding  
5 the product and other sources of information can appear on  
6 an OTC container not only to preserve legibility but to  
7 encourage the consumer to read the label.

8 APHA agrees that OTC product labeling should  
9 advise the consumer to speak with a health professional  
10 before purchasing or using a nonprescription drug. I  
11 believe it's safe to predict that this advisory committee  
12 and the FDA itself will be asked by organizations  
13 representing most, if not all, health professionals to  
14 recognize their contribution to patient education on the  
15 proper use of nonprescription drugs.

16 We believe that doctors, nurses, and  
17 pharmacists are all health professionals who often possess  
18 valuable information and insights into the comparative  
19 risks and benefits of these products. APHA will propose  
20 two suggestions or guidelines for making the decision as to  
21 which health professionals the label might most usefully  
22 direct the consumer to consult.

23 The first guideline is that the labeling should  
24 direct the consumer to health professionals who have the

1 requisite information and training. Most pharmacists,  
2 physicians, and nurses can be expected to provide useful  
3 advice to many consumers regarding directions for use,  
4 ingredients, and warnings.

5           However, because of the widely varying amounts  
6 of formal education on pharmacotherapy provided to these  
7 different health professionals, it may be expected, for  
8 example, that doctors will be more knowledgeable about drug  
9 disease contraindications and pharmacists will be more  
10 knowledgeable about drug side effects, interactions, and  
11 active ingredients in general.

12           However, if the labeling were simply to suggest  
13 that the consumer consult with a health professional, we  
14 would expect that consumers will consult with a very wide  
15 array of individuals, many of which will have received  
16 little or no formal preparation in pharmacotherapy. Let me  
17 give you an example of one of my concerns.

18           With the plethora of health food stores and  
19 nature centers and those types of institutions, what we see  
20 is clerks in these facilities wearing white coats who look  
21 to me at least like a health care professional. My concern  
22 is consumers may or may not be able to differentiate  
23 between those folks and a true professional that has had  
24 formal preparation in pharmacotherapy. So, our opinion at

1 APHA is specificity on the OTC product label is needed to  
2 identify the professionals which are most likely to be  
3 capable of providing useful advice.

4 Our second guideline. We suggest that labeling  
5 should direct the consumer to the health professional which  
6 is most likely to be accessible when and where a decision  
7 regarding an OTC purchase or use is going to be made.  
8 Currently out of some \$29 billion in sales of OTC drug  
9 products in the U.S., about \$20 billion of that is sold in  
10 retail pharmacies. Much of the reason for this is that no  
11 one needs to get past a pesky managed care gatekeeper to  
12 walk into a pharmacy. Even before managed care became an  
13 important impediment to seeing one's physician, no one  
14 needed an appointment to visit and make a purchase at a  
15 retail pharmacy. Walk-in convenience, long hours of  
16 operation, and location in high traffic areas of urban,  
17 rural, and suburban communities simply are historical  
18 advantages of the pharmacy when it comes to making a  
19 contact with our consumers. These facts strongly suggest  
20 that the pharmacist is the most likely health professional  
21 to be physically available when the consumer is thinking  
22 about or actually making an OTC drug purchase.

23 Taking into consideration these two guidelines,  
24 APHA would recommend including the doctor, nurse, and

1 pharmacist on the label as a possible source of OTC drug  
2 information. Consumers would be better served by more  
3 consultation with any of these professionals. However, we  
4 recognize that the need for parsimony and comprehensibility  
5 in labeling may become paramount in your deliberations.  
6 Under those constraints, APHA believes that the in-depth  
7 education of the pharmacist and pharmacotherapy, as well as  
8 the tremendous advantage inherent in having the pharmacist  
9 located precisely where and when most OTC drug purchasing  
10 decisions are made argues in favor of including the  
11 pharmacist as a primary source of OTC information.

12           Switching gears just a little bit, I'd like to  
13 make a quick comment on what's listed as question number 2  
14 on your agenda. APHA does strongly recommend that poison  
15 control centers be retained in the OTC labeling.

16           Finally, I'd like to conclude with an anecdote  
17 to illustrate the dilemma of many patients who are often  
18 confused when confronted with the plethora of OTC products  
19 available to treat certain ailments. I've had many  
20 patients consult me when the results they expected from a  
21 particular OTC product did not occur. Let me give you an  
22 example.

23           An elderly patient came into my pharmacy  
24 complaining of insomnia and asked me for a recommendation

1 for an OTC sleep aid. Upon questioning the patient, I  
2 noted that he had started to take a new brand of analgesic  
3 at bedtime for his arthritis. The product contained  
4 caffeine which was the most likely cause of his insomnia.  
5 Rather than recommending an OTC sleep aid, I recommended a  
6 plain analgesic that did not contain caffeine. The result:  
7 his insomnia resolved, his arthritis pain was controlled.

8 Had this patient not consulted me, he would  
9 have been taking an unnecessary OTC product to treat his  
10 insomnia. Had this patient consulted a physician, the  
11 physician may have not done a medication history or maybe  
12 would not have been aware that this particular OTC  
13 analgesic contained caffeine if only because the patient  
14 probably would not have had the product with him at the  
15 doctor's office or would have referred to it by its product  
16 line brand name.

17 I appreciate your consideration of my comments.  
18 We can provide these comments later and the studies that I  
19 referenced.

20 DR. D'AGOSTINO: Thank you very much.

21 In the sake of time, we're going to move to the  
22 next speaker, the American Association of Poison Control  
23 Centers.

24 MS. SOLOWAY: Good afternoon. I'm Rose Ann

1 Soloway, and I'm Administrator of the American Association  
2 of Poison Control Centers. My professional background is  
3 as a registered nurse. I'm a board certified clinical  
4 toxicologist. I am also clinical toxicologist at the  
5 National Capital Poison Center, but I am here today  
6 speaking on behalf of the American Association of Poison  
7 Control Centers.

8           The AAPCC is the professional organization in  
9 the United States for poison centers and for those  
10 interested in poison prevention and treatment. Activities  
11 include certification of regional poison centers,  
12 certification of health care professionals as specialists  
13 in poison information, cosponsorship of the only national  
14 scientific meeting devoted to clinical toxicology and  
15 operation and publication of the only national data  
16 collection system for poison exposures in the United  
17 States. This data collection system, by the way, was  
18 developed cooperatively with FDA in 1983 when FDA became no  
19 longer able to conduct poisoning surveillance activities.

20           Poison centers do serve the entire United  
21 States population 24 hours a day, 7 days a week. We  
22 provide immediate treatment advice to nonmedical callers,  
23 as well as health care professional callers, telephone  
24 follow-up, education for health care providers in the

1 recognition and treatment of poison emergencies, and  
2 especially related to the issue under discussion today,  
3 community education in poison prevention and immediate  
4 actions to take in case of a poisoning.

5           This action includes immediately calling a  
6 poison center. Extensive community outreach includes using  
7 many means to be sure that the emergency telephone number  
8 of the poison center is immediately available to potential  
9 users. This is done by distributing materials through  
10 physicians' offices, schools, work places, community  
11 organizations, but whether or not one has access to a  
12 source like that, the emergency telephone number of poison  
13 centers is inside the front cover of telephone books, along  
14 with other emergency telephone numbers.

15           In 1996, poison centers in the United States  
16 answered more than 2 million poison emergency calls. 87  
17 percent of those calls were from nonmedical professionals,  
18 and 74 percent of them were managed entirely over the  
19 telephone.

20           We wish to address the proposed change in  
21 labeling from the current "in case of accidental overdose,  
22 seek professional assistance or contact a poison control  
23 center immediately" to the proposed label wording which  
24 says, "in case of overdose, get medical help right away."

1 This is a phrase that can be interpreted in a number of  
2 ways. "Get medical help right away" might mean go to the  
3 emergency department. It might mean call your doctor. It  
4 might mean ask your neighbor who's an EMT.

5 But without a doubt, this proposed change in  
6 wording will deflect or delay calls to poison centers. In  
7 effect, this will change the standard of care for poisoned  
8 patients in the United States. It will increase costs for  
9 health care in the United States and it will also affect  
10 the ability of FDA to monitor public health and of industry  
11 to monitor the safety of over-the-counter drug products.

12 A summary of reasons why patient care will be  
13 negatively affected. Poison centers provide regional  
14 centers of expertise in the management of poisoned  
15 patients. Direction for poison centers is provided by  
16 board certified medical and clinical toxicologists. The  
17 front line personnel are physicians, nurses, and  
18 pharmacists who are specially trained and certified. In  
19 fact, when the certification examination was first  
20 developed and validated, specialists in poison information  
21 scored higher than practicing emergency department  
22 physicians. The point of that simply is that there is a  
23 core of expertise in poison centers which can and should be  
24 tapped.

1                   In 1995 Wigder, et al. published a study of  
2 emergency department poison advice telephone calls, and  
3 they concluded that poison advice by ED personnel proved to  
4 be inaccurate and inconsistent. As a result, patients may  
5 be better served if advice calls are redirected to regional  
6 poison centers.

7                   A study by Mullen, et al. published in 1997, a  
8 physician consultation of the PDR for overdose management  
9 advice, concluded we found serious discrepancies in  
10 overdose management advice in the PDR compared with the  
11 consensus of current toxicology references. All together  
12 five PDR entries were deficient and almost half advised  
13 ineffective or frankly contraindicated therapies.

14                   Now, this is especially alarming. This is no  
15 longer a quote. This is especially alarming because 50  
16 percent of the physicians surveyed, all of whom had also  
17 consulted the poison center, had in fact consulted the PDR  
18 for overdose information in the preceding 12 months.

19                   Also, patients who interpret "get medical help"  
20 to mean calling the physician will often wait perhaps for  
21 several hours for that physician to receive the message and  
22 return the call. That response is delayed perhaps turning  
23 a situation that might have been benign into one which is  
24 serious and perhaps even life-threatening, specifically

1 because assessment and management were delayed.

2 Health care costs would also rise. Numerous  
3 studies have documented the cost savings of poison centers.  
4 The most recent in 1997 by Miller and Lestina stated the  
5 average public call to a poison control center for aid  
6 prevented \$175 in other medical spending.

7 In a 1995 study by Kearney, et al., 79 percent  
8 of poison center callers stated they would have sought  
9 assistance from their local emergency health care system  
10 had the poison center not been available.

11 Nationally the cost of answering a poisoning  
12 call for a center with 30,000 or more calls per year is  
13 under \$30 according to a 1995 study by the American  
14 Association of Poison Control Centers. Without a doubt,  
15 the cost of a call to an ambulance dispatch center,  
16 transportation to an emergency department, and evaluation  
17 and treatment in an emergency department will far exceed  
18 the cost of a poison center call, in addition to delaying  
19 treatment. That is another reason why we feel that people  
20 should not be discouraged or deflected from calling poison  
21 centers.

22 Finally, deflecting calls to poison centers  
23 will affect the ability of FDA and other regulatory  
24 agencies to monitor the public health. The American

1 Association of Poison Control Centers' toxic exposure  
2 surveillance system is the only national data collection  
3 system for poison exposures. The more than 2 million calls  
4 documented in 1996 represent an estimated 87 percent of all  
5 calls to poison centers during that year.

6           These data are used to identify unsuspected  
7 hazards. In a situation recently acted on by FDA, test  
8 data were used to identify iron poisoning as a leading  
9 cause of poisoning death in children. FDA and other  
10 regulatory agencies used poison center data as one basis  
11 for instituting educational campaigns, requiring changes in  
12 packaging to limit the amount of iron available to young  
13 children, and require warning labels on packages. Now,  
14 this is for a product that is widely available over the  
15 counter.

16           Test data have also been evaluated by FDA in  
17 assessing the safety of drugs for which prescription to  
18 over-the-counter switches have been sought, for example,  
19 nicotine patches and nonsteroidal anti-inflammatory drugs.  
20 The nonprescription drug industry itself also uses test  
21 data for internal monitoring of product safety. So, by  
22 deflecting calls to poison centers, FDA would be decreasing  
23 the reports of poison exposures, limiting the ability of  
24 the agency and others to monitor drug safety.

1                   In summary, we believe that over-the-counter  
2 drug labels provide an opportunity to steer poisoning  
3 victims in the direction of the most appropriate treatment  
4 which also happens to be the most cost effective. By  
5 deflecting calls to poison centers, FDA will in effect be  
6 changing the standard of care for poisoned patients,  
7 increasing the burden on health care professionals who do  
8 not have specialty training and experience in toxicology,  
9 increasing health care expenditures, and decreasing its own  
10 ability to monitor the public health.

11                   DR. D'AGOSTINO: Thank you very much.

12                   Our third speaker is Jann Keenan from the  
13 Keenan Group Lose Literacy Specialists.

14                   MS. KEENAN: Good afternoon. I thank you for  
15 the opportunity to speak with you. I always like speaking  
16 directly after lunch in a room that has no windows, so I  
17 will be succinct.

18                   My name is Jann Keenan. I do bring over a  
19 decade of experience in writing and designing easy to read  
20 and easy to understand materials. For 13 and a half years  
21 I served as the low literacy expert for the Maryland State  
22 Department of Health and Mental Hygiene, and I have free-  
23 lanced during that time for 13 years and I currently own my  
24 own business. I'm President of a firm that does low

1 literacy design.

2 I have in the past served as a consultant for  
3 NDMA and to one major OTC drug company. Please note -- I  
4 think it's important to note -- that I am here today to  
5 represent myself. I am not being paid. I have been very  
6 interested in this topic, attended the meetings two years  
7 ago, put in written comment, recently put in comment to the  
8 Office of Management and Budget regarding FDA proposed  
9 studies A and B and did not receive any funding for that.

10 So, lest you think I'm an OTC label zealot, I'm  
11 coming here to bring a readability perspective and also I  
12 am a mom of a young boy who has a chronic disease who  
13 relies heavily on OTCs and prescription drugs. And I am a  
14 daughter of parents who are in their 80s. So, I wanted to  
15 bring a consumer perspective also.

16 My colleague, Janet Ohene-Frempong, and I will  
17 be submitting a jointly written report on the six points  
18 I'm going to bring up today. Janet is the Director of the  
19 Health Literacy Project with the Health Promotion Council  
20 of Southeastern Pennsylvania. She's a colleague and close  
21 friend and has given me permission to present these points  
22 that we came up with. We've been talking and bantering  
23 about on the phone a good bit.

24 I do think FDA has done a great job in giving a

1 good direction. In fact, over the years I've seen an  
2 incredible metamorphosis of the labels. It has just been  
3 phenomenal. They are so much better, significantly better  
4 than they were in the past.

5 Let me go over my quick, brief suggestions and  
6 then my other comments.

7 I did have a suggestion regarding consistent  
8 structure. We heard presentations this morning by FDA. In  
9 the warnings sections, there were a paragraph for  
10 pregnancy, specialty warnings, Reye's syndrome, then they  
11 were broken up by bullets. My firm suggestion as a  
12 readability expert is to tell you to leave everything in  
13 bulleted format. It's very hard for the reader to go from  
14 a paragraph form to bullet. So, I would suggest putting  
15 all the specialty warnings together and bulleted. Janet  
16 Ohene and I concur on that.

17 Another area. We were sitting and we  
18 brainstormed. In readability you want parallel structure.  
19 You want the reader to be able to get consistent  
20 information. FDA in their suggestions kept along that in  
21 all areas except for one, and that is in the warnings  
22 subheading. The term is "when using this product." Janet  
23 came up with -- and I do concur with -- "be aware." It  
24 keeps it in the active voice.

1           Also I agree with -- like the logical flow,  
2           FDA's suggestion that warnings definitely come before  
3           directions. We want folks to know what to look out for  
4           before we tell them how to use something.

5           I strongly urge the committee to strongly urge  
6           FDA to ask people to use interchangeable terms. We came up  
7           with a list of interchangeable terms and submitted that to  
8           NDMA. It just makes good logical sense. Instead of saying  
9           "excessive phlegm," "too much mucus;" "call immediately,"  
10          "call right away." Everybody wants that. I'm a mom of  
11          four kids. I want my stuff quick and to the point. That's  
12          just the way we should go.

13          I suggest also in making it consumer friendly  
14          with your actives first, as suggested by FDA, so that not  
15          only the pharmacist can do an easy consult, I can do a cost  
16          comparison as a consumer.

17          I'm going to pass real quickly. I have seen a  
18          tremendous change in the labels. They're so much better to  
19          read now. We have to strongly let our folks know that red  
20          lettering with a yellow background are the only two colors  
21          that cause an unnatural astigmatism. You just can't read  
22          it. Even if it's set just right and if the registration is  
23          slightly off, you've got blurred vision from the get-go.

24          So, my strong suggestion is to have a lot of

1 contrast, no reverse type, as NDMA discussed this morning.  
2 I'm in complete agreement with that. Even if the copy is  
3 double struck and you have white copy, you can't read it.

4 This morning in the presentations for FDA -- I  
5 understand they were just prototypes, but columns were not  
6 used. Columns are definitely much better. You don't want  
7 to go more than 52 characters.

8 I know this is a lot of information. I will  
9 follow-up in writing, but these are principles. Dr. Soller  
10 showed the Doak's book. I have my dog-eared copy that I  
11 carry with me all the time in my briefcase like the Bible.

12 We've just go so much. It doesn't take a  
13 rocket scientist to know that simple is better. So, we're  
14 in the right direction.

15 With that note, I urge the committee today --  
16 you know, this is not an esoteric situation. This is real  
17 life. At 6 point, they don't fit. A lot of them just  
18 don't fit. Let's move forward. We have gone round and  
19 round, and I say we don't have to get it perfect. Let's  
20 make those steps.

21 I know a good idea when I hear one, and two  
22 years back NDMA made a presentation on the phases. That  
23 makes a lot of sense. Let's phase in. We're ready to  
24 roll.

1           I have watched them. As I said, not to be  
2 redundant, I've seen the metamorphosis. They are so much  
3 easier, the bullets, the contrasting colors, upper and  
4 lower case, all those readability things we know that work.  
5 I don't think we need another couple decades to move this  
6 on.

7           As a readability specialist, you can ask any of  
8 us. It's ready to roll. We're in good shape. We're going  
9 to have to do some tweaking but let's get the first round  
10 going.

11           As a consumer, I am simply frustrated.

12           So, without ado, thank you much for your time  
13 and we will follow up.

14           DR. D'AGOSTINO: Thank you very much.

15           We're now going to hear from the National  
16 Consumers League.

17           MS. BURKHOLDER: Good afternoon. My name is  
18 Rebecca Burkholder. I'm a Program Associate with the  
19 National Consumers League, and I'm here on behalf of the  
20 League this afternoon.

21           The National Consumers League is a national  
22 nonprofit consumer organization that has represented  
23 consumers and workers in the marketplace and work place for  
24 almost 100 years. Assuring that consumers can purchase

1 safe and effective medication is a primary concern to our  
2 organization.

3           The League supports FDA's proposed labeling  
4 requirements for over-the-counter drug products. As  
5 consumers assume greater responsibility for their own  
6 health and as more drugs become available over the counter,  
7 consumers must be provided easy to read and understandable  
8 information on the drug label. While the League applauds  
9 FDA's efforts in this area, we have a few comments on ways  
10 to make the label even more consumer friendly.

11           There is evidence that consumers are more  
12 health conscious today than ever before, and the government  
13 has responded to consumers' need for more information to  
14 help them make wise health decisions. The new food label  
15 is an example of government response to consumers' desire  
16 for information on the nutritional content of food  
17 products. The proposed OTC label is another response to  
18 consumers who want to be better informed about what is in  
19 an OTC product, what it is used for, and what are the risks  
20 and benefits of taking the medication.

21           Increasingly consumers are practicing self-  
22 diagnosis and are self-treating with OTC products instead  
23 of seeing a physician. Understandable labels will help  
24 consumers choose the right medication and avoid harmful

1 mistakes. By reading an OTC label, consumers should be  
2 able to determine if this is the appropriate drug for the  
3 condition being treated, the benefits of the drug,  
4 necessary precautions, and when to consult a pharmacist or  
5 other health professional.

6           The new label not only responds to consumers  
7 taking greater responsibility for their health, but also  
8 complements the ongoing work of the Department of Health  
9 and Human Services in assuring consumers receive written  
10 information on their prescription medications. It is just  
11 as important, if not more important, for consumers to  
12 receive comprehensible written information about OTC drugs.  
13 The information presented on the label of an OTC drug is  
14 most likely the only information a consumer will receive on  
15 how to take that medication safely.

16           Consumers are now able to purchase over-the-  
17 counter drugs previously only available by prescription.  
18 With nearly 70 prescription products now switched to OTC,  
19 consumers are asking more questions about using these  
20 products correctly. To avoid medication errors when using  
21 these drugs, consumers must have clear, concise information  
22 readily available. Information on a drug's active  
23 ingredients and purpose is especially important for  
24 consumers using unfamiliar drugs.

1           The League supports the FDA's proposed labeling  
2 rule, particularly the requirement that a minimum of 6  
3 point type be used on the label. In order for the  
4 information appearing on the new OTC drug label to be of  
5 any use to the consumer, it must be in large enough type to  
6 be read. Surveys have shown that a significant proportion  
7 of the adult population is not able to read a smaller size  
8 type such as 4.5. Even with 6 point type, some elderly  
9 consumers and others who have vision impairment will be  
10 unable to read the label.

11           The League also strongly supports the order of  
12 the label information required by the proposed rule,  
13 particularly the listing of the drug's active ingredients  
14 and purpose first. With the active ingredients first, the  
15 consumer is easily able to determine what is in the drug  
16 product being purchased and to compare products.

17           In addition, the rule's provision allowing  
18 certain terms to be used interchangeably on the label will  
19 promote greater comprehension among people with low or  
20 moderate literacy skills.

21           While the League supports the new labeling  
22 format, we also believe it could be made even more consumer  
23 friendly with a few additions. Adding at the bottom of the  
24 label the sentence "If you have any questions about this

1 medication, consult your pharmacist or other health  
2 professional" would direct the consumer to the proper  
3 sources for additional verbal guidance on using the OTC  
4 product. Although the new label is fairly comprehensive,  
5 consumers will still have questions that are best answered  
6 face to face. Consumers should be specifically encouraged  
7 to consult a pharmacist because they are trained to counsel  
8 and give advice on OTC products and are usually immediately  
9 accessible to the consumer at the point of purchase.

10 The new format should also include in the  
11 accidental overdose or ingestion warning the recommendation  
12 to contact a poison control center. FDA proposes to delete  
13 the recommendation because poison control centers do not  
14 exist in every state, but for consumers who do have access  
15 to poison control centers, they should be instructed to  
16 utilize this valuable resource. The label should state in  
17 case of accidental overdose or ingestion "get medical help  
18 right away or contact a poison control center."

19 Thank you for providing this opportunity to  
20 comment.

21 DR. D'AGOSTINO: Thank you.

22 The next statement is from the American  
23 Optometric Association and Andrea Neal will read it.

24 MS. NEAL: I am reading this on behalf of the

1 AOA, and I'm pleased that they submitted it in 12 point  
2 type.

3 (Laughter.)

4 MS. NEAL: The American Optometric Association,  
5 AOA, appreciates the opportunity to submit comments to the  
6 Food and Drug Administration's Nonprescription Drugs  
7 Advisory Committee on the proposed labeling requirements  
8 for over-the-counter, OTC, drug products that will enable  
9 consumers to better read and understand OTC drug labeling.

10 The AOA is a national organization representing  
11 over 31,000 practicing optometrists, students, and  
12 educators. The mission of the profession of optometry is  
13 to fulfill the vision and eye care needs of the public  
14 through clinical care, research, and education, all of  
15 which enhance the quality of life. Doctors of optometry  
16 are independent primary health care providers who examine,  
17 diagnose, treat, and manage diseases and disorders of the  
18 visual system, the eye, and associated structures, as well  
19 as diagnose related systemic conditions.

20 Reduction in visual efficiency with age is  
21 universal. This decrease in visual efficiency can  
22 significantly interfere with the ability to perform many  
23 common, yet critical activities such as reading directions  
24 on a drug product label. It is estimated that 1 of every

1 20 people in the United States suffers from a significant  
2 impairment of vision which cannot be further improved by  
3 corrective lenses. In addition, many individuals have  
4 uncorrected or under-corrected vision problems which limit  
5 their visual ability. These individuals could  
6 significantly benefit from improved readability and  
7 legibility of many drug product labels.

8 Any regulations or guidelines developed  
9 regarding drug product labeling should consider factors  
10 relating to both readability and legibility. Readability  
11 is determined primarily by the arrangement of the printed  
12 information, e.g., spacing, line length, et cetera.  
13 Legibility is affected by type size and style. In  
14 addition, ink color and paper color and texture are also  
15 important factors that will impact on readability and  
16 legibility.

17 There are also factors which are beyond the  
18 control of the product labeling process. These would  
19 include lighting used when reading the label, the distance  
20 the label is held from the eyes, and whether the reader is  
21 using the appropriate vision correction if needed. The  
22 complexity of these variables makes it very difficult to  
23 establish minimum criteria that will satisfy all needs.

24 The AOA firmly supports the FDA's efforts to

1 simplify over-the-counter text and formatting.

2           Also we have reviewed the recommendations  
3 proposed by the Nonprescription Drug Manufacturers  
4 Association, NDMA. These recommendations include standard  
5 order of information: active ingredients and actions,  
6 followed in order by uses, directions and warnings. The  
7 reproducible placing of information allows a consistency  
8 across product types and package configurations, allowing  
9 simpler use of OTCs as a category of products, and allows  
10 desired information to be found more easily.

11           Standard set of headings: Actives, Actions,  
12 Uses or For, Directions, and Warnings. The use of standard  
13 headings allows a reproducible identification of major text  
14 material across all categories of OTCs.

15           Warning subheadings. The use of a standard set  
16 of warning subheadings will allow the current single  
17 paragraph format for warnings to be broken into smaller  
18 items of information, thereby making OTC labels more  
19 consumer friendly and easier to use. Also this would  
20 provide consumers with a common set of instructions to  
21 apply across different product categories and will enhance  
22 comparisons across products.

23           The AOA has agreed to support the proposed  
24 guidelines of the NDMA. We feel that these proposed

1 changes will allow consistent information across all  
2 categories of nonprescription drugs and will make OTC  
3 product comparisons much easier. The warning subheadings  
4 will increase readability of the current, often confusing,  
5 single warning paragraphs. These changes are especially  
6 important to older people.

7 We therefore recommend that the FDA adopt the  
8 NDMA guidelines, and that the NDMA proposal be adopted into  
9 regulation by the FDA, and that the FDA allow companies to  
10 move forward now to implement these changes. Support for  
11 action per the NDMA proposal is the fact that it would  
12 result in significant improvement in readability of OTC  
13 labels without the delays inherent in regulatory action.  
14 Since there is no evidence of a public health problem  
15 relating to OTC label format per se, there is no need for  
16 rushing into a full scale implementation of regulatory  
17 action which may be based on incomplete analysis of  
18 readability and economic and environmental impacts.

19 We hope that the FDA will take into  
20 consideration the American Optometric Association's  
21 recommendations on labeling requirements for over-the-  
22 counter drug products. Again, we thank you for the  
23 opportunity to comment.

24 DR. D'AGOSTINO: Thank you, Andrea.

1                   The National Community Pharmacists Association  
2 will now present.

3                   MR. RECTOR: Thank you for the opportunity to  
4 make some brief comments this afternoon. My name is John  
5 Rector. I'm General Counsel for the National Community  
6 Pharmacists Association, formerly for about 100 years the  
7 National Association of Retail Druggists. We represent the  
8 independent pharmacy practitioner both in the single store  
9 setting, multiple store, and the franchise setting.

10                   Although we have not completely finalized our  
11 statement on the proposed rule, we do have several comments  
12 for today. Certainly we'll have a very comprehensive  
13 statement filed before the October 6th deadline.

14                   One primary concern we have which we alluded to  
15 just briefly at the May 29th health professionals FDA  
16 meeting relates to the state and local law preemption  
17 section. We're concerned that there may be a problem with  
18 preempting state and local pharmacy practice laws and, for  
19 that matter, medical practice, but we're not necessarily  
20 concerned about that. We're concerned specifically about  
21 pharmacy practice. So, we would recommend that there be a  
22 specific reference to non-preemption in this proposal,  
23 somewhat akin to the language that's in the FDA  
24 authorization bill that is pending in the Senate, S. 830.

1           On concerns that relate to issues that we've  
2 heard about such as shelf space and whether or not a  
3 pharmacy can tolerate additional storage and presentation  
4 space, we request that in addition to those who manufacture  
5 the products, that you remember to talk to those of us who  
6 are in the pharmacy business who actually stock these  
7 shelves and can provide you some additional points of view  
8 on issues such as that.

9           We do endorse the reference to pharmacists on  
10 the label, as you might imagine. We endorse it on all  
11 products. I should add we did forward to the committee a  
12 letter from the Joint Commission of Pharmacy Practitioners  
13 that represents all the national pharmacy groups, and each  
14 of the national pharmacy groups, in addition to the two  
15 that here today, similarly represent adding the reference  
16 to pharmacists.

17           I should add that we endorse the comments of  
18 the National Consumer League and the criteria as set out by  
19 the American Pharmaceutical Association a while ago.

20           In terms of our basic public policy  
21 orientation, I found what I consider to be an interesting  
22 observation by Senator Daschle that captures our point of  
23 view. He introduced a resolution recently urging that  
24 pharmacists be added to the OTC label, Senate Resolution

1 99. I'll quote in part from his introductory remarks where  
2 he said that "as OTC products proliferate and more potent  
3 medications become available, the risks to the seniors and  
4 other consumers compound. It makes sense to foster the  
5 pharmacist-consumer link to minimize the potential problems  
6 that may result from this trend. It is a minor revision  
7 adding pharmacists to the label that could make a major  
8 difference as consumers negotiate the increasingly complex  
9 array of medications available without a prescription."

10 One of the other groups noted that there's some  
11 synergism between adding pharmacists to the OTC labeling  
12 and the recent Med Guide proposal which highly ironically  
13 referenced only the pharmacists and not the physician, but  
14 we would recommend that the physician be added to the OTC  
15 as well.

16 Thank you very much.

17 DR. D'AGOSTINO: Thank you.

18 The next speaker is from the American Academy  
19 of Nurse Practitioners. That was Dr. O'Hara. Has she  
20 arrived? She may be a little late.

21 Why don't we skip to the next one, the WCE  
22 Clinical Evaluations.

23 MS. SHELLABARGER: Good afternoon. Ladies and  
24 gentlemen, thank you very much for the opportunity to

1 present our views today on OTC labeling. My name is Susan  
2 Shellabarger. I am the Senior Director of Business  
3 Development and Client Services for WCE Clinical  
4 Evaluations. We were formerly Walker Clinical Evaluations  
5 until about eight months ago.

6 I've not been paid by any organization or  
7 company to appear here today. I'm here on my own behalf.

8 When considering the design of OTC product  
9 labeling, we need to be aware that the path to consumer  
10 comprehension and ultimately compliance consists of a  
11 series of progressive steps. The first step is what we're  
12 here talking about today and that is readability or  
13 legibility; in other words, how easy is it for the consumer  
14 to read the label.

15 The next step in this process is  
16 understandability. Can the consumer actually comprehend or  
17 make sense of the words that they have read?

18 Next comes interpretability. This is the  
19 process whereby the consumer determines whether the product  
20 does or does not fit their personal requirements. For  
21 example, this product is for the relief of cold symptoms  
22 and not acid indigestion.

23 After interpretability comes behavioral  
24 intention. This is where the consumer develops a plan of

1 action to purchase and use the product. An excellent  
2 example for this step is whether the consumer will "see a  
3 doctor before using the product," as is now being  
4 considered for some of the cholesterol lowering products.

5 Finally, the last step is compliance. Will the  
6 consumer use the product according to the information on  
7 the label and in a safe and an effective manner?

8 Now, while all of these steps are very  
9 important, clearly the readability or legibility of the  
10 label has the most influence on the consumer's behavior.  
11 And it's here that the FDA, the NDMA, and industry have  
12 been concentrating their efforts resulting in NDMA's 1991  
13 Voluntary Guidelines on OTC Label Readability and the FDA's  
14 1997 label proposal.

15 To add some credibility to the NDMA's work and  
16 the FDA's work, we have in the past three years as an  
17 organization worked with many label comprehension studies  
18 for Rx to OTC switch products. This work covers a broad  
19 range of therapeutic categories, including analgesics,  
20 heartburn, smoking cessation, hair growth, ocular allergy,  
21 seasonal allergy, antivirals, and insulin. In nearly every  
22 study that we have conducted, the manufacturer has used a  
23 label that has incorporated many, if not all, of the  
24 technical factors that have been identified to improve

1 label readability, such as substitution of simple words,  
2 use of headers and subheaders to chunk information,  
3 typographic cues such as highlighting, color, bullet  
4 points, and increased white space on the label.

5           The results of these label comprehension  
6 studies have been very positive and I believe encouraging.  
7 It's clear that consumers not only can read these labels,  
8 but also to a great degree, they intend to use the products  
9 in a safe and efficacious manner. The readability of these  
10 labels is further evidenced by the fact that nearly 20  
11 products have been approved for switch from Rx to OTC  
12 status since early 1995.

13           In summary, the initiatives taken by the FDA,  
14 the NDMA, and industry on label readability are working.  
15 The Rx to OTC labels are well understood by the general  
16 population. There is no health crisis related to the  
17 readability of OTC labels and we do not believe that any  
18 additional testing related to these technical factors is  
19 required.

20           Thank you very much for your time, and time  
21 permitting, I'll be happy to answer any questions.

22           DR. D'AGOSTINO: Thank you very much.

23           The next speaker is from the American  
24 Association of Retired Persons, Sandra Eskin.

1 MS. ESKIN: Good afternoon. My name is Sandra  
2 Eskin and I'm a consultant to the American Association of  
3 Retired Persons on food and drug issues. I'm pleased to  
4 present the views of the Association to this advisory  
5 committee on FDA's proposal regarding the labeling of OTC  
6 drugs.

7 AARP commends the agency for issuing this  
8 proposal which represents another important step in the  
9 positive trend to provide consumers with more and better  
10 information that enables them to improve their health and  
11 welfare. Following up on the agency's redesign of the  
12 nutrition label and food products and on the recent release  
13 of the action plan for the voluntary provision of  
14 prescription drug information, the proposed regulations for  
15 OTC drug labels will give consumers the information they  
16 need to properly choose and use OTC drugs.

17 The Association will save its more detailed  
18 remarks on the FDA proposal for its written comments. We  
19 would like to focus the testimony today on the proposed  
20 format requirements for OTC drug labels. AARP generally  
21 supports FDA's proposed format requirements which reflect  
22 the fact that label readability depends on a number of  
23 interrelated factors, including type size, type style, line  
24 length, and leading. The proposed regulation is consistent

1 with generally recognized readability standards. It  
2 requires the use of upper and lower case letters rather  
3 than the more difficult to read all upper case lettering.  
4 The proposal also limits use of reverse type. It requires  
5 at least 1 point leading and mandates the use of bullet  
6 points to set off information.

7           Of all the readability factors, type size  
8 continues to be the most contentious. AARP, along with the  
9 National Consumers League and other consumer groups, has  
10 consistently asserted that label information must be  
11 printed in a type size large enough for people to be able  
12 to read it, especially older people who comprise the  
13 largest group of OTC drug users and suffer  
14 disproportionately from vision problems.

15           There is widespread agreement among readability  
16 experts that 12 point type is the best type size for older  
17 persons. We recognize that this type size is not feasible  
18 for the labels of most, if not all, OTC drug products. We  
19 would prefer a type size minimum that is closer to the 12  
20 point optimal figure than the 6 point minimum that has been  
21 proposed, but we appreciate the agency's efforts in  
22 addressing the other readability factors besides type size  
23 in its proposed rule.

24           We are concerned that 6 point type will become

1 the type size used on all OTC drug labels rather than the  
2 absolute minimum type size used only when necessary. To  
3 address this concern, we urge FDA to establish a sliding  
4 scale type size minimum that is tied to the available label  
5 space, container size, or other appropriate criterion. The  
6 larger the container or the greater the label space, the  
7 larger type that should be used. Such an approach we  
8 believe would better ensure that the largest possible type  
9 size is being used on a particular product label.

10 NDMA has consistently urged FDA to establish a  
11 minimum type size of 4.5 point. NDMA asserts that an  
12 overwhelming number of generic OTC products and a  
13 significant number of brand name OTC drugs could not fit on  
14 product labels the required information in the required  
15 format in 6 point type.

16 We urge the agency not to revise the type size  
17 minimum down to 4.5 point or, at the very least, not to  
18 adopt a 4.5 point type size minimum without clear evidence,  
19 in the form of consumer testing, that older consumers can  
20 read it. A new and improved label for OTC drugs with a  
21 better format and better content will be of no value if a  
22 significant portion of the population who are significant  
23 users of OTC drugs cannot read it. It's just that simple.

24 Before lowering the type size minimum, we would

1     urge the agency first to consider other ways to ensure that  
2     the required information is available in a readable format.  
3     One possibility to be considered is use of a wraparound  
4     label or a label with wings or tabs that fold out to  
5     provide the additional space necessary to include all of  
6     the required information. Another would be a simplified  
7     format for those OTC drug products that cannot fit the  
8     required information in 6 point type. A similar approach  
9     is followed for food labels. We would want any label that  
10    includes a simplified format to include prominently a toll-  
11    free number where consumers can contact the manufacturers  
12    for more information.

13                 On behalf of AARP, I would like to thank you  
14    for this opportunity to share the Association's views on  
15    this important issue.

16                 DR. D'AGOSTINO: Thank you very much.

17                 The American Dental Association is the next  
18    organization.

19                 DR. WHALL: Thank you. My name is Dr. Clifford  
20    Whall. I'm the Director of Product Evaluations in the Seal  
21    of Acceptance Program at the American Dental Association.

22                 I have no vested interest in any company or  
23    product, nor does the ADA have any vested interest in  
24    either of those.

1                   We in fact have the same goals as the FDA does  
2                   and that is to provide safe and effective drugs for  
3                   consumers and meaningful and understandable product  
4                   labeling.

5                   My comments today are somewhat informal and are  
6                   not yet the official ADA policy and may be revised  
7                   somewhat, but these are the issues we are concerned with  
8                   and which we would ask you to consider. We're preparing  
9                   the official position paper which will be submitted to you  
10                  soon.

11                  For the most part, the ADA strongly supports  
12                  the FDA in its efforts to require uniform labeling in the  
13                  seven label areas indicated in the proposed rule. We like  
14                  the FDA believe that the uniformity will benefit consumer  
15                  understanding as it has for food labeling, and we applaud  
16                  your efforts with this proposed rule.

17                  I will bring a different perspective from what  
18                  you've heard today and that is the perspective of the ADA  
19                  Seal Program. In this program, which has functioned  
20                  effectively since 1930, long before the FDA even got  
21                  involved with the safety and effectiveness of dental oral  
22                  care products, the ADA critically evaluates laboratory and  
23                  clinical data on safety and effectiveness of dental  
24                  products, including oral care OTC drug products.

1                   Now, there are a few areas in the proposed rule  
2                   that the ADA is concerned about because we anticipate they  
3                   may adversely affect the ADA's Seal of Acceptance Program  
4                   and the service it gives to consumers.

5                   In addition, I have a comment to make about the  
6                   health care provider issue that has been raised.

7                   Regarding the areas that could adversely affect  
8                   the program, the most important has to do with the  
9                   allowable claims under directions and warnings. As we  
10                  interpret the proposed rule, the only wording under these  
11                  headings that will be allowed will be wording specified  
12                  either in the OTC labeling rule itself or in FDA  
13                  monographs. This is most apparent in the large section on  
14                  preemption which will disallow state and local governments  
15                  from imposing labeling format or content that differs from  
16                  or adds to that established by the FDA.

17                  And it was the "adds to" that got our  
18                  attention. The proposed prohibition of additional content  
19                  information in the warnings and directions sections is of  
20                  concern to the ADA's program because we sometimes find the  
21                  need to require additional labeling directions or warnings  
22                  over those required by the FDA.

23                  When I've testified before to the Dental  
24                  Products Panel or the FDA Placque Subcommittee about the

1 ADA and its product evaluation Seal Program, most of those  
2 individuals had some knowledge of the program. My guess is  
3 that most of the individuals in this advisory committee are  
4 not familiar with the Seal of Acceptance Program.

5 In our official comments to the FDA, we will  
6 present evidence of the longstanding excellence and  
7 objectivity of the ADA's Seal Program in evaluating OTC  
8 dental drug products. This evidence will show that since  
9 1930 the program has been in the forefront of providing  
10 consumers with information on OTC dental drug products and  
11 oral care products which are safe and effective. There's  
12 no question that the Seal Program has provided over the  
13 past 67 years a great service to consumers.

14 In the process of our rigorous product  
15 evaluation, we sometimes determine, as I said before, that  
16 additional warning or direction wording over that required  
17 by the FDA would be of benefit to consumers. In the past  
18 it has never posed a problem to require this extra wording.

19 An example I'll give you of a fluoride  
20 toothpaste. One of the things that the Council on  
21 Scientific Affairs, which actually runs the program, has  
22 required is the phrase "use a pea-sized amount." This is  
23 something ghat the FDA does not require although the FDA  
24 does have warning statements on the label indicating that

1 patients should not swallow fluoride toothpaste. We've had  
2 many meetings with experts in fluorides and they have  
3 advised us that besides that warning, it would be  
4 beneficial to have a warning to decrease the actual amount  
5 of fluoride toothpaste used by a child.

6 Another example would have to do with tartar  
7 control toothpastes. The perception could be that these  
8 products, besides reducing tartar, the cosmetic tartar that  
9 has no effect on any kind gingival health, also benefit  
10 gingival health by their tartar reducing ability. Well,  
11 they do not and we've required a statement to that effect  
12 on the tube.

13 So, what the ADA would like for the FDA to  
14 consider is that the Seal of Acceptance Program be exempt  
15 from the preemption section of the labeling rule so that  
16 when the ADA does deem it necessary to augment the FDA's  
17 OTC wording, manufacturers are able to comply.

18 I'd like to stress the following. This won't  
19 happen that often because most of the time we agree with  
20 the FDA, but when it does happen, we feel it's very  
21 important.

22 Number two, the FDA will still have control  
23 over what it wants on the label. We wouldn't require  
24 manufacturers to take anything off the label that the FDA

1 wanted.

2 Third, we wouldn't be putting manufacturers at  
3 any additional mandated expense, which has been discussed.  
4 Since our program is voluntary, manufacturers don't have to  
5 become part of our program. They like to because it helps  
6 them sell their product because of what the seal means, but  
7 they don't have to be part of it.

8 In addition, it will be a national label, just  
9 like the FDA's label. It won't be a state by state  
10 wording.

11 Fourth, it would be unwieldy to require  
12 manufacturers to request specific exemptions each time the  
13 ADA might require separate wording.

14 Fifth, the dual FDA/ADA required labeling has  
15 worked well in the past as the strengths of each  
16 organization complement each other.

17 My second comment briefly has to do with the  
18 type size issue and I think that has been batted around a  
19 lot. We don't have a lot of comments about that other than  
20 to say that we would like the type size to be such that it  
21 doesn't preclude the ADA seal from appearing on the label  
22 and the ADA box statement appearing on the label. If  
23 there's no enough room for those items, we think that would  
24 be a disservice to consumers because they do use that in

1 their purchase decisions.

2 My last comment has to do with the issue of  
3 oral health care provider and what should appear on the  
4 label. Of course, if the FDA decides to put individuals  
5 such as pharmacists and doctors on there, dentists would  
6 like to be on there also for oral health care products. It  
7 just makes sense. If you decide to go with health care  
8 provider, I think we could live with that.

9 The final issue related to that has to do with  
10 the issue of "doctor." Dentists are doctors also. We've  
11 always indicated to the FDA we'd prefer the term  
12 "physicians" when you actually mean a medical doctor and  
13 "dentists" when you mean a dental doctor and stay away from  
14 the term "doctor" but go after the specifics.

15 The last comment is if the FDA deems that this  
16 would be helpful, I would request that the full comments  
17 that we do put together and provide to you be provided to  
18 the panel.

19 Thank you.

20 DR. D'AGOSTINO: Thank you.

21 The next speaker is from the American Academy  
22 of Pediatrics.

23 MS. HOLLAND: Thank you. My name is Elaine  
24 Holland. I'm with the American Academy of Pediatrics

1 Washington office and I am actually pitch-hitting here  
2 today for Dr. John Wilson who was unable to make it at the  
3 last minute. So, thank you for the opportunity to speak on  
4 behalf of 53,000 pediatricians in the nation who are  
5 dedicated to the health and well-being of children.

6 The Academy is going to be providing specific  
7 and comprehensive comments related to the OTC regulations  
8 and I wanted to just focus my comments this afternoon on  
9 two issues of importance.

10 The Academy does not have a policy on the  
11 proposed OTC labeling regulations and changes, but is  
12 interested in the impact on the safety and effectiveness of  
13 the use of OTC drugs in children.

14 There are two issues that I wanted to raise  
15 today, the first being that there is a lack of labeling of  
16 drugs for pediatric populations prior to the over-the-  
17 counter switch. The primary condition noted for over-the-  
18 counter switches is a safety profile and that a  
19 prescription drug that has been on the market for a long  
20 time labeled for use in adults does not provide the safety  
21 profile questions for children.

22 Dr. John Wilson had surveyed a selected number  
23 of drugs undergoing the OTC switch from 1976 to 1996 and  
24 the pediatric labeling problem with the data summary is

1 revealed in the following ways.

2           Only 28 percent of prescription drugs  
3 participating in an over-the-counter switch had a pediatric  
4 label, whereas even fewer, 7 percent, of the over-the-  
5 counter switch drugs had labeling for all children except  
6 infants.

7           As compared to prescription status, more over-  
8 the-counter switch drugs had a higher disclaimer age,  
9 usually that of children under age 12.

10           And third, the trend for the same or higher  
11 disclaimer age was noted when paired comparisons of  
12 prescriptions to corresponding over-the-counter switch  
13 products were made.

14           These findings impact on what we now describe  
15 as consumer off-label self-prescribing. Children are at  
16 risk because prescription drugs are being switched without  
17 pediatric labeling.

18           The second area that I wanted to just mention  
19 -- and these will be expounded on, as well as additional  
20 issues in our written comments -- is a request by the  
21 Academy that all active ingredients be included in the  
22 labeling, on the front of the labeling. This may also  
23 apply to considering some of the inactive ingredients as  
24 well. Acetaminophen is an example where there are many

1 drugs that have that same product in it and if it is not  
2 clearly noted on the front of the label, there is the  
3 possibility of overdose of that particular drug along with  
4 several others. That's just one example.

5 The Academy supports many of the changes  
6 leading to the clarity of the presentation of the  
7 information by using a standard format and the print size  
8 and the educational level of the language. We congratulate  
9 the agency for the activities in the areas in taking a look  
10 at this labeling and we look forward to providing some  
11 written statements for the record.

12 Thank you.

13 DR. D'AGOSTINO: Thank you very much.

14 Did Dr. O'Hara arrive yet? Oh, great. The  
15 next speaker will be from the American Academy of Nurse  
16 Practitioners. You can use either the podium or the mike.

17 MS. O'HARA: My name is Delia O'Hara, and I am  
18 a nurse practitioner. I came here from the Washington  
19 Hospital Center where I work, along with 50 other nurse  
20 practitioners and a number of physicians' assistants.

21 I wanted to speak to this group -- I think I  
22 met with you one other time -- about the labeling for over-  
23 the-counter medications. As you might surmise because I'm  
24 a nurse practitioner, I would like to request that where

1 you use the term "doctor" on the label, that it be changed  
2 to read health care provider or health care practitioner  
3 because in the District of Columbia where I practice and  
4 many other states, nurse practitioners are allowed to  
5 prescribe and we also utilize over-the-counter drugs.

6 In addition to working at the Hospital Center,  
7 I work in the evening with a group of adolescents at  
8 something called the Presidential Classroom for Young  
9 Americans. And there I try to use over-the-counter  
10 medications as much as I can to avoid prescribing  
11 antibiotics and so forth for people who just have viral  
12 illnesses. So, I think it would be confusing when I do  
13 prescribe an over-the-counter medication -- and I am a  
14 nurse practitioner -- for my adolescents or even my adults  
15 that I care for to have something on the label that says  
16 "please see a doctor" instead of "ask your health  
17 practitioner, your health professional."

18 I also would like to say that since space is I  
19 know an issue that you've discussed in the past and it has  
20 been made clear that that's an issue about the label, it  
21 would be a good use of space if you titled the warning  
22 section "ask your health professional" or "ask your health  
23 practitioner" if you have these following problems.

24 Now, I understand that the reason that it says

1 "ask a doctor beforehand" is because it's considered that a  
2 physician can make diagnoses, but I can tell you that I  
3 make diagnoses based on lab data and my own physical  
4 assessment of a patient. I know that physicians'  
5 assistants that I work with do the same. So, I think that  
6 you could easily include us in the category of somebody who  
7 can make a determination whether a drug would be useful or  
8 beneficial or detrimental to somebody who has the following  
9 conditions.

10 What else would I like to tell you? That's  
11 essentially what I'd like to say.

12 I work with a gerontologic nurse practitioner  
13 who always has told me that the size of the words on the  
14 label are not large enough, and so I applaud your saying  
15 that it has to be an aerial 12 point because I know that  
16 senior citizens, such as my 88-year-old mother-in-law who  
17 lives with me, have trouble reading the labels. I always  
18 have to go down to read the labels, and I explain it to her  
19 as well, sometimes I think better than what her physician  
20 does.

21 I want to ask you to consider one more. The  
22 word "doctor" which I guess you've talked about at length,  
23 using the word "doctor" -- I've heard that you have. My  
24 own son, the mechanical engineer is a doctor, and he uses

1 the title doctor. So, I think that if you really want to  
2 use the term that applies to the health care provider who  
3 was a doctor, you should use the word physician.

4 And I thank you for giving me the time, just as  
5 I walked in the door and found you, to speak to you on how  
6 nurse practitioners feel on your labeling for over-the-  
7 counter drugs.

8 Do you have any questions?

9 DR. D'AGOSTINO: We're not taking questions.

10 MS. O'HARA: Oh, you're not taking questions.  
11 Okay. We will be providing a written statement.

12 Thank you for giving me this time to speak.

13 DR. D'AGOSTINO: Thank you very much.

14 That ends the open public hearing session. I  
15 think probably the wise thing to do is to take a break  
16 right now and please come back at quarter of. We'll begin  
17 without you. Tell the fellow who's running the speaking  
18 system also. And then we'll go into the charge to the  
19 committee. Thank you.

20 (Recess.)

21 DR. D'AGOSTINO: We are going to now move on to  
22 the charge to the committee and then the discussion and  
23 answering of the questions. Dr. Bowen?

24 DR. BOWEN: Thanks, Ralph.

1           I wanted to congratulate all the committee  
2 members for being persistent with us about this process and  
3 going through our part 15 hearings and our other meetings  
4 and sitting in the background and listening and providing  
5 insightful comments.

6           Today is your day to give us your direct input.  
7 We're not limiting your input today to the questions that  
8 you've seen. You've heard comments from FDA staff. You've  
9 heard from industry. You've heard from a very diverse  
10 group of interested and affected parties because in fact  
11 we're all OTC consumers. We invite you today to comment on  
12 the labeling proposal and on any labeling element that has  
13 been discussed today or in any of our other public  
14 hearings. You're not limited, again, to providing  
15 responses to the specific list of questions we've  
16 developed.

17           We did develop the questions based on the bulk  
18 of comments that we've received to the proposal so far, and  
19 I'll just review them briefly. Again, as you go through  
20 the questions, you'll be able to read them in more detail,  
21 but that is reference to health care professionals,  
22 providers, or doctors, pharmacists, dentists, et cetera;  
23 reference to minimum point size for type on the labels;  
24 reference to poison control center in the accidental

1 ingestion/overdose warning. In addition, although the  
2 fourth question is about a specific header for required  
3 dietary information, the same could be true for any  
4 specific header for a warning. We'd like you to discuss  
5 that and give us your direct input on those questions.  
6 However, you're open and free to give us any input you want  
7 to.

8 DR. D'AGOSTINO: Thank you very much.

9 I would suggest that we go through the four  
10 questions, as you suggested them here, and then introduce a  
11 fifth question afterwards for other comments and  
12 suggestions.

13 The first question before us is, the agency is  
14 proposing a minimum 6 point print size for OTC drug  
15 labeling. Please discuss this proposal. If your  
16 recommendation is different, please provide your reasons.

17 If I can summarize the discussion, even a 6  
18 point size doesn't necessarily satisfy the ability of many  
19 of the consumers to read the material, though it's a big  
20 improvement over the 4.5. If the 6 is suggested and agreed  
21 upon and then ultimately becomes the regulation, we've been  
22 told that this has an impact on the ability of some of the  
23 existing drugs to in fact accommodate with the size and all  
24 of the material that's going to be put on the label. We

1 obviously want to take that into consideration.

2 But I think that it's basically a matter of how  
3 legible is it and do we as a committee think that the 6  
4 point is in fact appropriate, do we think there should be  
5 some flexibility in it, should it go down, should it go up.  
6 I'll leave it to the committee to start the discussion.  
7 Does anybody want to begin the discussion? Eric?

8 DR. BRASS: As I listened to the discussion  
9 this morning and have reviewed the data that was available,  
10 I was struck that there's an intent of consensus that  
11 everybody agrees that the label should be readable and  
12 understandable and that point size is a component of that.

13 At the same time, I'm struck by the challenge  
14 to the agency in trying to articulate a specific set of  
15 requirements that they can evaluate a label against. For  
16 example, if you simply said, make it readable, then you  
17 would have a challenge enforcing that I would think.

18 So, my perception is what you are trying to do  
19 is develop a set of standards which everybody would agree,  
20 if those standards were met, the label would be readable.  
21 That's not to say that there are not other ways to make the  
22 label readable. That was illustrated I think in some of  
23 the material provided by the NDMA. But I think those same  
24 standards, as put forth by the NDMA, could have been

1 rearranged into an unreadable label.

2           So, the challenge is where is this gray area in  
3 terms of your comfort with it being readable. I think  
4 you've set a bar which clearly there are other ways below  
5 that bar to make it readable but not in a definable way.

6           I guess one of my questions would be to you --  
7 let's take the extreme. What would be your intent of how  
8 the Roloids little packet could possibly meet the  
9 recommendation? I think that's an example where there are  
10 products in small packages which can't possibly meet the  
11 regulations as articulated. So, you obviously have some  
12 plan for those situations.

13           DR. WEINTRAUB: Actually we do. We will let  
14 those very small package sizes -- much, I might admit, as  
15 the food label did -- maintain their small package size and  
16 get a waiver, or there will be a class waiver, is our  
17 attempt to do that.

18           DR. BRASS: So, if a package size simply --  
19 there's no way any panel combination could contain the 6  
20 point, it would be your expectation that you would then  
21 modify?

22           DR. BERNSTEIN: Yes. In the proposal, as Dr.  
23 Weintraub just said, we actually asked for comment on how  
24 do we handle small packages and we recognize that it

1 wouldn't work in a lot of cases. But we also asked a  
2 question of whether there was some sort of performance  
3 standard that could be used to try and figure out,  
4 recognizing that you can go below a 6 point and use all  
5 these other factors together to make something readable.

6 DR. BRASS: I guess my answer to the question  
7 would be I'm convinced that 6 point is better than 4.5.  
8 I'm convinced that 4.5 is not adequate based on the data  
9 that was provided, but I'm equally convinced that there are  
10 circumstances under which 4.5 does work.

11 DR. D'AGOSTINO: Other comments? Yes,  
12 Kathleen?

13 MS. HAMILTON: I just have a question related  
14 to the discussion that just started. Has there been the  
15 possibility of a disclosure on small packages that says,  
16 the labeling or the information provided on this package  
17 doesn't meet current FDA requirements and here's where you  
18 get the information if you want it?

19 DR. WEINTRAUB: We're open to all suggestions.

20 MS. HAMILTON: That was a question, not a  
21 suggestion.

22 DR. WEINTRAUB: The questions are tougher than  
23 suggestions.

24 (Laughter.)

1 DR. BERNSTEIN: Can I answer that? We're kind  
2 of constrained by the Food, Drug, and Cosmetic Act which  
3 says that the information has to be on the label and it's  
4 readable and understandable for the ordinary consumer at  
5 time of purchase and use. So, at the time of purchase,  
6 that information would have to be available to them.

7 DR. WEINTRAUB: Yes, but you could still have a  
8 piece on the label saying that this label doesn't meet the  
9 standards for format, type size, et cetera, but it has to  
10 meet the standards for all the information.

11 DR. D'AGOSTINO: Mary Anne?

12 DR. KODA-KIMBLE: Does the information have to  
13 be on the container itself? For example, if you had a  
14 blister pack and the information were on the back of the  
15 blister pack, would that meet the requirement?

16 DR. BERNSTEIN: You mean if it were inside the  
17 package? Well, then the consumer would have to open the  
18 package to get the information and it would be -- maybe I'm  
19 misunderstanding.

20 DR. KODA-KIMBLE: You know those super glue  
21 things? You have super glue. It's in a blister pack, but  
22 on the back is all the information, the back of the  
23 cardboard, and there's also some information obviously on  
24 the super glue tube, but it's teeny, teeny, tiny.

1 DR. WEINTRAUB: It depends a little bit on how  
2 one takes out the tablets or capsules. If it goes through  
3 the information, it would destroy it, but if it goes the  
4 other way, it would be fine.

5 DR. D'AGOSTINO: How does the discussion about  
6 the multiple panels and double panels fit in here? They  
7 were talking about being able, with the particular size, if  
8 you went to multiple panels and double panels, to sort of  
9 accommodate everything. Are we worried about the warnings  
10 being split up or are we worried about the label being  
11 split?

12 DR. BOWEN: The proposal says that the warnings  
13 should be all together. It doesn't mean every single  
14 element of the label has to be together. They have to  
15 follow each other in sequence.

16 DR. D'AGOSTINO: So, that's not a restriction  
17 actually right now.

18 DR. BOWEN: No.

19 DR. D'AGOSTINO: You could do multiple and  
20 double panels.

21 Other questions?

22 DR. TONG: I'd like to pursue the question  
23 about performance standard. Is there a common ground from  
24 all the discussants and people we've heard today? I

1 understand about the standard for all the information if we  
2 decided that this information has to be on there, but the  
3 readability and legibility -- is there such a thing as a  
4 common performance standard that we're measuring against?

5 DR. BERNSTEIN: That was one thing that we  
6 actually asked for comment on, whether there was any type  
7 of performance standard. We actually asked for  
8 suggestions. We didn't have any as a starting point. I  
9 think we put an example in there that says that if the  
10 label were X inches away, a person with a certain vision  
11 could see it.

12 DR. TONG: So, we don't have something like a  
13 USP standard, that type of thing.

14 DR. BOWEN: Yes. I think it's an interesting  
15 thought and it may even be possible in our discussions with  
16 a couple of ophthalmologists, but to our knowledge, one  
17 hasn't been developed yet.

18 DR. D'AGOSTINO: Yes, Beth?

19 MS. SLINGLUFF: I was struck by the sample that  
20 was passed around of the red lettering on a yellow  
21 background as being appallingly difficult to read. So, I  
22 can also understand where in order to meet some of the  
23 manufacturer's concerns, we certainly would not preclude  
24 the use of 4.5 type, but I would certainly endorse the idea

1 that the reverse type is not going to be permitted,  
2 certainly not permitted with the smaller type and that that  
3 kind of printing -- I don't have any astigmatism. I found  
4 it virtually impossible to read even with my little glasses  
5 here.

6 DR. D'AGOSTINO: I would like to suggest to the  
7 advisory committee that we actually make a clear statement  
8 about the 6 point. Obviously one can be flexible, but it's  
9 an opportunity to say that we think that the 6 point is the  
10 right target as opposed to the 4.5 or as opposed to the 12.  
11 Would someone like to formulate that, rather than myself,  
12 as a motion, if you agree with it?

13 DR. BRASS: Okay. That the rule attempt to use  
14 the 6 point as the standard and that any modification from  
15 that be evaluated to ensure that readability is preserved.

16 DR. D'AGOSTINO: Any second on that?

17 MS. McGRATH: Second.

18 DR. D'AGOSTINO: Second.

19 Shall we take a vote then? All those in favor,  
20 please raise your hand.

21 DR. JOHNSON: No discussion?

22 DR. D'AGOSTINO: Do you want a discussion? I  
23 thought we had a discussion. I'm sorry.

24 DR. JOHNSON: Specific to the motion. It seems

1 to me from what I've heard that there's no criterion by  
2 which to judge whether any variation from the 6 point is  
3 going to be able to be measured somehow.

4 DR. BRASS: I don't disagree and that was part  
5 of point of my question. But that's also why I tried to  
6 use wording that would recognize that. I think I said  
7 "effort made to" or something like that, recognizing that  
8 there is no way to ensure by any gold standard that 6  
9 point, or anything less, will in fact be readable. I think  
10 the data provided indicates that this specific set of  
11 standards is more likely to do that, but what percentage of  
12 the population can't read this standard still isn't even  
13 presented. So, I don't think we have anything to provide  
14 us a gold standard, but I do think that we have information  
15 that broad-based 4.5 is much less readable than the 6.

16 DR. BLEWITT: It seems to me, though, that  
17 you're putting the 6 point in a vacuum, and that is that  
18 you're considering it in and of itself. If I go to  
19 Bradley's speech earlier, he talked about a number of  
20 factors working together.

21 Frankly, although I think NDMA feels that 6  
22 point is a reasonable type size, what I see is attention  
23 among three different factors here. The first is  
24 information. Then the second is readability, and then the

1 third is space. So, you want to give as much information  
2 as possible. You want to assure that people can read it,  
3 readability meaning also understanding it. But then you  
4 have the factor of how do you get all of this into a given  
5 space.

6 I see the 6 point as being a somewhat arbitrary  
7 point, particularly given what I've heard today. I say  
8 that because there seem to be conflicting data to support 6  
9 point and other type sizes. It seems to me that maybe more  
10 work has to be done in working through the 6 point.

11 But I also think that there is a need to have  
12 minimum type size. You wouldn't want to go below 4.5, but  
13 if there were a set of circumstances, the Bradley  
14 variations, which would enable you to fit all of that  
15 information and were it readable and it were 4.5, then you  
16 may have satisfied all of your concerns.

17 DR. BRASS: That's right, and I think that's  
18 the point I was trying to make in terms of the absence of a  
19 gold standard. I am completely convinced that there are  
20 things less than 6 point which with other features of the  
21 label and under optimal conditions, perhaps not at 2  
22 o'clock in the morning when you're in the bathroom fumbling  
23 for the sleeping aid, but that all those factors interplay.  
24 And I am in full agreement.

1           I would also suggest that we don't have the  
2 data to say 4.5 is better than 3, but I think at some point  
3 common sense prevails and that the amount of data we do  
4 have I feel suggests that the 6 point in combination with  
5 the other factors provided by the agency --

6           DR. BLEWITT: Okay. That was my concern, that  
7 it was being looked at in and of itself and not related to  
8 the other factors.

9           DR. D'AGOSTINO: Mary Anne?

10          DR. KODA-KIMBLE: I guess I'd like further  
11 clarification on what you mean because NDMA did present 6  
12 point with less leading and without listed bullets, but  
13 sort of run-on bullets in which they could get the  
14 information in a smaller space. So, if you were given a  
15 choice of 5.5 in a listed format, bulleted format, versus 6  
16 point in the same space, where are we in that particular  
17 situation?

18          DR. BRASS: Well, again that was my remark at  
19 the start of the discussion. The agency is faced with a  
20 challenge of trying to define a standard for other people  
21 to look at and say, yes, we meet it; no, we don't meet it.  
22 I think that we do not; as opposed to, we're kind of close,  
23 let's see if we get it through. The parameters that they  
24 have put forth define a label specification that is pretty

1 reasonable. I have no question again that there are  
2 combinations which involve smaller point size that would  
3 also work.

4 But in responding to the specific question of  
5 point size within the construct of the rule, that's what I  
6 was trying to respond to, but worded it in a way, though I  
7 was not invited to by the Chair, to put that additional  
8 clause in that makes it clear that there are other  
9 circumstances where you can meet the spirit of the rule  
10 with a different combination of parameters.

11 DR. KODA-KIMBLE: I also think it suggests to  
12 us, as we evaluate products from Rx to OTC, that we might  
13 think about asking for some of these studies as part of the  
14 criteria.

15 DR. D'AGOSTINO: I think the proposal and  
16 certainly the way I interpret the question to be put before  
17 us is to try to make the distinction between, say, the  
18 present and the 6 point as opposed to can you not have  
19 flexibility. So, it's really trying to move it from where  
20 we are right now in the CVS as opposed to all of these  
21 flexible situations that you can find with proposals that  
22 are being made before us.

23 Are there other comments on that? Bill, yes.

24 DR. SOLLER: If I could for just a second.

1 Bill Soller, NDMA.

2 Dr. Brass, returning to your point and it is on  
3 this general issue. What we were trying to do, if you just  
4 kind of stood back and looked at the landscape here, is to  
5 recognize -- at least we know more information on the  
6 national brands, so I'll speak to that for a moment -- that  
7 we're already in a situation where we will have many  
8 products that will have this arbitrary 6 point or higher.  
9 So, I think that's one of the base pieces to take here.

10 In looking at that, this is not unlike where we  
11 were in 1986 and 1989 with the TRP rule where much of the  
12 industry had already done something with TRP, and the  
13 question was where do you take that portion and then move  
14 it. So, you weren't sort of rechanging the entire  
15 landscape, but you were trying to do the appropriate  
16 refinement that would make it work in a reasonable way.  
17 That's what Chris was trying to present to you.

18 So, what we were looking at was to define the  
19 principles -- and we may not have all the answers right  
20 now. We are working very hard on it -- to specify what it  
21 would be to optimize the use of the largest type possible  
22 because that can, I believe, be put into a regulatory  
23 construct that allows you to look at it in a compliance  
24 framework.

1                   So, looking at it by taking away the 2 M,  
2                   making the 1 point an optional -- it doesn't have to be 1  
3                   point -- looking at those sorts of things I think allows  
4                   you to have that scale and maybe you move it down somewhere  
5                   from 6 to whatever, but never go below 4.5, as is the case  
6                   for dietary supplements.

7                   So, we thought there ought to be some  
8                   comparability across consumer products within this kind of  
9                   flexibility, recognizing that most of this is going to be  
10                  at 6 point or higher, but then how do you do it without now  
11                  putting a regulatory burden on where you'd have thousands  
12                  and thousands of petitions for exemption. That wouldn't  
13                  make sense either.

14                  So, returning to your point, I think there is a  
15                  way to create that rationale for how you start with 6. If  
16                  it doesn't work, then you move down and then create the  
17                  label that works.

18                  DR. BRASS: I hope there is too. I think  
19                  particularly for the agency's and industry's sake, that if  
20                  the second clause of my motion is to be actualized, it  
21                  should be with a blanket set of guidelines and conditions  
22                  where you have to start making compromises and what those  
23                  compromises are. But I would encourage the agency to  
24                  develop those, and that's why I picked the other extreme.

1 Clearly you have to for the Rolaid's package and there's a  
2 lot in between the 1,000 pill container of ibuprofen and  
3 the Rolaid's package. How you define that is just going to  
4 make it that much easier --

5 DR. SOLLER: Can I see if I heard that right  
6 and also for my members, that what you're talking about is  
7 shooting for an optimum of 6 point or greater, and that's  
8 consistent actually with our guidelines as well, but that  
9 there would be rules of the road, as it were, for how you  
10 would then handle fitting a label. Is that the --

11 DR. BOWEN: I would like to say that we're not  
12 voting on the rules of the road for that part, that we're  
13 working with you about that, yes.

14 DR. D'AGOSTINO: Right.

15 DR. BOWEN: I think what we're voting on is the  
16 type size within the context of the proposal right now.

17 DR. BRASS: Yes, but again, in the specific  
18 motion, that clause of flexibility was to recognize that 6  
19 cannot be in my opinion an absolute for every product under  
20 every condition.

21 DR. D'AGOSTINO: Cage?

22 DR. JOHNSON: I think we may want to revise the  
23 motion a little bit.

24 DR. BRASS: Only if you can remember it.

1 (Laughter.)

2 DR. JOHNSON: We're going to have trouble with  
3 the vagueness of the subordinate clause.

4 DR. BRASS: Did you have a suggestion?

5 DR. JOHNSON: I can't put a second motion on  
6 the floor till we deal with the first one.

7 DR. D'AGOSTINO: Is that your suggestion?

8 (Laughter.)

9 DR. D'AGOSTINO: I don't think we have problems  
10 with putting a clarification on the motion actually. Go  
11 right ahead if you have a clarification of it because I  
12 think the way Eric was suggesting it was to leave latitude.

13 DR. JOHNSON: I agree with Eric's suggestion to  
14 leave some latitude, and clearly there needs to be  
15 flexibility on this issue because of the constraints of the  
16 various products. But unless the agency is happy with the  
17 subordinate clause. If you're happy with it, I can live  
18 with it, but I think it's going to give you a lot of  
19 trouble.

20 DR. WEINTRAUB: I have it as if it is modified,  
21 that is, the 6 point, that an effort will be made to  
22 maintain readability or that readability be maintained.  
23 It's a little tough to follow exactly and to act on, but we  
24 can live with it probably.

1 DR. BOWEN: We could take it as a caveat.

2 DR. D'AGOSTINO: Well, the alternative is that  
3 if you don't say anything, then 4.5 basically becomes the  
4 ground rule by default, or whatever exists now.

5 Kathleen?

6 MS. HAMILTON: Well, let me suggest that the  
7 way I heard the original motion and what I have a sense  
8 that the group might be comfortable with is that the  
9 committee would like to recommend that support for the  
10 standard of 6 point be the standard by which labels are  
11 presented and permit the FDA to grant exemptions subject to  
12 standards to be developed to retain readability.

13 DR. JOHNSON: That's essentially the same  
14 motion.

15 DR. D'AGOSTINO: Yes.

16 Ted?

17 DR. TONG: I'd like to comment on something  
18 that we heard earlier this afternoon that the larger the  
19 package should also allow the possibility of a larger size  
20 point, and this is again something industry might address.  
21 But we shouldn't make 6 as the only standard.

22 DR. D'AGOSTINO: Any other comments?

23 (No response.)

24 DR. D'AGOSTINO: Are we now ready to vote on

1 it? I'm sorry, yes. It's unusual for me in terms of these  
2 deliberations to recognize people from the floor, but  
3 because of this particular issue I will in fact recognize.

4 MR. BRADLEY: My name is Bill Bradley. I'm  
5 with the Nonprescription Drug Manufacturers Association.

6 I would just like to say that there seems to be  
7 perhaps a misperception that whatever the lower limit is  
8 set at, that's where all products will gravitate to. In  
9 other words, if the limit were set at below 6 point, then  
10 all products would have labeling below 6 point. That is  
11 not the case. That has not been our experience, and in  
12 fact our own survey confirms the survey result that was  
13 cited by the APHA representative, that three-quarters or so  
14 of the labels already have 6 point or more labeling. This  
15 is consistent with the way manufacturers do. They don't  
16 try to make their labels as hard to read as possible. They  
17 try to make them as easy to read as possible.

18 So, in thinking about what you want to say  
19 about this, I would hope that you'd keep in mind that not  
20 everybody is going to rush to the minimum allowable type  
21 size. They're going to make it as large as they can for  
22 their given label constraints.

23 DR. D'AGOSTINO: Thank you.

24 Are there other comments?

1 (No response.)

2 DR. D'AGOSTINO: Then if we're ready to take  
3 the vote, again it's quite clear that the motion does have,  
4 especially in the clause that tacks on, indecision to it,  
5 but I think what is being asked and what the motion is  
6 saying is that there be some minimum that one uses as the  
7 start-out point, realizing that as we just heard, that  
8 industry in fact oftentimes exceeds it and that's great,  
9 and that there are in fact ways, if they presented, where  
10 there can be variations of this. But this is to move up a  
11 level in terms of what the minimum is right now, and that  
12 is what is really being voted on with all of the other  
13 caveats.

14 All those in favor of the motion, please raise  
15 your hand.

16 (A show of hands.)

17 DR. D'AGOSTINO: Are there any opposed?

18 (No response.)

19 DR. D'AGOSTINO: For the sake of the  
20 transcriber and the committee, what is the number? Was  
21 that nine? Eight yeses and no noes and no abstentions.

22 DR. KODA-KIMBLE: Ralph?

23 DR. D'AGOSTINO: I'm sorry.

24 DR. KODA-KIMBLE: Can I just say something

1 about readability? We had lots of testimony today which  
2 suggests to us that the elderly could be the highest  
3 consumers of over-the-counter medications, that their  
4 eyesight grows poorer over time, that they need more light,  
5 and that readability is the number one issue, if we're  
6 going to get to any of these other issues like  
7 comprehensibility, interpretability, and that sort of  
8 thing.

9                   When we review our submissions, I don't ever  
10 recall hearing any evidence of readability under normal  
11 conditions of use or light or any of that sort of thing.  
12 So, I am just suggesting to the committee and to the FDA  
13 that we might think about asking the industry to begin to  
14 try to provide that data. I don't know what that would  
15 look like and I would suggest that's something to be worked  
16 out between the industry and the FDA with a typical  
17 consumer with typical range of eyesight under typical  
18 lighting conditions like this room here because I even find  
19 myself -- I must admit -- you should have a bunch of  
20 teenagers on this panel -- doing this and shifting my paper  
21 around trying to read what are supposed to be pretty ideal  
22 labels I think. So, that's just a comment I would make.

23                   DR. D'AGOSTINO: I think that is a good  
24 comment.

1                   Are there other comments related to this?

2                   (No response.)

3                   DR. D'AGOSTINO: Why don't we move to the  
4 second one then? The agency has proposed to make the  
5 accidental overdose/ingestion warning more concise --  
6 change from "In case of accidental overdose or ingestion,  
7 seek professional assistance or contact a Poison Control  
8 Center immediately" to "In case of overdose, get medical  
9 help right away" for oral drugs and "If swallowed, get  
10 medical help right away" for topical drugs. We're asked  
11 again to comment and, if our recommendation is different,  
12 to provide some reasons.

13                   I think this is not a situation of a vote but  
14 rather comment on the wording that is being suggested.  
15 This is certainly the discussion where I think we'll bring  
16 back the poison control center, all the items we've heard  
17 and all of the people that have mentioned that.

18                   But who would like to begin the discussion on  
19 this particular item? Everybody is happy? Cage?

20                   DR. JOHNSON: Well, I would strongly support  
21 the inclusion of the poison control center as a source of  
22 assistance in case of overdose, rather than restrict it to  
23 the somewhat nebulous "get medical help."

24                   DR. D'AGOSTINO: Well, there was a comment made

1 that if you get medical help, that suddenly you might start  
2 seeing the emergency rooms being overfilled with people.  
3 Do we think that that is a possibility? Is the word  
4 "medical help" so loose that it implies that? Because I  
5 think that's very serious. Kathleen?

6 MS. HAMILTON: I do think that's a genuine  
7 concern. I know every community has different experiences  
8 with this, but being familiar with the California  
9 experience, the emergency rooms are the physicians of first  
10 resort often in California. I think it's really an  
11 invitation to an emergency room presentation.

12 So, I want to second the various comments that  
13 have been made to reinsert an advisory to contact a poison  
14 control center, and I do think that for both reasons. One,  
15 I think that may be the best resource and I do think that  
16 it could produce presentations at the ER that aren't  
17 indicated and aren't going to give the best quality of  
18 support.

19 I'd also like to raise a question of whether or  
20 not it's appropriate or adequate to limit this advisory to  
21 "in the case of an overdose or accidental overdose." I'll  
22 defer to the physicians pharmacists on the committee, but  
23 it occurs to me that patients could have severe reactions,  
24 either allergic reactions or drug interaction reactions, or

1 a misuse of the product, a misapplication, a  
2 misappropriation of the product that could also result in  
3 some need for immediate medical care. So, I ask the  
4 question whether or not we want to limit that comment to  
5 overdose or to expand it somewhat.

6 DR. D'AGOSTINO: Ted, did you have a comment  
7 related to that?

8 DR. TONG: Well, I was just going to respond to  
9 your question. I imagine in our community, 911 would be  
10 another resource where people who would read this would  
11 contact, and it would just delay reaching the poison center  
12 because in communities where poison centers are functioning  
13 -- and we've heard compelling discussion today from a  
14 number of areas that it is -- that we're just delaying  
15 getting the call to the poison center.

16 DR. D'AGOSTINO: Cage?

17 DR. JOHNSON: I want to emphasize what Kathleen  
18 said. I think the poison center is the source of the most  
19 topical and the most accurate information in cases of  
20 accidental overdose. But I want to separate the toxicity,  
21 drug interaction, adverse drug experience which I think  
22 comes in the "stop using this product" part and then ask  
23 your physician or other health care worker to help you with  
24 that part. I think that's a separate aspect.

1 DR. D'AGOSTINO: I do also and I think that  
2 that will be picked up.

3 DR. BRASS: I was just going to comment I agree  
4 with everything that has been said, including that I was  
5 going to comment that I think 911 becomes the emergency  
6 access of last resort.

7 But there's sort of a logical corollary to this  
8 discussion and that is what we really say is necessary is  
9 that there be a 1-800 standardized number for all poison  
10 control centers and phone switching can actually connect  
11 you to the closest poison control center or even right at  
12 the same number. Then you could actually put that number  
13 on the label reachable anyplace in the United States. All  
14 of a sudden, you really have a meaningful access that  
15 addresses both concerns.

16 DR. D'AGOSTINO: Ted?

17 DR. TONG: I have a vested interest in this, of  
18 course, having started a poison center and managing two  
19 others. What Dr. Brass is commenting on may happen because  
20 the technology is there to allow for a national toll-free  
21 poison center number. Rose Ann Soloway is not here, but I  
22 know -- oh, Rose Ann is here. Am I correct in that there  
23 is effort in developing that process?

24 MS. SOLOWAY: It would be ideal to have a

1 national 800 number for poison centers, and our poison  
2 center directors have addressed this issue and certainly  
3 would like it. The issue for now is money. The technology  
4 has become available and finding a way to actually put that  
5 into effect would be a wonderful next step. But we all  
6 agree with you on that.

7 DR. D'AGOSTINO: I have a question to ask here  
8 for the committee the way the discussion is going. I think  
9 there's sentiment that poison control centers certainly  
10 should be in there. There are also comments that "medical  
11 help" may actually be confusing.

12 Are there other terms, other sources for  
13 overdoses? Are we suggesting the way the tone is going  
14 that we think it should be poison control centers and  
15 nothing else, or do we have open other options and what are  
16 those other options?

17 DR. BRASS: Well, the current language is  
18 "professional assistance" I think. Is that correct? I  
19 don't know if that terminology is understandable by  
20 anybody, much like health care provider or health care  
21 professional. I don't know if anybody knows -- and we'll  
22 talk about that later, but I think "seek medical assistance  
23 or contact" or "seek medical help" actually. "Get medical  
24 help." I'll get there eventually.

1 (Laughter.)

2 DR. BRASS: I think I've changed every word  
3 now. So, I think it's okay.

4 DR. D'AGOSTINO: Cage?

5 DR. JOHNSON: Yes. I would think that in this  
6 kind of situation, the poison control center should be  
7 first as your route of contact because they're the place  
8 where the knowledge is. Even if you call your personal  
9 physician, that physician may not have the expertise to  
10 deal with the poisoning, accidental overdose. If your kid  
11 has just swallowed 100 of some kind of tablet, and you're  
12 all excited, 911 might be the first number you would call  
13 and that would be very unfortunate because it may be a  
14 while before you get routed to the right place. So, I  
15 would strongly support the poison control center being  
16 first and physician help of some sort being secondary.

17 DR. D'AGOSTINO: That seems to be the sentiment  
18 of the committee.

19 Any further comments on that?

20 (No response.)

21 DR. D'AGOSTINO: Then we move to the third one,  
22 which is "ask a doctor" is the phrase proposed in the  
23 warnings section. Should this wording be expanded to  
24 include other health care professionals? If so, provide

1 alternative phrasing. Explain your choice. Please discuss  
2 whether you would recommend specific phrases for certain  
3 OTC drug products, dentists, so forth and so on.

4           Before we begin the discussion, I think as  
5 Chair I should throw in something. I've found the sort of  
6 "Ask your doctor. These may be signs of serious  
7 conditions" put at the bottom somehow or other to be  
8 jarring, and the suggestion that was made "stop using this  
9 product and ask your doctor or call your doctor" I thought  
10 was actually a fairly nice suggestion.

11           After having said that, are there other  
12 comments on the question? Eric?

13           DR. BRASS: I have to preface this by saying  
14 that I believe extremely strongly in the role of nurse  
15 practitioners, physicians' assistants, pharmacists, and  
16 dentists in the health care continuum, and I have all of  
17 them in my primary care environment.

18           My only issue is what's conveyed to the  
19 consumer and do they understand what's being said. I know  
20 for the patients who are in my practices who have a nurse  
21 practitioner as their primary care provider, if they were  
22 told to ask their doctor a question, they would ask that  
23 nurse practitioner. They wouldn't ask anybody else. There  
24 would be no ambiguity about it whatsoever in their minds.

1           I'm concerned that if we adopt more complex  
2     syntax, we will induce more confusion than clarity as to  
3     who they should contact.

4           But again, this is an example where I don't  
5     know. I don't know how the person on the street with an  
6     eighth grade education who speaks English as a second  
7     language is going to interpret these phrases, but I'm  
8     pretty sure that doctor gets a message across.

9           DR. D'AGOSTINO: Cage?

10          DR. JOHNSON: Ralph, I want to second what you  
11     said, that last sentence. "This may be a sign of a serious  
12     condition." I was waiting for something to come next. It  
13     took me a while to realize that went with the preceding  
14     part. So, I think that is adversely communicative.

15          I think the inclusion of a pharmacist as an  
16     alternate source of information at this point is very  
17     important, but I also support Eric's point of view that if  
18     we make it 17 different people you can call, are we going  
19     to be increasing our communication with the consumer or  
20     reducing it?

21          MS. KEENAN: May I make a quick comment?

22          DR. D'AGOSTINO: Yes.

23          MS. KEENAN: In Maryland, I had worked a lot  
24     with Medicaid clients and we have adopted "ask a doctor,"

1     although we know that it doesn't meet all the criteria, of  
2     course, because when we did ask -- I did a quick, not a  
3     formalized study, but I did go to inner city clinics, and  
4     when asked, people did recognize health care professional,  
5     but that also could be an acupuncturist, massage therapist,  
6     anybody. So, we did and for our state that is acceptable.

7             DR. D'AGOSTINO: What about the comment of  
8     "doctor" versus "physician"? Is the word "doctor" clear  
9     enough in this context? It is a label of a drug.

10            Well, let's go through the a, b, c, to make  
11     sure we understand what we're suggesting here or agreeing  
12     what we're suggesting. Should this wording be expanded to  
13     include other health care professionals?

14            The few members who did speak on this said yes,  
15     but along the way is the concern that if you make it too  
16     inclusive, then it might be confusing and defeat its  
17     purpose. Is that the right sentiment of the committee?  
18     Beth?

19            MS. HAMILTON: My general suggestion is that we  
20     use health care professional. I have some concern that if  
21     we limit it to "consult with a doctor," that one result  
22     will be that consumers won't consult with anyone, that they  
23     either don't have a doctor or they don't have an  
24     established relationship with a doctor, they don't have a

1 doctor that they can telephone and get an answer. They may  
2 have a more accessible relationship with some other  
3 category of health care professional. Certainly the  
4 pharmacist falls into that category and is arguably more  
5 readily available.

6 So, I worry that what will happen if we don't  
7 let consumers know that they should consult with the health  
8 care professional of their choice and then trust that  
9 health care person who is sought out to know whether or not  
10 this is something you need to talk with your personal  
11 physician about, the pharmacist to know whether or not it's  
12 within the pharmacist's area of expertise or the situation  
13 is more particular and requires physician consultation. My  
14 inclination is to think consumers will seek out  
15 consultation more if we don't limit it to doctors.

16 DR. BRASS: I agree with everything you've said  
17 if I was assured that a consumer reading "health care  
18 professional" knew that included pharmacists and excluded  
19 hair dressers.

20 MS. HAMILTON: I would support specific  
21 language excluding hair dressers.

22 (Laughter.)

23 DR. D'AGOSTINO: Beth, did you have a comment  
24 or question?

1                   MS. SLINGLUFF: Obviously I've already really  
2                   stated my opinion on this. I do think that the inclusive  
3                   term "health care professionals" is probably indicated  
4                   here. There are obviously a number of health care  
5                   professionals who are in a position to provide good advice  
6                   to consumers on how to use an OTC product, what to do if  
7                   you're having problems with the OTC product. We've listed  
8                   the various professionals under that category several times  
9                   around the table. It's not practical to suggest that we  
10                  can list all those professionals by name on the label.

11                  I understand exactly what you're saying, Eric.  
12                  I had a meeting with a group of nurse practitioners before  
13                  I came to this meeting. I got hammered that I had to go  
14                  and I had to present the party line. And I really do  
15                  believe that, and at the same time, I was also saying to  
16                  them, you know, we're talking about people with eighth  
17                  grade educations. Do they really understand the term  
18                  health care professional? I really believe that they  
19                  probably do and I do not have any data to support that  
20                  opinion, but I think it is the most logical, reasonable  
21                  thing to do with the information we currently have  
22                  available to us.

23                  DR. D'AGOSTINO: Cage?

24                  DR. JOHNSON: I'm forced to agree with

1 everybody at the table.

2 (Laughter.)

3 DR. D'AGOSTINO: Quick, take a vote.

4 (Laughter.)

5 DR. JOHNSON: I want to hold out for the  
6 pharmacist for two reasons. One, the pharmacist is likely  
7 to be the most knowledgeable about the vast majority of  
8 drug interactions. Face it. If you ask me about a drug, I  
9 may or may not have ever used the drug. I may not even  
10 know what it is. The pharmacist is most likely to know  
11 many more drugs than the physician is going to know.

12 And too, the pharmacist is most likely to be  
13 available because there are 24-hour chains, and at 10  
14 o'clock at night or even later, the pharmacist may be the  
15 easiest person to get to.

16 So, I agree that your doctor may include all of  
17 these health care professionals that we think are adequate  
18 sources of information, but I really want to hold out for  
19 specifically identifying the pharmacist and giving the  
20 consumer permission to ask him.

21 DR. D'AGOSTINO: Other comments?

22 DR. KODA-KIMBLE: Ralph?

23 DR. D'AGOSTINO: Yes, Mary Anne?

24 DR. KODA-KIMBLE: I actually think we ought to

1 promote the idea that consumers ought to consult with their  
2 pharmacist in selecting over-the-counter medications as we  
3 become more complex in the nonprescription market. I see  
4 things coming through the committee that, frankly, I'd feel  
5 more comfortable with if someone did consult. I'd be more  
6 likely to say, yes, let's put this out there if that were  
7 the habit of consumers. I do realize that these are sold  
8 in grocery stores and 7-11s and that sort of thing, but I  
9 do think we heard some evidence here that the vast majority  
10 of nonprescription drugs are sold where pharmacists are  
11 available. And I'm not saying pharmacists are always  
12 available either. But if asked, I think more and more  
13 pharmacists are willing and are likely to consult with a  
14 patient, and this is an area of expertise. You can count  
15 on that.

16 DR. D'AGOSTINO: I do want to call the  
17 committee's attention to the "ask a doctor" appears a  
18 couple of times, and you're obviously talking about the  
19 front end "before the use"?

20 DR. KODA-KIMBLE: I think that the consumer is  
21 most likely to ask when they are making the decision, and  
22 when they are making the decision, I agree that nurse  
23 practitioners are qualified. I agree that physicians are  
24 qualified, but the physician and nurses are not there.

1 Frankly, the ingredients of these over-the-counter products  
2 change from time to time.

3 I really love the labeling that's proposed  
4 because I've got everything I need on the first two lines  
5 of the label if I'm a pharmacist. If patients were  
6 carrying around these drugs to the nurse practitioner and  
7 the physician, I think they'd be in equal position to  
8 advise. But I think the majority of the time it's going to  
9 be the pharmacist.

10 DR. D'AGOSTINO: Just to make sure we are all  
11 saying the same thing, when we have this discussion about  
12 "ask a doctor," there is the before use and there's also  
13 "ask a doctor" if you stop using the product. Does our  
14 previous discussion relate to both of those, that we're  
15 talking about both health professionals and pharmacists at  
16 both of those points, or are we emphasizing more the "ask  
17 the doctor, ask the pharmacist, the health professional"  
18 before use? Maybe we should take both of those items  
19 separately?

20 DR. BRASS: I think there's a difference, but I  
21 think I would actually advocate not making that difference  
22 too large simply because in the spirit of all these people  
23 acting as professionals, if a pharmacist was asked a  
24 question that clearly required a physician, the pharmacist

1 would tell the patient to go see a physician. They  
2 wouldn't try to manage the problem inappropriately.

3 So, I think that whatever is agreed to works  
4 well, though the "stop using the product" -- and then again  
5 I agree with the language that was suggested by the NDMA,  
6 whatever that was, because it incorporated the "ask a  
7 doctor" into the one sentence, that is, if a problem has  
8 developed. But I would suspect most of those could  
9 actually be handled by a pharmacist as well.

10 DR. D'AGOSTINO: I just wanted to make that  
11 clear, that we were talking about both of these in our  
12 recommendations.

13 So, I guess the sentiment is that we do think  
14 it could be expanded to others, and there have been some  
15 strong feelings about the pharmacist. Then there have been  
16 also feelings about the nurse practitioner and even the  
17 health care professional. The health care professional  
18 seems to be diminished somewhat, though, in terms of the  
19 advisory committee's willingness to make a suggestion that  
20 that's a good term. Is that correct?

21 MS. HAMILTON: I wonder if there would be any  
22 exception taken to "pharmacist or other health care  
23 professional."

24 DR. D'AGOSTINO: Bill?

1 DR. SOLLER: Well, I just wanted to make a  
2 comment that we've had basically a 25-year history of use  
3 for health care professional on the label and collapsing  
4 those warnings into a health professional warning I think  
5 adds to the flow of information, as well as to our ability  
6 to optimize the type size because we do get some space  
7 savings.

8 We advocate something like health professional  
9 as a catchall word, and the reason is it allows us to put  
10 that into a concise two words and incorporate a number of  
11 different professionals that are important to self-care  
12 therapeutics in practice today.

13 I'll be very brief. We get more information in  
14 our pediatric practice from Nurse McDonald than we get from  
15 our pharmacists, and that's not a criticism against  
16 pharmacists. It's how a mother deals with children and  
17 what her main source of orientation is. Our experience has  
18 been that the dental practice is much more knowledgeable,  
19 as an example, than going to a pharmacy, and that's how  
20 people orient their information transfer in the oral care  
21 area.

22 So, our very strong plea would be to capture  
23 the concept of health professional into a very concise  
24 phrase and that would basically maintain FDA's policy which

1 has repeatedly been looked at over the years and repeatedly  
2 has defended the use of health professional on the label.

3 Thank you.

4 DR. D'AGOSTINO: Now, Bill, would you stay up  
5 just for a second?

6 You're saying doctor and health professional?

7 DR. SOLLER: Where there needs to be a  
8 diagnosis, we'd say doctor. That's how we would basically  
9 cut that. So, the first one would be "ask a doctor before  
10 use if you have" and the contraindicated conditions such as  
11 heart disease, diabetes, thyroid disease for a nasal  
12 decongestant. "Ask a health professional before use."  
13 That would incorporate doctor. Then we would include, for  
14 example, the pregnancy/nursing warning or drug-drug  
15 interactions. And then "stop using and ask a doctor." At  
16 that point, at least as we've looked at the labels, an  
17 individual was getting into a situation where they probably  
18 had to contact and maybe even go into a diagnosis  
19 situation. So, at least as we're looking at it today,  
20 that's where our group is netting out.

21 DR. D'AGOSTINO: So, where you feel it  
22 appropriate, you would replace "ask a doctor before use"  
23 with "ask a health professional before use." I understand  
24 that those conditions that need to be diagnosed say

1 doctors.

2 DR. SOLLER: It doesn't change the current  
3 warning for pregnancy/nursing. I think many of the  
4 original panel suggested doctor or pharmacists, and then  
5 the agency, as they went through the monographs and came to  
6 final monographs, changed that to health professional.

7 So, what we were trying to do was to create the  
8 kind of framework that would allow us to sort of leapfrog a  
9 re-review of all monograph ingredients and be able to have  
10 the kind of skeleton framework that could be applied across  
11 the entire board. So, we created these subheadings that  
12 would allow the final monograph wording to be used by  
13 fitting into either doctor or to health professional. We  
14 provided a reformatting of all the final monograph language  
15 in our November 14, 1995 proposal to FDA to support that.

16 DR. D'AGOSTINO: And we have "ask the doctor  
17 before use," and putting aside the conditions that have to  
18 be diagnosed, we have "ask a health professional before  
19 use." Does the advisory committee have comments on that  
20 range? That doesn't include the pharmacist explicitly or  
21 the nurse explicitly but the term "health professional."

22 DR. BLEWITT: Ralph, just to make a suggestion  
23 here, all of this comes under the overall theme of  
24 consolidating the text, the warnings text. Just for

1 review, page 31 of Dr. Soller's presentation enables us to  
2 take a look at that. I would suggest that it's sort of a  
3 hierarchy of warnings, starting with the absolute  
4 contraindications, relative contraindications, and this  
5 compares the FDA and NDMA. I think that's probably the  
6 best example, don't you?

7 DR. SOLLER: Yes. It's side by side.

8 DR. BLEWITT: What you have there is "ask a  
9 doctor before use if you have," and so that would be  
10 diabetes or hypertension or something like that. Then the  
11 health professional would be pregnant or breast-feeding,  
12 sedatives or tranquilizers such as drug-drug interaction  
13 concerns, and then an alcohol warning or alcohol-drug  
14 interactions. So, that's the hierarchy, if you will, of  
15 warnings which also takes you back to Dr. Brass' comment  
16 about certain things that the pharmacist isn't going to  
17 address. You need the doctor to address those.

18 DR. D'AGOSTINO: I think that's a good page  
19 actually for what I was trying to get the discussion on.

20 Beth?

21 MS. SLINGLUFF: Okay. I would like to depart  
22 from that recommendation.

23 I think there is absolutely no reason why in  
24 any case where you currently have in the label "ask a

1 doctor" you can't put ask a health professional. There  
2 are, as Eric pointed out, many nurse practitioners as well  
3 as P.A.s who diagnose and treat patients with chronic and  
4 acute illness. I do. Lots of nurse practitioners in my  
5 state do. There's no reason why you can't use the all-  
6 encompassing term health professional in each scenario  
7 here. I think it's less confusing. I think it becomes  
8 confusing to say you have to ask a doctor under these  
9 conditions, but you ask a health professional under these  
10 conditions. I think you just replace everything. Instead  
11 of saying "ask a doctor," you put "ask a health  
12 professional."

13 Now, the second part of that is that there are  
14 times I absolutely call a pharmacist myself. I don't know  
15 what to do with this particular drug if the patient is  
16 taking drugs from multiple different providers. There are  
17 times that the pharmacist would be asked and they'd say,  
18 you know, this is a really good question for your own  
19 personal physician. I think we all refer and use each  
20 other as resources. But I think that in terms of an OTC  
21 label that's the least confusing and the most consolidated,  
22 you just put "ask a health professional."

23 DR. D'AGOSTINO: I thought there was a  
24 sentiment in the committee that health professional by

1       itself might be a bit too loose. Did I misread that?

2                   DR. BLEWITT: Well, that probably puts it in  
3       its loosest sense if health professional will now encompass  
4       physicians as well as everyone else in the chain -- or the  
5       continuum I should say.

6                   DR. D'AGOSTINO: Kathleen?

7                   MS. HAMILTON: Well, I essentially support  
8       Beth's comments and I am comfortable with having consistent  
9       language that says "health care professional." However, my  
10      preference would be pharmacist or other health care  
11      professional.

12                   I think that some of the interesting data that  
13      we've heard over time and certainly today demonstrate this  
14      sort of growth of the OTC industry, the OTC consumer  
15      market, and we have an opportunity here, as we standardize  
16      these labels, to educate consumers on who their specialist  
17      is on OTC products, and that specialist is a pharmacist.  
18      We have a wonderful opportunity to begin to let the public  
19      know that this is a specialist that they can consult with.  
20      I think there are lots of people that don't know that.  
21      This is an area of expertise that has grown over the last  
22      20 years. I know older people that don't know that. I  
23      know younger people that don't know it, and we have an  
24      opportunity here to educate the public that we don't get

1 very often.

2                   So, I would be comfortable, quite honestly,  
3 with health care professional, but my personal  
4 recommendation and choice would be pharmacist or other  
5 health care professional.

6                   DR. D'AGOSTINO: The last meeting we had  
7 dealing with lipid lowering drugs possibly going over the  
8 counter and so forth, some of us had concerns that one may  
9 really need a doctor and may need the appropriate tests and  
10 so forth to diagnose what level, say, the cholesterol is.  
11 Are we saying now that other health professionals can do  
12 that, or are we saying that doctors should do that?

13                   DR. BRASS: Well, clearly for any specific  
14 agent, one can recommend specific language based on the  
15 specific agent. That's always possible to do.

16                   But again I'm just struck by a couple of  
17 things. I can't overemphasize how much I agree with the  
18 sentiment about health care professionals and their role in  
19 modern health care delivery. But we're talking about  
20 things that are at the expense of valuable space on the  
21 label which compromises everything we said about point 1.  
22 Every word we add to the label decreases the size of those  
23 words.

24                   The second is I do not feel professionally

1 qualified to say how the consumers, particularly the kind  
2 of consumers I have in my facility, will interpret this  
3 language and whether they will read it in the same  
4 enlightened way we will. So, I just completely agree but  
5 don't know what's right in this context.

6 DR. JOHNSON: I think that sums up the feeling  
7 pretty good.

8 (Laughter.)

9 MS. KEENAN: I don't mean to beat a dead horse  
10 at all, but I've worked in literacy for so long that if we  
11 say "ask a pharmacist or other health care professional,"  
12 I've got 14 syllables and I've raised my readability quite  
13 a bit versus "ask a doctor," 4 syllables. I've just worked  
14 so much with inner city people, that I'd be concerned the  
15 message wouldn't get through.

16 DR. D'AGOSTINO: You'd be concerned what?

17 MS. KEENAN: When you raise your syllable  
18 levels -- there are so many things to readability, and this  
19 isn't the proper forum. But 14 syllables versus 4 or even  
20 "ask a health care professional," I just become more  
21 uncomfortable that people who really need to gain those  
22 services -- they'll skip over the words. The term  
23 "pharmacist" is an extremely hard word to read.

24 DR. D'AGOSTINO: Well, the word "pharmacist" --

1 I think many of those people you are describing will in  
2 fact know what a pharmacist is. They may not know what a  
3 health care professional is in a generic sense.

4 So, we've gone nowhere with helping you on  
5 this.

6 (Laughter.)

7 DR. BOWEN: Mixed I think is what we got out of  
8 this.

9 DR. D'AGOSTINO: But I think we should focus  
10 again on it. Let's go back. We have the "ask a doctor"  
11 and it has been mentioned that we're talking about before  
12 use and then if there's any adverse effects coming on. But  
13 a number of people on the committee have suggested that the  
14 "ask the doctor" is probably appropriate with confusion  
15 being generated beyond that, but then certainly others have  
16 also said that they think the pharmacist and health care  
17 professional should in fact be considered. Some of us have  
18 taken the extreme position that health care professional is  
19 all we need. But we do have a real divergence.

20 I'd really like to go through the committee and  
21 find out where the sentiment on this. Maybe what we should  
22 do is just poll the committee. It's not a vote but rather  
23 polling. Mary Anne, do you want to start by sort of  
24 telling us what you believe?

1 DR. KODA-KIMBLE: Well, I think I've told you  
2 what I believe.

3 DR. D'AGOSTINO: Would you repeat it?

4 DR. KODA-KIMBLE: It's very uncomfortable to  
5 talk when you're a pharmacist, but I'm not sitting in a  
6 pharmacy and all those things.

7 I, honest to God, believe that the specialist  
8 in over-the-counter medications -- and I do understand the  
9 podiatrists know foot care products better, dentists  
10 understand dental products better, et cetera. But overall,  
11 generally speaking, a pharmacist is the most articulate and  
12 expert member of the health care team as it relates to  
13 over-the-counter drugs.

14 And I am thinking into the future, and I am  
15 thinking about the kind of Rx to OTC switches we may be  
16 considering. In fact, even at this meeting we're  
17 considering an agent which I think would feel safer about  
18 if it were behind the counter in a pharmacy. We're not  
19 going to have "sold in pharmacies only."

20 So, given that reality, I just echo what  
21 Kathleen says. We have an opportunity here to change the  
22 culture in terms of health care in terms of what the  
23 consumer expects of this person called a pharmacist.

24 DR. D'AGOSTINO: Yes, but I think she's saying

1 use the word "health professional" not "pharmacist."

2 DR. KODA-KIMBLE: Well, I'll say "pharmacist."

3 DR. TONG: Can I get a clarification on Mary  
4 Anne's comment?

5 DR. D'AGOSTINO: Yes, please do.

6 DR. TONG: Is it simply "ask the pharmacist"?

7 DR. KODA-KIMBLE: Yes.

8 DR. TONG: Okay.

9 DR. McGRATH: I find this a very interesting  
10 and challenging question. I very much support the use of  
11 health care providers, but this is without any data except  
12 what we see in our pain clinic working with families and  
13 children. People don't know what the word means. They  
14 interpret it based on who they have most access to and  
15 that's an array of individuals who vary in content  
16 expertise.

17 My feeling is people are in some sense, if you  
18 want to use the word, "downloading" care to the community,  
19 sometimes with very early releases from hospital, that  
20 often primary care physicians are not as familiar with the  
21 combination of OTC and prescription medication that people  
22 are on. I think pharmacists are an untapped resource and  
23 in some cases the first line of defense.

24 For those reasons -- the committee has concerns

1 about obviously labeling space, but I like the idea of  
2 simply "ask a doctor" because of the interpretation or  
3 possible misinterpretation. While we as a society try to  
4 educate people about what health care providers are, I  
5 think right now the current level of knowledge is not  
6 adequate to substitute that term.

7 I would be prepared to do "ask a doctor and  
8 check with your pharmacist" or "and pharmacist."

9 I also think that perhaps the pharmacies need  
10 to begin to put up big signs saying, "Check with the  
11 pharmacist. Confused by the array of products?" But  
12 things like that to help the common person understand that  
13 they have a variety of knowledge and depth of experience.

14 So, I'm not sure this helps us out of the  
15 muddle, but it's a difficult issue because I think health  
16 care provider means different things to different people.  
17 I am concerned, as I said based mainly on clinical  
18 experience, that people could not get the information they  
19 need if we use that kind of labeling.

20 DR. D'AGOSTINO: Eric?

21 DR. BRASS: I'm going to give you my rank  
22 order. Number one, a doctor. Number two, a health  
23 professional. Number three, a doctor or pharmacist.  
24 Number four, a health care professional or pharmacist.

1 Notice I don't have health professional or pharmacist  
2 because I consider a pharmacist a health professional and  
3 therefore the clause is unnecessary.

4 DR. D'AGOSTINO: Cage?

5 DR. JOHNSON: Eric and I both work in the same  
6 city. Despite that, I'm swayed by Dr. Koda-Kimble's  
7 argument and by Ms. Hamilton's argument. I think the  
8 pharmacist is the expert here.

9 I think the point articulated by Bill Soller,  
10 representing the NDMA, is not an incorrect point, and I  
11 understand the hierarchy of diagnosis, questions, acute  
12 complications. Ideally the physician may be the most  
13 appropriate in some of those situations.

14 The point made by the literacy people that the  
15 smaller the words, the more you communicate is a very good  
16 point. I think that phraseology is also very appropriate.

17 But I prefer the pharmacist because I think  
18 that is the expert. That is the right individual to cover  
19 most of the field in this situation.

20 And that's 34 percent for "the pharmacist," 33  
21 for "ask your doctor," and 33 for "health care  
22 professional" or some variation thereof. These are all  
23 proper. They are all correct. Pick the best one. This is  
24 like internal medicine. Make a life and death decision in

1 the next three minutes on no information. You have no data  
2 supporting any of the choices.

3 DR. D'AGOSTINO: It's less dramatic here,  
4 though.

5 (Laughter.)

6 DR. JOHNSON: Yes, that's true.

7 DR. D'AGOSTINO: Beth, did you have a comment  
8 on that?

9 MS. SLINGLUFF: Okay. I'll rank order my  
10 choices. Acknowledging everything that has been said, I  
11 absolutely bow to the literacy experts. I don't doubt at  
12 all that "health care professional" is a more difficult  
13 term than "doctor." Having said that, I still think that  
14 "health professional" or "health care professional" is the  
15 most all-inclusive term. If that were not an acceptable  
16 phrase to the agency, I would then secondarily recommend  
17 the phrase "pharmacist or doctor."

18 DR. D'AGOSTINO: Ted?

19 DR. TONG: Here goes self-interest again. No.

20 I'm a little disturbed that our literacy expert  
21 has brought out the point that people would have difficulty  
22 recognizing pharmacists or a health care professional. If  
23 I had my druthers, that's what I would want to see.

24 There are probably issues on over-the-counter

1       selections that I think a pediatrician or a podiatrist  
2       might be the appropriate individual, and that interaction  
3       goes on in the doctor's office.

4                I do know that pharmacists are extending  
5       themselves to take on the responsibilities of counseling  
6       and advising on over-the-counter preparations, and I think  
7       that's a very important part of the pharmacist's  
8       responsibility.

9                But you really want an opinion. I'll recommend  
10       to the FDA staff that we consider pharmacist and a health  
11       care professional. Perhaps our literacy persons can help  
12       us in terms of somehow getting that to our patients to help  
13       them understand those syllabuses because they are important  
14       for their care. So, I opt for a pharmacist or a health  
15       care provider.

16               DR. D'AGOSTINO: And not "doctor"? Ted, you  
17       would drop "doctor" from that?

18               DR. TONG: I'm including physicians in the  
19       health care provider.

20               DR. D'AGOSTINO: Health care professional.

21               DR. TONG: I'm not knocking doctors out of this  
22       at all.

23               DR. D'AGOSTINO: No, but not the word "doctor."

24               DR. TONG: Right. "Pharmacist or a health care

1 provider."

2 DR. D'AGOSTINO: George?

3 DR. BLEWITT: May I comment?

4 DR. D'AGOSTINO: Yes, please.

5 DR. BLEWITT: I recall it may have been the  
6 first NDAC meeting of all time, and Dr. Weintraub made  
7 comments at that time about the changing role of the  
8 physician in the health care system. Although he didn't  
9 define what it was exactly, he did mention that it was  
10 changing, and it certainly has.

11 I am not at the point yet where I'm comfortable  
12 -- and I don't think the system is at the point yet where  
13 you can be comfortable -- that a doctor doesn't play a key  
14 role in certain decisions regarding OTCs, particularly  
15 where there are certain disease states that are present  
16 where a physician knows what medications are being taken  
17 and, if it's a good physician, has access to databases that  
18 can tell him about drug interactions and so forth. So, I  
19 think there's good reason to retain "a doctor."

20 In a sense, there's the doctor -- in my view  
21 anyway -- and there's the rest of the health care  
22 armamentarium, the accessory facilities, if you will, that  
23 exist. I would be inclined to group them under health  
24 professional at this point rather than to try to split them

1 out in any specific way.

2           Somebody raised a point earlier about, well,  
3 what's the skill base? The skill base could be different  
4 for different people and different backgrounds. A  
5 pharmacist has a different base than a nurse practitioner,  
6 for instance. Well, if you try to work through all of  
7 those issues, then you're not going to solve the problem  
8 that's here.

9           So, I would be more comfortable today, 1997, in  
10 having a physician and then the health care professional  
11 because I think most people recognize that pharmacists are  
12 health care professionals. So, I would suggest, given  
13 that, that the hierarchy that has been described here by  
14 NDMA and, to a certain extent, by Dr. Brass is acceptable.

15           DR. D'AGOSTINO: Kathleen?

16           MS. HAMILTON: I'm inclined to prefer  
17 "pharmacist or other health care professional," although I  
18 noticed that Eric dropped the word "care" to shorten the  
19 space a little bit. "Health professional" maybe works.

20           I do think that there's a nuance of a  
21 difference between "professional" and "provider" that's  
22 worth noting.

23           My preference would be both. I'd settle for  
24 "pharmacist" only.

1 DR. D'AGOSTINO: And not have "doctor"? It  
2 would say just "ask a pharmacist before use"?

3 MS. HAMILTON: "Pharmacist or other health  
4 professional," which would include doctors.

5 DR. D'AGOSTINO: So, you got a number of  
6 opinions that would remove the physician from the label.

7 My own opinion is that it would be "doctor and  
8 pharmacist." I think the health professional is still a  
9 bit too ambiguous on what that actually means and it just  
10 goes on and on in terms of labeling, but that's one more  
11 opinion that you can sort of meld.

12 You wanted to say something, Michael?

13 DR. WEINTRAUB: Well, first of all, I was going  
14 to ask you for your opinions.

15 I just want to point out that the ranks are  
16 rank because, unfortunately, you didn't help us very much.

17 (Laughter.)

18 DR. WEINTRAUB: But I think what we can do is  
19 deal with the rank ranks, along with the comments made to  
20 the docket, and figure out what is the best.

21 There is another attempt at that and we'll have  
22 to see about whether we can get that into the studies.

23 DR. D'AGOSTINO: Yes. I think there actually  
24 is a strong sentiment that you heard. I think to a person,

1 the pharmacist is being mentioned. That I think is clear.  
2 And obviously the physician. No one is suggesting the  
3 physician be removed. Does the physician become part of  
4 the health care professional or does the physician stand  
5 alone has been voiced by different people. But I think the  
6 very strong sentiment for the pharmacist is certainly  
7 coming through here.

8 DR. BRASS: I would just like to clarify -- and  
9 feel free to drop everything I said after my first choice  
10 if that helps you in any way, Mike.

11 (Laughter.)

12 DR. BRASS: But I specifically said "doctor"  
13 not "physician" because I think doctor has a meaning in lay  
14 usage which is different. I don't think it means to the  
15 average person a person who graduated from a four-year  
16 school of medicine, passed the national boards, then did a  
17 residency, and did et cetera, et cetera. I think in lay  
18 terms it means the person taking care of them for their  
19 health problems, and that was my intent to convey that in  
20 the simplest way as possible and not say M.D., not say  
21 physician, not intent elitism, but try to get the message  
22 across to the population.

23 DR. D'AGOSTINO: I think that was actually  
24 understood in the statements. It was the ranking that got

1 fuzzy.

2           Anyway, I think again certainly the doctor's  
3 role is quite clear, but the addition of the pharmacist is  
4 also being mentioned. Then there are a number of  
5 individuals on the advisory committee who feel that health  
6 care professional is something that should find its way in  
7 the label and is clear enough to many individuals. There  
8 are the literacy and the space problems that one has to  
9 address obviously, but I'd like to move on.

10           Part c of this, explain your choice. We've  
11 been explaining our choices all along.

12           (Laughter.)

13           DR. D'AGOSTINO: But it's the second part of  
14 that, please discuss whether you would recommend specific  
15 phrases for certain OTC products, things with dentists for  
16 oral cavity products. I'd like to get a discussion going  
17 on that. Why don't we start off with Kathleen this time.

18           MS. HAMILTON: I'm not inclined to suggest that  
19 OTC labels include referrals to specific kinds of specialty  
20 doctors. I think that is a literacy issue. That may  
21 actually confuse people, and I'm satisfied that they can  
22 seek the advice of a health care professional or their  
23 pharmacist who in turn may refer them to a dentist or a  
24 podiatrist.

1 DR. D'AGOSTINO: George, do you want to make a  
2 comment?

3 DR. BLEWITT: No, I really don't, other than to  
4 say, although it may not be desirable today, you probably  
5 want to leave the options open for specific cases in the  
6 future. I can't think of what they might be.

7 DR. D'AGOSTINO: Ted?

8 DR. TONG: That's fine.

9 DR. D'AGOSTINO: Beth?

10 MS. SLINGLUFF: I think Kathleen summarized  
11 that succinctly and quite well.

12 DR. JOHNSON: I'll agree with Kathleen with the  
13 proviso that the pharmacist be listed first as the most  
14 expert in the management of over-the-counter drugs.

15 DR. D'AGOSTINO: Eric?

16 DR. BRASS: Hey, they're both doctors. No.

17 (Laughter.)

18 DR. BRASS: I have nothing to add.

19 DR. D'AGOSTINO: Patricia?

20 DR. McGRATH: I have nothing to add.

21 DR. D'AGOSTINO: Mary Anne?

22 DR. KODA-KIMBLE: Nothing.

23 DR. D'AGOSTINO: Having worked with so many  
24 dentists, I'm concerned that there might be conditions

1 actually in fact where the dentist would be appropriate to  
2 be mentioned explicitly on the label. Again, that adds  
3 things but the sentiment of the committee in general is  
4 that they'll find their way to the appropriate person by  
5 going through the doctor. Is that the way I interpret it?  
6 Okay, good.

7 Now we have question number 4. The agency is  
8 requiring that cation information appear in OTC drug  
9 labeling. The header "Dietary Information" has been  
10 proposed to precede this information. Please discuss this  
11 proposal.

12 Is it just going to be mentioning it? I guess  
13 I'm confused on what one does with it when it's in the  
14 label, before we begin the discussion of the proposal.  
15 It's in the label and what is the consumer to do with it?  
16 Is there going to be a script on don't overdo it or  
17 something like that, or is it just going to mention it?

18 DR. BOWEN: Yes. It's just going to list what  
19 it is and how much is in there per dose.

20 DR. WEINTRAUB: When it's over a certain limit.  
21 If it's below a certain limit, you don't have to list it.

22 DR. JOHNSON: Question. This will be in  
23 addition to other ingredients or as part of other  
24 ingredients? I just want to be clear. Is this going to be

1 separate from other ingredients?

2 DR. WEINTRAUB: Well, that's one of the  
3 questions we're asking you, if it should be listed under  
4 dietary information or something else.

5 DR. BRASS: Eric?

6 DR. BRASS: First, for those classes of  
7 products that already have a nutritional label that  
8 contains the information, I don't think there should be  
9 dual provision of the information.

10 Personally I don't like the phrase "dietary  
11 information" because it has an implication that the product  
12 is in some way relevant as a dietary adjunct, or who knows  
13 how it might be construed. So, I would personally prefer  
14 to see it -- if you don't require other ingredients to be  
15 listed, that for products that contain this, require an  
16 other ingredients listing these beyond the label, if you're  
17 going to require these, would be my suggestion.

18 DR. D'AGOSTINO: Any other comments? Mary  
19 Anne?

20 DR. KODA-KIMBLE: I think it might be useful to  
21 know the milligram content of some of these cations.  
22 However, I also agree with Eric that dietary information I  
23 think could be quite confusing to the consumer and might  
24 lead even to some misuse of the product.

1 DR. D'AGOSTINO: Other comments on it?

2 Can I go back to the FDA, either Debra or  
3 Michael? What are the types of responses that you're  
4 looking for? I'm not sure that a yes or no is -- it seems  
5 to me like there's something else that's involved in this  
6 question that we may not be really addressing.

7 DR. BOWEN: Actually I don't think there is.  
8 We wanted to know if this information is required to be in  
9 the label -- because we currently do not require inactive  
10 ingredients to be listed, but for these particular ones, we  
11 will require it -- should it be under a separate heading?  
12 And do you like this heading or are there alternative  
13 headings that you might suggest? Or should it just be  
14 under an "other ingredient" type of heading?

15 DR. D'AGOSTINO: Yes, I guess our sentiment at  
16 this point is "other ingredients" if it's listed. Is that  
17 right?

18 DR. JOHNSON: Yes.

19 DR. D'AGOSTINO: That addresses the four  
20 questions, but there were a number of other suggestions and  
21 concerns that were raised today like the 800 number, for  
22 example. I think it might be good to poll the committee  
23 and see what other concerns or other suggestions. Mary  
24 Anne, do you want to start that? Do you have any sort of

1 residual --

2 DR. KODA-KIMBLE: Well, it's related to this  
3 last issue and it was raised by several members of the  
4 committee early on, that there will be an inactive  
5 ingredients section because I do think there are people who  
6 are hypersensitive to some of these agents, intolerant, and  
7 these agents can actually contribute to some of the adverse  
8 events of some of the over-the-counter agents. So, I hope  
9 that that would be included.

10 DR. D'AGOSTINO: Patricia, do you have any  
11 residual?

12 DR. McGRATH: I don't have any new points, just  
13 one that has already been noted in terms of the confusion  
14 between the word "purpose" and "category," that for the  
15 category information to maybe call it "category" and  
16 "purpose" "use" to really relate to that.

17 DR. D'AGOSTINO: Eric?

18 DR. BRASS: Just reiterating a couple of  
19 points. First, again given the new premium that's being  
20 placed on space, I think all language -- and again the  
21 issue about driving, the caution -- that any phrase you're  
22 insisting putting on, challenge is this really contributing  
23 to the benefit of the consumer or is it just using space  
24 that could be better used for other things.

1                   And the second about the inactive ingredients.  
2           I just would really encourage the agency to try to get an  
3           assessment of what are the health problems associated with  
4           inactive ingredients, what are their magnitude, and if  
5           there are inactive ingredients that do contribute to health  
6           problems, that at least those ingredients be required to be  
7           listed, just as you're doing for sodium.

8                   DR. BOWEN:  Actually that is something that we  
9           do now when it comes to our attention that there are  
10          problems, such as tartrazine.  There is a requirement.

11                   DR. D'AGOSTINO:  Cage?

12                   DR. JOHNSON:  No, I have nothing further to  
13          add.

14                   DR. D'AGOSTINO:  Beth?

15                   MS. SLINGLUFF:  No, nothing.  Thank you.

16                   DR. D'AGOSTINO:  Ted?

17                   DR. TONG:  I think all the significant comments  
18          have been made at that end of the table, but I do want to  
19          suggest that not as a standard or a regulation, but the  
20          toll-free 800 number on a product is certainly reassuring  
21          to the consumer to say, hey, somebody is responsible.  This  
22          is not to be put into a standard, but I'm sure when you  
23          examine and demonstrate the prototypes of a product  
24          packaging, labeling, that you might look at those that take

1 that responsibility. This is not requesting that it be  
2 mandated, but that a toll-free number to the company is  
3 really reassuring to the consumer, and I've had patients  
4 tell me that, asking me whether they should call that  
5 number for poisonings or other details.

6 But I'm sure the companies who have those  
7 numbers have found it also a good way to respond to your  
8 consumers. So, it may be a marketing issue rather than a  
9 safety or efficacy issue.

10 DR. D'AGOSTINO: George, do you have anything  
11 else?

12 DR. BLEWITT: No further comment.

13 DR. D'AGOSTINO: Kathleen?

14 MS. HAMILTON: I did want to make a couple of  
15 additional comments. One, we haven't talked around this  
16 table about the preemption issue, and I'm actually not  
17 fully prepared to offer much comment on it myself at this  
18 point except to say I'm not entirely comfortable with the  
19 nature of the preemption clauses in the proposal.

20 I guess I should own right up front, some of  
21 you here have economic conflicts related to your medical  
22 professions. I work for a state legislature, so that's my  
23 conflict on the preemption issue.

24 I'd like to look at it in a little more detail,

1 and I will tell you the area of concern that I have is  
2 tobacco related products, especially in California where  
3 we're actually in the process of enacting some disclosure  
4 language. I need to think through and kind of go back and  
5 see whether or not there are implications there that we  
6 maybe ought to bring to your attention. So, I just want to  
7 raise it as an area of concern without having a  
8 particularly thoughtful comment to make.

9           And my other comment is the proposal starts off  
10 with specifying the five elements that sort of characterize  
11 the labeling proposal, and one of the things that isn't  
12 spelled out, although it has been certainly discussed in  
13 some depth here today and it's implicit throughout the  
14 proposed reg, but I'd actually like to suggest that we talk  
15 about a six-prong proposal and that the sixth issue be a  
16 specific intention to simplify language used on OTC  
17 labeling that's designed to enhance practical  
18 comprehension. That isn't spelled out. It's danced around  
19 a little bit.

20           While some of the mockups that we've looked at  
21 from a structural standpoint, formatting standpoint, I  
22 think are terrific improvements and really, really moving  
23 in a great direction -- my compliments to everybody that  
24 participated -- I still find, as I go through the actual

1 mockups, language that I think can be simplified. So, I  
2 want to suggest that we continue to look at that very  
3 specifically.

4 DR. D'AGOSTINO: Thank you.

5 Debra and Michael, Dr. Bernstein, do you have  
6 any comments? Linda? Yes, Mary Anne?

7 DR. KODA-KIMBLE: I don't think we had an  
8 opportunity to really congratulate the FDA and the NDMA for  
9 moving ahead in a major way on this issue. I found the  
10 comments really useful. I'm thrilled every time I see a  
11 label that uses the standard format. I think as a  
12 professional, it makes it really easy to use, and so I hope  
13 that none of these comments were taken as major criticisms  
14 because I do think these are major improvements in  
15 labeling.

16 DR. D'AGOSTINO: Michael?

17 DR. WEINTRAUB: We didn't take them as any  
18 critique. In fact, we're asking for these comments both in  
19 the proposal and with this meeting. So, I appreciate what  
20 you said, and we're really grateful for all of you putting  
21 in the time and effort and I mentioned NDMA and our  
22 colleagues in the cosmetic industry as well. We're  
23 thankful that you're all working on this together --  
24 hopefully together.

1 DR. D'AGOSTINO: Thank you.

2 I'd like to ask the committee members to stay  
3 for a couple of minutes after the adjournment.

4 The meeting is adjourned.

5 (Whereupon, at 4:16 p.m., the meeting was  
6 adjourned.)

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