

1 percent, if you combine somewhat and very confident,  
2 three-fourths again of the population feel confident  
3 that they could use this correctly.

4 So our conclusions: People are already  
5 taking some actions. They are concerned, as you saw -  
6 - Unfortunately, I breezed through it quickly --  
7 people are taking supplements and garlic and these  
8 other products already. They are concerned about it.  
9 They are trying to exercise. They are watching their  
10 diet.

11 Consumers have -- There's a solid belief  
12 in consultation and visitation to the doctor. They  
13 think it's overwhelmingly a good idea if this medicine  
14 were made available, and from that consumers will  
15 still talk to their doctors. They will consult with  
16 pharmacists, and few people will avoid cholesterol  
17 checks and doctor visits.

18 Finally, our recommendations: If such a  
19 product were made available, our recommendations --  
20 Let me stress this. We are not advocating a position  
21 on a low-dose OTC cholesterol medication, but we are  
22 recommending that, if a product does switch into a  
23 nonprescription status, that there be clear label  
24 directions about warning, that it be easy to read and  
25 understand, that there be a large-size type so people

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1 can follow it, that package inserts and other  
2 materials should be easy to understand and read, that  
3 they should see their doctor before taking this  
4 product, and that it should state that clearly on the  
5 label, as well as it should state clearly on the label  
6 that it's important for regular doctor visits,  
7 continued check-ups.

8 Finally, it's important to know your  
9 cholesterol test, to have a cholesterol test  
10 regularly, and important to know the numbers. Know  
11 the warnings, precautions, side effects, who should  
12 take this medicine, who should not, is it appropriate  
13 for you, and there should be an emphasis on  
14 interactions, food-to-drug, drug-to-drug, and dietary  
15 supplement-to-drug, as that's an increasing market.

16 Finally, we feel that there should be an  
17 ongoing consumer education campaign that the FDA and  
18 manufacturers and consumers and everyone should  
19 support since coronary heart disease and cholesterol  
20 are still major causes of death and disability in the  
21 United States. Thank you.

22 MODERATOR DeLAP: Russell, you have a  
23 question?

24 MR. CAMPBELL: I have a question for Linda  
25 Golodner. We were told earlier by James Leyden that

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1 consumers aren't especially interested in some of the  
2 stuff on the small packages. Can you comment on that?

3 MS. GOLODNER: I'm sorry?

4 MR. CAMPBELL: Like cosmetics -- like  
5 sunscreen in cosmetics, small packages.

6 MR. KAY: Are you talking about the  
7 ingredients?

8 MR. CAMPBELL: Yes, the labeling.

9 MR. KAY: About labeling? I think that  
10 this shows that consumers are interested. It may be  
11 that they don't want to read every single ingredient  
12 on the back of a suntan product, for instance, but I  
13 think that they are concerned when it comes to  
14 questions of safety, of precautions, side effects,  
15 clear labeling directions.

16 I think that the data we've had over the  
17 past couple of years has stated clearly that consumers  
18 want that information and, in our opinion, need that  
19 information.

20 MR. CAMPBELL: And what about print size  
21 for small packages?

22 MS. GOLODNER: Print size -- I don't think  
23 there should be any exception for print size. I think  
24 manufacturers can be innovative in packaging so that  
25 the print size can be large enough to read.

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1 This is your only measure of safety. If  
2 that's the only thing that you've got is the label,  
3 you've got to be able to read it. I also wanted to  
4 point out that I think that consumers are more and  
5 more looking at labels probably because of the food  
6 labels that are available now that provide health  
7 information to consumers.

8 If that information is clear and available  
9 on over-the-counter drugs, dietary supplements and  
10 other products, consumers will read it.

11 MR. CAMPBELL: Thank you.

12 DR. WOODCOCK: Bob, I have a question  
13 here. I'd like to know, to what extent do you think  
14 that self-reporting is accurate in your surveys about  
15 reading the labels?

16 MS. GOLODNER: It's hard to tell. I think  
17 probably in doing some mall intercept or, you know,  
18 personal interviews and trying to find out if a  
19 consumer comprehends what's on the label would be a  
20 better survey method.

21 Obviously, some people will say they're  
22 reading the labels when they are not, and knowing data  
23 about those people who can't read or have difficulty  
24 reading, we don't know how much they are able to  
25 comprehend on the label.

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1 DR. WOODCOCK: Thanks.

2 MODERATOR DeLAP: In the instance where  
3 there are multiple products available for a similar  
4 indication, do you have information that would speak  
5 to consumers' confidence in their ability to select  
6 among the different competing products?

7 MR. KAY: We didn't ask that specific  
8 question. Basically, it was a general, if such a  
9 product were available. So we don't have data that  
10 would answer that question directly.

11 I think that some of the issues about  
12 labeling, if it were clear, if it were easy to read,  
13 would help some of that. If consumers can look at two  
14 things and compare them evenly and equally, I think it  
15 will make it a lot easier for consumers to make those  
16 choices appropriately.

17 MODERATOR DeLAP: Dr. Kweder.

18 DR. KWEDER: I had a question, and you  
19 might have said this. I'm sorry if I missed it. In  
20 your surveys was there a -- did you identify people  
21 and screen them out if they -- Did you ask them if  
22 they could read, what their reading level was, and  
23 also whether English was their first language? Was it  
24 only English -- primarily English speakers who  
25 answered the survey?

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1 MS. GOLODNER: It would be English  
2 speakers who answered the survey, and we did not ask  
3 them skill or reading level.

4 MR. KAY: More than half the survey  
5 population, at least in the one I was discussing, has  
6 some or more college education. So that would assume  
7 there is. I can get you -- I have the cross-tabs. I  
8 can give you, you know, below high school or whatever,  
9 but we didn't ask could they read.

10 MODERATOR DeLAP: Well, if there are no  
11 further questions, we'll need to keep moving. Thank  
12 you very much.

13 The next speaker on the agenda is Kaiser  
14 Permanente, Anthony Barrueta, counsel, Government  
15 Relations.s

16 MR. BARRUETA: Good morning. My name is  
17 Tony Barrueta. I'm counsel in the Government  
18 Relations Department at Kaiser Permanente.

19 The reason that we felt it was important  
20 to register our interest in this subject today is  
21 primarily because of the unique nature of our  
22 organization. We're the largest nonprofit HMO in the  
23 country.

24 We serve approximately 8.6 million members  
25 internally through our own organization. There are

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1 10,000 Permanente physicians who treat those patients.  
2 As a pharmacy provider, we have hundreds of pharmacies  
3 in our own facilities. In terms of prescription  
4 drugs, we purchase about \$1.6 billion a year in  
5 prescription drugs. More than 90 percent of our  
6 members have a prescription drug benefit.

7 This issue is particularly interesting to  
8 us in an environment when the prescription drug  
9 benefit is increasing in cost at a range of -- for  
10 Kaiser Permanente it's 17-18 percent a year. For many  
11 other third party payers and those who subsidize  
12 prescription drug benefits, they are seeing increases  
13 in prescription drug costs in the range of 25 and 30  
14 percent a year.

15 In fact, we see a number of public  
16 programs that are experiencing increases in that  
17 range, and this is a very troubling phenomenon, I  
18 think, because it starts to raise questions about the  
19 extent to which what have become very broad  
20 prescription drug benefits will continue to be  
21 affordable.

22 The physicians within our organization,  
23 when they look out at the pharmacopoeia that is  
24 available for treating their patients, they see  
25 certain market anomalies that exist, and they have to

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1 question whether consumers are really getting good  
2 value for money in terms of the money that's being put  
3 forward either in terms of the premiums that they pay  
4 us to provide a prescription drug benefit or paying  
5 out of pocket for particular drugs.

6           You've got my full statement. So in the  
7 interest of time, what I'd like to do is sort of give  
8 you our conclusions, the main concerns that we have,  
9 and see if you have any questions.

10           When it comes to considering prescription  
11 to over-the-counter switches for currently prescribed  
12 drugs, we really believe that the fundamental concerns  
13 need to be prioritized in the interests of patients  
14 and consumers, not necessarily in the interests of the  
15 product sponsors.

16           I think that the discussion so far today  
17 has really flushed this out as an important question  
18 that needs to be addressed by policy makers, not  
19 necessarily FDA alone but policy makers in general.

20           The first concern really has to be  
21 clinical safety. Our sense is that the current  
22 standards that FDA applies in looking at clinical  
23 safety seem to be pretty good. They seem to be pretty  
24 well focused on making sure that patients are not  
25 going to be harmed because a drug becomes available

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1 over-the-counter.

2 Second, the FDA really ought to be  
3 considering whether maximizing access to drugs through  
4 OTC status will be a substantial improvement in public  
5 health, both in terms of their ability to get access  
6 to the therapies in a timely fashion, in a continuous  
7 fashion, but also that the quality of care isn't  
8 impaired.

9 To the extent that certain therapies are  
10 considered to be moved over-the-counter, the specific  
11 questions in specific cases really need to be asked  
12 about whether there is something about prescription  
13 drugs that brings people to their physician providers  
14 and whether we are going to be losing something in  
15 particular areas.

16 I think there's going to be different  
17 answers to those questions in all cases, but it is a  
18 question that really needs to be asked on an  
19 indication by indication and possibly on a drug by  
20 drug basis.

21 Third, the economic interests of consumers  
22 and patients, both individually as patients and  
23 collectively as consumers who ultimately foot the bill  
24 for health care financing, whether as premium payers,  
25 as taxpayers to the state and Federal government, as

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1 workers who receive health insurance in exchange for  
2 lower wages, are really able to have this process work  
3 in their interest, to the extent that there doesn't  
4 appear to us to be in Federal law any specific  
5 property interest of the product sponsors in the  
6 question of whether or not a drug is prescribed versus  
7 over-the-counter.

8 We would really caution the FDA in  
9 designing a new process which may very well be in  
10 order for considering how to decide whether a drug  
11 should be OTC or Rx. Great caution should be made in  
12 designing that process to assure that it doesn't  
13 create a property interest that doesn't currently  
14 exist.

15 In terms of a little bit of specific  
16 information on a couple of specific therapies, I will  
17 say that it is the situation of the non-sedating  
18 antihistamines or the less sedating antihistamines  
19 that has been driving a tremendous amount of provider  
20 interest within our organization.

21 Within Kaiser Permanente, less sedating  
22 antihistamines represent the third largest class of  
23 drug expenditures; and when you have a situation where  
24 it seems to be relatively accepted that allergic  
25 rhinitis, allergies, are the type of drug that really

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1 naturally could be considered to be over-the-counter.

2 There are older drugs that are available  
3 over-the-counter at this point. The key question, it  
4 seems, really ought to be the relative safety, the  
5 relative efficacy of the current Rx drugs as opposed  
6 to what's already over-the-counter.

7 Certainly, the absolute safeties need to  
8 be questioned, but we have had situations where the  
9 product sponsors of the current Rx drugs are  
10 effectively promoting those drugs as having safety  
11 advantages because of the side effect profiles of some  
12 of the OTC drugs. So it really ought to be focused on  
13 the relative safety and efficacy.

14 We did survey physicians within our  
15 organization, and our drug information staff in  
16 Oakland and Downey, California, did review patient  
17 profiles. They went through the computer systems to  
18 try to identify patients who were taking less sedating  
19 antihistamines exclusively. They were treatment naive  
20 to any other therapy, and we came up with something  
21 along the order of 6,000 patients.

22 Within that patient population, there were  
23 approximately 12 cases that were identified where it  
24 was possible that there could be -- It didn't  
25 certainly mean that there was an adverse drug

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1 reaction, but there was information that made it a  
2 possibility.

3 That strikes us as being a fairly low  
4 incidence of adverse drug reactions. Informal surveys  
5 of our chiefs of allergy around northern California  
6 indicated that there was a high level of comfort about  
7 these drugs.

8 What I think this type of information  
9 really suggests is that FDA ought to be looking to the  
10 physicians in the community to get a sense of whether  
11 there are therapies that are available that ought to  
12 be moved over-the-counter.

13 Now one question that I think is  
14 appropriately raised by consumers when an organization  
15 that is a third party payer and finances prescription  
16 drugs -- they want to know, are you just trying to do  
17 this so that you don't have to pay for them anymore,  
18 which is an absolutely legitimate question; because it  
19 goes to the consumer's economic interest in whether or  
20 not a drug is prescribed or Rx.

21 To talk about this, it really requires  
22 talking a little bit about the marketplace dynamics  
23 that are out there. One of the earlier slides we saw  
24 showed that there was a decline in recent years in the  
25 number of drugs being switched from prescription

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1 status to OTC status.

2 Well, during this same period there's been  
3 a massive expansion in prescription drug coverage. So  
4 that in 1990 only about 25 percent of people -- 30  
5 percent of people had some form of prescription drug  
6 coverage. Today 75 percent of people have  
7 prescription drug coverage.

8 It seems quite obvious, if you're a  
9 product sponsor looking at a market like that where  
10 the benefits basically cover prescription drugs but  
11 not OTC drugs, that you're going to want to get the  
12 benefit of that potential subsidy and continue for a  
13 longer period perhaps having that drug be prescription  
14 status, moving it to over-the-counter status when  
15 you're facing a looming generic coming onto the market  
16 and using your brand in order to increase your  
17 profitability in the future.

18 There's nothing wrong with a manufacturer  
19 seeking to do that to pursue their economic interests.  
20 Our concern is really that the economic interests here  
21 have to be balanced. The consumer's interest needs to  
22 be balanced, and not only the consumer's interest  
23 whether or not they are going to be going from having  
24 a co-pay of five dollars to paying out of pocket \$20  
25 or \$25 for an OTC drug, if the benefit is lost.

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1           The consumer interest is also the ultimate  
2 premiums that get paid in terms of the prescription  
3 drugs and whether it makes sense for these types of  
4 costs to be individualized by making people pay out of  
5 pocket at the point of service or whether they should  
6 be part of a prepaid drug benefit. Ultimately, those  
7 are questions that really ought to be worked out  
8 between the consumers and the third party payers who  
9 are managing their drug benefits.

10           As it exists today, the way the process  
11 seems to work, I don't think because of legal mandate  
12 but simply we've fallen into this approach, that it's  
13 really the manufacturers who are the ones who are  
14 driving this process. That's something that probably  
15 needs to be reexamined.

16           Happy to take any questions that you might  
17 have.

18           MODERATOR DeLAP: I think I heard a  
19 comment in your presentation that you weren't  
20 advocating additional property rights for providers of  
21 drugs as part of this process. But I would ask if you  
22 think that there is some way that the incentives that  
23 are available could better stimulate the kind of  
24 behavior that you think would be optimal for the  
25 consumer.

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1 MR. BARRUETA: Well, I think in terms of  
2 providing financial incentives, I really wonder  
3 whether there aren't already adequate financial  
4 incentives for manufacturers to seek to maximize the  
5 profitability of the products that they currently  
6 have.

7 I think the real challenge for FDA and for  
8 the public as a whole is to find processes that are  
9 really consumer focused, to find ways for FDA to tap  
10 into the information that is available in the  
11 community so that there is another access to the types  
12 of safety information that really needs to be looked  
13 at before something can be comfortably moved over-the-  
14 counter.

15 I think, as FDA develops processes in this  
16 area, we certainly look forward to working together  
17 with FDA so that our databases are potentially made  
18 available. I know that other third party payers,  
19 other pharmacy benefit managers keep track of this  
20 kind of information, and it's the kind of information  
21 that exists today. It's not really being used in a  
22 way that can help to support the efforts that FDA, I  
23 think, ought to be pursuing.

24 DR. WOODCOCK: Does Kaiser know anything  
25 about the other costs of having some product, say, be

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1 prescription versus OTC, because from a consumer point  
2 of view or patient point of view, there are costs  
3 other than the out-of-pocket expenses. There's  
4 perhaps time lost off of work, having to go to the  
5 doctor's. For Kaiser you bear the cost of the doctor  
6 visits and the processing. Have you ever looked at  
7 any of that?

8 MR. BARRUETA: We haven't looked at that  
9 systematically. There are a number of studies that  
10 have been done for other purposes in terms of,  
11 particularly, pharmaco-economics studies that are  
12 currently being done to essentially support the  
13 pricing of existing Rx drugs which are trying to  
14 identify those types of costs.

15 Kaiser has participated in some of those  
16 studies to try to identify the extent to which lost  
17 time at work, the cost of coming into the facility,  
18 the cost to the organization, a visit to the  
19 physician. Those are things that are studied in other  
20 areas, and a properly designed study could certainly  
21 be applied in this case as well. But I'm not aware of  
22 any as it relates, really, to OTCs versus prescription  
23 drugs.

24 DR. MURPHY: In your database, the  
25 information you collect -- or is there another

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1 approach to this? -- do you have a mechanism to  
2 collect what products patients call you about that are  
3 OTC that they want information or clarification,  
4 particularly relevant to the prior speaker's  
5 statements that patients will call their doctors.

6 Do you have any way of addressing that or  
7 gathering that information?

8 MR. BARRUETA: Not systematically in the  
9 current database. I think that in the next several  
10 years, as we develop the clinical information systems,  
11 the electronic medical record which is being rolled  
12 out within Kaiser Permanente from kind of the far west  
13 coast in Hawaii east -- I don't think it's going to  
14 get here for a number of years yet, but once that is  
15 done, each of those interactions between the physician  
16 and the patient potentially will be put into a system  
17 that could be studied to try to identify those types  
18 of questions.

19 For now, the best, I think, we can do is  
20 informally surveying the physician experts and trying  
21 to get a sense from them what types of questions are  
22 coming back and the magnitude of those questions.

23 DR. MURPHY: Let me just go down that  
24 path, since you said you survey physicians. It sounds  
25 like you're proposing, when you say ask the doctors

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1 which, of course, we always include the doctors in our  
2 discussions -- are you saying that you think that  
3 there should be a development of a list of products  
4 that physicians feel would be to provide the public  
5 help if they went OTC?

6 I'm asking what you meant by that process.

7 MR. BARRUETA: Oh, I think --

8 DR. MURPHY: In addition to what we are  
9 doing already.

10 MR. BARRUETA: Yes. The sense that I have is,  
11 once there's a drug that's identified or an indication  
12 that's identified as potentially being subject to OTC,  
13 there ought to be significant outreach to physicians  
14 on the front lines, in addition to the experts who  
15 work on your advisory committees.

16 We haven't considered whether physicians  
17 ought to sit down and try to come up with a list that  
18 they think ought to move everything OTC or potentially  
19 look at OTC.

20 DR. HOUN: I had a question on your  
21 statement about making sure that, if the product goes  
22 OTC and you have greater access, that the quality of  
23 care not be impaired with decreased physician  
24 interaction.

25 Is this something your physicians were

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1 saying, and what was the basis for those kinds of  
2 statements? Was there an experience existing?

3 MR. BARRUETA: No. It's an interesting  
4 question. One of the things that we again informally  
5 surveyed the physicians within the organization was  
6 the question of the statins. There really is a  
7 panoply and a wide variety of opinion among our  
8 physicians on that subject.

9 There are some who think in some cases,  
10 particularly at higher doses, it's very important that  
11 the patient be continually seen, as some of the drugs  
12 are currently labeled. The question, I think, that  
13 has to be asked is, is there another way to make sure  
14 that whatever the optimal amount of physician-patient  
15 interaction happens still happens, even if the drug is  
16 made over-the-counter.

17 So in terms of the quality of care  
18 question, it's trying to look at specifically and make  
19 sure that it doesn't create a problem if you have a  
20 situation where the patient no longer has to come to  
21 the physician for the prescription.

22 MODERATOR DeLAP: It's been my observation  
23 that certain categories seem to come to the fore at  
24 different times and for different reasons. I think I  
25 am very interested, though, if you have any ideas as

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1 to how we can more routinely be obtaining physician  
2 input, consumer input, on these kinds of issues rather  
3 than, you know, the current pattern where certain  
4 things seem to come to the fore for different reasons.

5 MR. BARRUETA: I think one way to do that  
6 potentially is for FDA to enhance its communications  
7 with some of the pharmacy and therapeutics committees  
8 that exist within health plans, within PBMs. Those  
9 tend to be the experts within the payer community who  
10 have really substantial contacts out into the expert  
11 community, the people who they really rely on for  
12 expert opinion on what's the best way to manage a drug  
13 benefit.

14 That could be one source of information  
15 that you could reach out to. I know that the  
16 physicians that we have, both in our regional pharmacy  
17 and therapeutics committees, the local pharmacy and  
18 therapeutics committees, and also the chiefs of  
19 service are very interested in these questions, and  
20 we're always happy to throw those questions out to  
21 them as they come forward.

22 MODERATOR DeLAP: Okay. If there are no  
23 further questions, thank you very much.

24 The next on the agenda is Buchanan and  
25 Ingersoll, Attorneys at Law, Robert Pinco and Mary

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1 Johnson.

2 MR. PINCO: Good morning. My name is  
3 Robert Pinco. I was former Director of the OTC  
4 Review, and I was Executive Secretary of the  
5 Commissioner's Steering Committee for OTC Drugs.

6 I mentioned that, because I want to go  
7 back to what happened in the very beginning of this  
8 process and talk about where we've come from there.  
9 This was a process that in the FDA had a very high  
10 priority. The Commissioner did have a special  
11 steering committee that dealt with this issue.

12 It was focused on at a very high level, so  
13 that we could find a way to regulate over 400,000  
14 products. The reason this review came about was there  
15 was a perceived failure of litigation as a regulatory  
16 model:

17 In the early days, in the Sixties and so  
18 on earlier, they had brought actions against  
19 companies, but there was a limit to what the General  
20 Counsel's office could do and what they could achieve,  
21 and as fast as they got products off the market, the  
22 products changed and it was not an efficient mechanism  
23 to work with.

24 So what they went to, which I think showed  
25 a great deal of foresight by a gentleman by the name

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1 of Peter Hutt, was to go to a legislative approach,  
2 and I think it worked exceedingly well. This was an  
3 approach that was legislative rather than adversarial,  
4 and its purpose was really to get people talking.

5 They also instituted a moratorium. The  
6 moratorium, basically, was this: If you will modify  
7 your products while we're doing this review process,  
8 we won't bother you; we'll let you do it. It was an  
9 encouragement to industry to do things that they  
10 wanted them to do.

11 As long as it was consistent with the  
12 safety and efficacy requirements of what the expert  
13 panels were coming up with, this was encouraged. What  
14 this all did was to support a healthy and innovative  
15 industry. That was what I was told when I joined the  
16 agency. I think it was very important during the time  
17 that I was there.

18 I'm not sure if that's the case today. I  
19 think the mechanisms are such that it's not really  
20 working.

21 The legislative approach, I think, was  
22 successful because it was a win-win proposition. It  
23 was built on a dialogue between FDA and consumers,  
24 industry and scientists and other government agencies.  
25 Senior agency management, particularly people like

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1 Charles Edwards and Commissioner Schmidt, Mac Schmidt,  
2 were directly involved in policy. This resulted in  
3 very rapid change.

4 One of the first lessons that Peter Hutt  
5 taught me was, if you're going to do something,  
6 telegraph it to the industry, give them time, give  
7 them notice and time to make a change, and you'll get  
8 the change pretty quickly, and you won't have to  
9 litigate for years with these fancy law firms that  
10 charge a lot of money and make people like me very  
11 wealthy.

12 The best example of that is zirconium.  
13 When we thought zirconium was a problem, it was in  
14 antiperspirants. We could have litigated this issue  
15 with the major law firms in Washington. I bet you we  
16 would still be litigating the issue.

17 What I did was something that was a little  
18 extra-legal. We went to a couple of the major  
19 companies who had very, very important products in  
20 this marketplace, and we said we're going to ban this  
21 product, this ingredient. Now we know this would kill  
22 your market; if I got arthritis of the signing hands  
23 for about six weeks, would we be hearing from you?

24 I get a call about four weeks later from  
25 the President's office of this very large company, and

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1 he says we just want to announce to you that zirconium  
2 is no longer in our antiperspirant products. So in  
3 six weeks we had gotten exactly what the agency  
4 wanted.

5 Now I think it was because of the dialogue  
6 and because they knew that we could move quickly  
7 within the agency, if we had to move. I think what  
8 the industry wanted out of this is that they got  
9 respect. This was an industry that had had a history  
10 way, way back of being involved with snake oils, and  
11 they wanted some respect, and they were willing to be  
12 regulated to get that respect.

13 It also stimulated innovation. It's  
14 scientific research. It promoted quality products.  
15 Companies usually rushed to modify their products,  
16 sometimes too quickly from the agency's point of view,  
17 to get their products to meet the standards that were  
18 being evolved by the expert panels.

19 The ultimate winner in all of this was the  
20 public. New products were out there. Better products  
21 were out there, and we had a very healthy industry.

22 In the Eighties I think we lost that  
23 focus. There was a phasing out of personnel in the  
24 development of the OTC program. The interest in the  
25 senior management waned and then disappeared. A new

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1 breed of Center office and division directors with  
2 backgrounds in only new drugs came along.

3 Basically, it was the NDA way or the wrong  
4 way. The result was a shift in interest, and the only  
5 focus more recently has been Rx to OTC switches. I  
6 don't want to suggest that that's a bad thing, because  
7 it is important to consider that issue, but it's not  
8 the only issue.

9 Now maybe these changes were due to a  
10 number of factors, maybe the generic drug issues and  
11 things that were going on, maybe PDUFA and the user  
12 fees were the focus over on prescription drugs, maybe  
13 even the early successes of the review. Some people  
14 thought, well, we're finished with the review; we'll  
15 just go on to do other things.

16 Unfortunately, with the limited staffing  
17 and the downsizing persons with institutional  
18 knowledge were no longer present. They retired or  
19 were removed. There were limited resources. The  
20 focus is really going to the user fees areas.

21 Something that certainly wasn't the  
22 agency's fault was that the agency review, the  
23 governmental review, increased. When I was at the  
24 agency, sometimes six to ten levels of review were all  
25 that were needed to get an item in the Federal

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1 Register.

2           Somebody explained to me that more  
3 recently they looked at the numbers, and it's like 40  
4 levels of review. It's not something you can control,  
5 but it is a fact of life.

6           Then what we began to see is agency long  
7 delays in addressing industry petitions and completing  
8 rulemaking. The law says you're supposed to respond  
9 in six months, and that's honored in the breach.  
10 There's a sunscreen example. There's a petition  
11 that's 20 years old now.

12           Foreign marketing petitions that I know is  
13 finally coming to fruition is ten years old. That's  
14 a long time. One of the most frustrating things, I  
15 will tell you as a person representing industry, is to  
16 have somebody from FDA call me up on a petition that  
17 has been sitting, going nowhere, and ask me if I want  
18 to withdraw it because it hasn't been moved and  
19 because the data is outdated.

20           It becomes a little bit on the outrageous  
21 side, and that's exactly what we've gotten. Also I've  
22 begun to see that the relationship has become far more  
23 adversarial than collaborative. The whole purpose of  
24 the legislative approach was to get away from the  
25 adversarial approach, to get a dialogue between

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1 industry, science, and consumers and the agency. That  
2 seems to have been disappearing.

3 My personal experience in going to some  
4 feedback meetings on sunscreens and seeing some  
5 letters where people have asked for meetings with the  
6 agency, only basically to be told to go away or to  
7 start filing new data as though they hadn't been  
8 dealing with the agency for ten or 15 years is really  
9 very, very frustrating on the part of people who have  
10 to deal with this.

11 I don't know what the reticence to meet  
12 with industry is and to deal with these issues, but  
13 that's what FDA is supposed to do. They are supposed  
14 to regulate this industry, and I got to tell you, it's  
15 very frustrating, and it's caused a number of  
16 companies and others to go the Hill to force the  
17 issue, and that's not the way, I believe, to work with  
18 the agency.

19 I think the industry would like to -- I  
20 don't speak for all of the industry; I just speak from  
21 my views -- would like to have an arrangement where  
22 they do speak with the agency and have a running  
23 dialogue so they can understand what's wrong.

24 Where you don't get response in this, as  
25 we did in the phytomedicine petitions to the agency,

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1 then when DSHEA came along what happens is a good  
2 portion of the people who wanted to come to FDA's OTC  
3 review process said to heck with them, I'll go to  
4 DSHEA.

5 Now as I understand it, that's a \$21  
6 billion industry that you don't regulate, and you  
7 could have regulated it. That's what frustrates me  
8 the most. This could have been yours, and they wanted  
9 to come to you. They wanted to get the imprimatur of  
10 the FDA, but it took so long that they just went the  
11 easier route.

12 It's unfortunate, but most of those people  
13 are no longer interested in coming back to do the OTC  
14 review process.

15 One of the things, I think, I want to talk  
16 about quickly is that the statute distinguishes  
17 between old and new drug. It's not a one-size-fits-  
18 all approach. You need to deal with new drugs and old  
19 drugs in a slightly different way.

20 Remember, the old drugs have been around  
21 for a very long time. You've got experience with  
22 them. If you try to do that in an NDA framework, it  
23 causes all kinds of problems. You ask for all kinds  
24 of data that you don't need. The problem then is that  
25 it makes people want to move away from that process.

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1           The OTC review was not created by statute.  
2           If you will look, you'll never find anything in the  
3           statute to tell you to use it. It was really done as  
4           a regulatory mechanism for flexibility.

5           What I would like to see happen is that in  
6           addressing the 400,000 products, not just Rx to OTC,  
7           that we begin to look at some of the issues.

8           Sunscreens are a critical need which Tom  
9           Donegan spoke about and Dr. Leyden. It's a perfect  
10          exercise in frustration where we've seen the number of  
11          sunscreens drop by one-third in the United States from  
12          the ANPR to the final, while at the same time in  
13          Europe, which is where a lot of our products are being  
14          developed, the numbers are constantly increasing.

15          They are getting better ingredients, and  
16          if you go to Australia where they've combined the best  
17          of U.S. and the best of Europe, they've reduced the  
18          incidence of the epidemic of sunscreen cancers  
19          dramatically.

20          We need to do that. We need to have  
21          mechanisms that work. These mechanisms just don't  
22          work.

23          MS. JOHNSON: I think Bob's clearly laid  
24          out some of our concerns with regard to the OTC  
25          monograph process. What I wanted to talk about is

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1 just to address two ways that the process could be  
2 improved.

3 One has to do with the broadening of the  
4 eligibility criteria to encompass foreign marketed  
5 products. That, of course, is well underway. The  
6 other has to do with the timeliness of the review  
7 process.

8 With regard to the proposed foreign  
9 marketing rulemaking, we think this is a significant  
10 step in the right direction. It certainly is in line  
11 with world harmonization efforts such as those with  
12 regard to ICH, the International Conference on  
13 Harmonization. However, as has been noted in industry  
14 comments, the proposed standards really need to be  
15 commensurate with the types of products being  
16 regulated.

17 These are not intended -- This mechanism  
18 is not intended for new drugs, but it's supposed to  
19 address older drug products. As Bob mentioned, with  
20 the availability of DSHEA, it's unlikely that oral  
21 products will be reviewed under this proposed  
22 mechanism.

23 In contrast, though, topical products such  
24 as sunscreens are very likely candidates for the  
25 expanded eligibility program, because in particular,

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1 products like sunscreens are really ill suited to the  
2 NDA mechanism. As was brought out earlier, they are  
3 marketed in a variety of sizes and formulations, and  
4 from an economic standpoint it doesn't make sense to  
5 move forward with NDA supplements to get changes and  
6 modifications cleared for these formulations.

7 I think also it was noted in the comments  
8 to the proposed rulemaking that industry feels that  
9 the criteria at this point are overly burdensome.  
10 Several comments, for example, mentioned concern  
11 regarding the lack of interim marketing or at-risk  
12 marketing as a mechanism.

13 This is already a mechanism in place for  
14 products that are marketed in the U.S. and reviewed  
15 under the monograph system.

16 The second issue I wanted to talk about  
17 was the timeliness of the review. As Bob has  
18 mentioned, and others, the agency response time on OTC  
19 drug petitions through the monograph process has been  
20 extremely slow. One, in particular, has pended for 20  
21 years, but others anywhere from five to 20 years.

22 This is difficult to rationalize, and I  
23 think it's led a very frustrated industry to seek  
24 attention to these matters through other means, such  
25 as through lobbying efforts on the Hill.

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1           The decision making process on these  
2 petitions needs to take place within a reasonable time  
3 frame. Understandably, the agency has limited  
4 resources available.

5           One idea that was brought to the attention  
6 of the agency in 1998 was the concept of using a third  
7 party review program. This is a concept that's  
8 already in place in the Center for Devices. It's a  
9 voluntary program, and the goal is to use it in order  
10 to expedite the review time.

11           The nuts and bolts of such proposal would  
12 include, basically, accrediting -- FDA would accredit  
13 outside organizations to conduct the initial review of  
14 petitions for eligibility. The industry would again  
15 pay for the initial review, and recommendations would  
16 be made to FDA by the accredited parties. At that  
17 point, of course, FDA would make the final  
18 determination with regard to safety and efficacy.

19           So we feel this is a relatively simple  
20 mechanism that has already been tested in the device  
21 area and should be explored in this area. Thank you.

22           MR. PINCO: Well, one of the very nice  
23 signs that you are rethinking this issue, obviously,  
24 is this meeting here today, and I hope that this is a  
25 sign that some of these issues are going to be

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1 considered.

2 I would like you to consider the  
3 following: We need mechanisms to make this process  
4 work. The OTC review is over. I don't want to go  
5 back -- harken back to old times again. That's not  
6 what I would like to see. What I'd like to see is  
7 rethinking of a new direction and new approaches.

8 Those new approaches need to address three  
9 categories: The foreign marketed products, as we go  
10 into internationalization; modifications to existing  
11 products, because there are a lot of them that are  
12 changing; and, of course, the Rx to OTC switches.  
13 They are important.

14 Unless those things are happening, we're  
15 going to see that this industry is going to stagnate,  
16 and in the case of the sunscreens, for example, you're  
17 going to see that people will make business decisions  
18 to develop new products or not to develop new  
19 products, because they can't get them through the U.S.  
20 system. That, I think, is really unfortunate.

21 A major loser in all of this scenario,  
22 obviously, is going to be the American public. So I  
23 would like to see something to establish mechanisms  
24 that are usable, and that we look at, more or less,  
25 the big picture.

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1 Obviously, the number of people here in  
2 this room and in the other room, I guess, if we were  
3 to see them, shows that there's great interest in all  
4 of this. I would like you to take out of that perhaps  
5 that we really do want to see this mechanism become  
6 viable and not become a backwater, as I believe it has  
7 become more recently. Thank you very much.

8 MODERATOR DeLAP: Thank you, and I think  
9 again, as you just said, I think with the number of  
10 people that you have in this room from the agency is  
11 a measure of our interest in trying to see ways that  
12 we can improve processes and continue to serve the  
13 public health.

14 Questions from the panel?

15 DR. GANLEY: Yes. I just had a question  
16 or a few questions probably. I think one of the  
17 interesting things you brought up is the OTC review  
18 process, and that has become a cumbersome process.

19 What has changed from the 1980s on to now  
20 that has made it cumbersome? I mean, you had given  
21 the example of resources. I'm not familiar with what  
22 resources were available, but the number of rules that  
23 are in the final monograph stage still are significant  
24 and has to be addressed somehow. But you really  
25 haven't provided any concrete examples of how to do

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1 that.

2 I'm not sure if just meeting with industry  
3 or individuals about this pushes the process forward.

4 MR. PINCO: I agree with you. One of the  
5 things, I guess, that struck me -- and of course, no  
6 one ever likes to believe that they made mistakes or  
7 didn't do things in the proper way -- I think the  
8 three-step process was overkill.

9 It was intended -- It had good intentions  
10 in the very beginning, and in the system where you  
11 have six or eight levels of clearance to get Federal  
12 Register documents out, clearly that was -- it made  
13 sense there.

14 Now if you have 40 -- I don't know if I'm  
15 right or not, but 40 levels of clearance through HHS  
16 and OMB and all the other things you have to do,  
17 you've got a mechanism, but you have to find other  
18 mechanisms to deal with it. That's why it's important  
19 to try to find the ways to streamline some of these  
20 things as much as possible, to cut down the levels of  
21 review, the re-review, to look for mechanisms by which  
22 the industry can get products to the marketplace.

23 For example, we suggested interim  
24 marketing. Once you've decided that a product is out  
25 there and it's perfectly safe, why do we do the rest

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1 of the process. That's the way the whole OTC review  
2 process worked.

3 That's why there was no pressure. We  
4 told people, you can be on the market until we finish  
5 the final monographs. Now if they're not on the  
6 market and years go by, there's great pressure for  
7 them to do something to get their product to the  
8 marketplace. They can't wait ten or 20 years.

9 So that's one mechanism that you could  
10 deal with. The pilot mechanism that Mary mentioned is  
11 a mechanism to review things. If you don't have the  
12 people, use this process. It speeds up the effort.  
13 It makes it work better.

14 The foreign marketing approach is an  
15 attempt -- I think, is a good attempt to try to deal  
16 with the international harmonization issue. It  
17 doesn't go nearly far enough. It requires much too  
18 much in the way of the kinds of requirements that you  
19 need, considering the kinds of products. We're only  
20 talking about topicals now, because the orals all have  
21 gone the route of DSHEA.

22 So it may be mechanisms to find ways to  
23 harmonize with the approaches taken in Europe, which  
24 has, in the process of forming the European Union,  
25 found ways to speed things up and make their processes

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1 work much better than we have. I could go on, but I  
2 don't know that you want me to continue.

3 DR. GANLEY: Well, I guess the other thing  
4 is that I think that what some of us have a concern  
5 about is that, in providing feedback prior to  
6 finalizing a rule or a monograph, is that we don't  
7 necessary have input from all the stakeholders.

8 Certainly, industry has a motivation to be  
9 involved in the process, but oftentimes the consumers  
10 aren't involved in that process or academia is not  
11 involved in that process unless they are, you know,  
12 individuals that are sponsored by industry.

13 So I think that's a concern that I have,  
14 regarding your comments about providing some type of  
15 input back to industry during the rulemaking process  
16 where we don't always have all the stakeholders  
17 involved.

18 MR. PINCO: Well, part of it this is not -  
19 - We're not talking about what we call an ex parte  
20 kind of an arrangement where you go and have a side  
21 conversation with somebody, and nobody else inputs.

22 These are public meetings, and I don't  
23 think the industry cares if other people show up to  
24 these things. We're not getting private licenses in  
25 the monograph system. There you do want a private

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1 meeting, and you don't want it public.

2           These are situations in which they have  
3 questions. They're not sure how you're reacting to  
4 what they have submitted. They have concerns about  
5 what else you think you want because, as I said to you  
6 before, if you will tell industry what you need or  
7 what you like or don't like, you'll find rather than  
8 fight, they will switch. It's in their interest to do  
9 so.

10           If you do that in a consistent way, you'll  
11 find that the industry is very cooperative. I  
12 couldn't believe how cooperative they were. The  
13 example I gave you was zirconium. I was very  
14 pleasantly surprised. I had people in the old Bureau  
15 of Drugs tell me that I had done something really  
16 terrible by having the side conversation with them,  
17 but I got what we wanted, what the agency wanted. I  
18 thought that was in the public interest.

19           So I guess I would say that it is not  
20 something that you're violating any law and, if  
21 anybody is interested, they can come into those  
22 meetings. I think what we need is a way to have a  
23 dialogue to know what you're thinking and whether  
24 we're off track with where the agency is at any  
25 particular point in time.

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1           That would really help in developing some  
2 kind of a dialogue, a continuing dialogue, with the  
3 industry, not just the major trade associations but  
4 individual companies or individuals.

5           DR. MURPHY:    Could I go back to the  
6 Australia example and ask you to summarize for us what  
7 were the elements that you thought -- you mentioned  
8 them as taking from two systems, and it made the  
9 process work in Australia.  Could you summarize for us  
10 what the important elements were that you thought were  
11 extracted from the different systems to make it work?

12           MR. PINCO:  Well, I can't tell you I have  
13 all the data.  But what I understand is what happened  
14 here is that the Australians, who are, obviously,  
15 linked to the Brits historically, picked up from the  
16 European Union all of the new UVA sunscreens that were  
17 being evolved.  They have a lot more going through  
18 their process.

19           They've got a very streamlined system that  
20 works.  Even though they are cosmetics, it's a  
21 preclearance mechanism that they have.  They then  
22 realized they had a very serious problem of skin  
23 cancer epidemic, worse than ours.  It was increasing  
24 at a very rapid rate.

25           So they undertook, as I understand, a

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1 very, very complicated campaign of consumer education,  
2 physician -- discussions with physicians and get them  
3 to speak to the public in general, and then also  
4 expansion of these sunscreens.

5 What it does is it allows the industry is  
6 they can bring more ingredients into mix and match and  
7 to get the best product they can get out on the  
8 market, and the competition will take care of the  
9 rest.

10 Here in the United States, none of those  
11 sunscreens have been made available. So what we ended  
12 up doing is we took sunscreens that were around in the  
13 1970s and we decreased the number of those products,  
14 while at the same time the rest of the world was  
15 getting all of these new and better sunscreens.

16 We have not solved our problem, and that  
17 has been communicated to the agency by American  
18 Academy of Dermatology and a number of others, and  
19 it's very frustrating to see that even now after all  
20 these years with the sunscreen monograph finalized, we  
21 still haven't dealt with this issue.

22 MODERATOR DeLAP: I think we will need to  
23 move on. I would encourage you, if there are things  
24 that you think we could learn from that Australian  
25 experience that we haven't already heard from you

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1 about, please go ahead and submit them to the docket,  
2 and we'll certainly look at them.

3 MR. PINCO: I'd be happy to. Thank you.

4 MODERATOR DeLAP: Thank you. The next  
5 speaker on the agenda is David Steinberg of Steinberg  
6 and Associates.

7 MR. STEINBERG: Thank you. In the  
8 interest of time, I am not going to be being redundant  
9 and cover some of the issues that other people have  
10 already covered. I will not be following my written  
11 notes, because it's just being redundant.

12 Since 1995 I have written a column for  
13 Cosmetics and Toiletries magazine on international  
14 personal care regulations, and on their behalf is why  
15 I'm here today.

16 Tom Donegan described this group of over-  
17 the-counter drugs as being cosmetic drugs. They are  
18 sold frequently for their cosmetic properties, even  
19 though they do have drug actions. The last speaker  
20 also addressed some of the issues.

21 These drugs are unique in two other  
22 factors. One is that they do not have dose  
23 restrictions. These products are sold with the basic  
24 directions, "apply as frequently as needed." You  
25 don't overdose on lip balms. You don't overdose on

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1 sunscreens. You apply it as often as it's needed.

2 The second reason that these are different  
3 is the reason for me being here. These drugs are  
4 basically produced and discovered by chemical  
5 companies who invent the raw material. They then try  
6 to market this not to a single marketer of a finished  
7 drug but to sell it to every producer of sunscreens or  
8 antiperspirants or anti-dandruff shampoos.

9 These are chemicals as opposed to being  
10 drugs which go through an NDA process. In fact, when  
11 you talk to a chemical company who has invented a new  
12 UVA filter and you try to explain that to sell this in  
13 the United States you basically have to become a drug  
14 manufacturer, a retail drug manufacturer, they throw  
15 up their hands.

16 We need a simple way to add new chemical  
17 drugs like this to the monographs for these limited  
18 purposes. They are drugs that have no dose  
19 dependency.

20 Now since the start of the process, if we  
21 look at the different categories, we have not added  
22 any new skin protectants. We have not added any new  
23 antiperspirants. We have not added any new anti-  
24 dandruff agents to the monograph. We've added one new  
25 UV filter, and that took close to 20 years to do.

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1           The OTC system has been great for the  
2 consumer in terms of competition, but we've stifled  
3 innovation to the new actives for this narrow purpose.

4           In April I attended the World Conference  
5 on Cosmetic Regulations in Malta. Speaker after  
6 speaker got up and criticized the FDA. They called  
7 the FDA old-fashioned. They called the FDA out of  
8 step with reality.

9           I didn't understand this. There were over  
10 75 different regulatory agencies present from 75  
11 different countries, and they kept saying that there's  
12 something wrong with the FDA, and they kept on  
13 pointing to the European Union's method of regulations  
14 as being the way for the future.

15           I just didn't understand this, because I  
16 find the European regulations to be extremely onerous.  
17 They are much more complicated and much more difficult  
18 than in the United States.

19           They have these products that I call the  
20 drugs without dose restrictions. They are all  
21 cosmetics, but they are not like nail polish or  
22 lipsticks. You can't just go into the marketplace.  
23 You must get a preapproval for the active ingredient,  
24 and they set up an independent organization called the  
25 SCCNFP which stands for the Scientific Committee,

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1       Cosmetics and Non-Food Products, to evaluate and  
2       approve these new actives.

3               Was this an easy process? No. In fact,  
4       it almost was funnier than our process in the time it  
5       took. In 1978 the FDA put octomethoxycinimate as a  
6       safe and effective Category I sunscreen. This is the  
7       standard for the European Union's SPF testing, and yet  
8       this was not approved until a couple of years ago.

9               Why was it left in regulatory limbo for  
10       18-20 years? For the same reasons that we have  
11       problems. They do not have a transparent system for  
12       approving new OTC actives like UV filters, anti-  
13       dandruff agents.

14               Finally, about three years ago they  
15       published a model submission. You fill out this form.  
16       You do these tests, and we can make a decision. Wow.  
17       No sooner was this document published that within two  
18       years all their provisionally approved UV filters  
19       finally were permanently approved. All the  
20       provisional preservatives were finally permanently  
21       approved.

22               It works. Now after this came out we've  
23       had six new sunscreens that went from being never used  
24       to being permanently approved, because the  
25       manufacturer of the UV filter knew what was asked of

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1 him. Run all these tests, we can make a decision as  
2 to whether they are safe.

3 All these sunscreens, incidentally, would  
4 have marketplaces in the United States, and also they  
5 all would be considered new drugs by the FDA.

6 As the FDA requires drugs to be safe and  
7 effective, the efficacy of these products is not a  
8 question. The monographs have defined the efficacy.  
9 It is the final formulation that you run SPF on. It's  
10 the final formulation that you run antiperspirant  
11 testing on. It is the question of safety that we must  
12 address.

13 Now it is really easy for everyone to get  
14 up and to criticize the FDA, like they did in Malta,  
15 because we don't have a simple system. However, I  
16 think it's much more productive if we have a  
17 suggestion on how to do this, and that is my purpose.

18 We have a mechanism right now in the  
19 United States called the Cosmetic Ingredient Review,  
20 independent. They review the safety. They set up the  
21 parameters and, by the way, the FDA sits on this  
22 panel. They happen to be the biggest voice at the  
23 Cosmetic Ingredient Review. If the FDA says time out,  
24 everyone stops and listens.

25 So why not have these products shifted

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1 away? Take it form your valuable time. Let you  
2 concentrate on all the drugs that other people are  
3 interested here. Take these cosmetic drugs. Shift  
4 over the safety responsibility, the preclearance to  
5 the Cosmetic Ingredient Review. Then bring it back to  
6 the agency for a final review, and let's move on.

7 I will tell you this, that if the FDA  
8 adopted this simple, transparent, simple and easy to  
9 follow, cost effective system for approving these new  
10 actives, that at the next World Harmonization meeting  
11 in Japan in 2002 I won't have to listen to speaker  
12 after speaker say that the FDA is out of step.  
13 Everyone will be saying why don't we harmonize with  
14 the U.S. methodologies. Thank you.

15 MODERATOR DeLAP: Okay. So if I can  
16 summarize one thing that I thought was central to your  
17 talk, you're suggesting that certain categories of  
18 products that are regulated as cosmetics in Europe,  
19 nonetheless have some preclearance requirements, and  
20 we could have a new mechanism in place that would  
21 consider these products separately as cosmetic drug  
22 products and incorporate some preclearance kinds of  
23 testing that would not be an option under our current  
24 cosmetic regulations.

25 MR. STEINBERG: That's correct. Yes.

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1 MODERATOR DeLAP: Any other questions or  
2 comments from the committee?

3 DR. GANLEY: I guess one of the things  
4 that comes to mind: If you have a new ingredient  
5 that's not marketed OTC anywhere in the world, in the  
6 U.S. it would require an NDA.

7 MR. STEINBERG: Yes.

8 DR. GANLEY: Assuming -- If we assume the  
9 foreign marketing document eventually gets published  
10 this year, are you saying that there should be another  
11 mechanism where, if there's a new active ingredient,  
12 a new process for these things to come into the U.S.  
13 market in the monograph rather than going the NDA  
14 route?

15 MR. STEINBERG: Yes. Absolutely. I don't  
16 remember the last time I went to my doctor and asked  
17 for a prescription for suntan or sunscreen or an  
18 antiperspirant or for lip balm. In fact, the problem  
19 that exists in regulations throughout the world is  
20 that the regulators come up with legal definitions  
21 which don't reflect consumer reality.

22 You can go to 100 consumers on the street  
23 there and tell them that their anti-dandruff shampoo  
24 is a drug. They're not going to believe you. They're  
25 not going to believe you that sunscreens are drugs.

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1 They're not going to believe you that lip balms are  
2 drugs.

3 We can put all the labels, we can put all  
4 the advertising in the world, and they still consider  
5 them cosmetics, and laws are not going to change  
6 consumer perception. So let's deal with it. Let's  
7 stop worrying about it.

8 DR. GANLEY: Well, I think the one  
9 difficulty with that is that we're saying that  
10 sunscreens prevent skin cancer. So I wouldn't  
11 necessarily characterize it purely as a cosmetic, if  
12 we're making some disease prevention claim on it,  
13 necessarily.

14 I guess the other issue would be to  
15 address the point about new active ingredients is the  
16 safety reporting. I think that would be an issue that  
17 would need to be addressed, because we really don't  
18 have a good handle on the safety or what is happening  
19 with some products out there that are marketed under  
20 a monograph.

21 You know, we hear about them sometimes,  
22 but not all the time. So should there -- If there is  
23 going to be a mechanism in place to allow new actives  
24 into the monograph that have not been marketed in the  
25 world in any other OTC market, does there have to be

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1 some change in the reporting of safety for these types  
2 of products that would contain these new actives?

3 MR. STEINBERG: Let me answer it this way.  
4 There were some questions by the previous speaker and  
5 comments on Australia, and I'm quite familiar with the  
6 regulations there. I've been involved with it.

7 They require mandatory adverse reaction  
8 finding. This has to be submitted once a year in  
9 order to get your license approved to be a  
10 manufacturer of these types of drugs, and sunscreens  
11 in Australia are regulated as drugs. They are not  
12 cosmetics.

13 They have a mandatory -- When they come up  
14 to get their license renewed each year, they must  
15 submit documentation on all adverse reactions that are  
16 found to their products. So it's doable.

17 MODERATOR DeLAP: Okay. Well, thank you  
18 very much. Next on the agenda, the American  
19 Pharmaceutical Association, Rebecca Chater, RPh.

20 MS. CHATER: Good morning. Thank you for  
21 the opportunity to present the views of the American  
22 Pharmaceutical Association, the national professional  
23 society of pharmacists.

24 I am Rebecca Chater, a community  
25 pharmacist with Kerr Drug in North Carolina. My

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1 practice experience is broad, including long term  
2 care, pharmacy management, academia, and clinical  
3 practice. In addition to having a great interest in  
4 public health within the context of my pharmacy  
5 background, my Master's degree is also in public  
6 health.

7 I am a past member of the APA board of  
8 trustees, and APA's more than 53,000 members are  
9 pharmacists providing care in a variety of practice  
10 settings such as community, hospital, long term care,  
11 and hospice settings, as well as pharmaceutical  
12 scientists and pharmacy students.

13 In each of these settings, pharmacists  
14 help consumers manage and improve their medication  
15 use, including the appropriate selection and use of  
16 over-the-counter products.

17 An important component of the discussions  
18 today is the site where the majority of our members  
19 practice, the pharmacy. Most OTC products are  
20 purchased at a pharmacy. This positions pharmacists  
21 well to interact with consumers at the point of  
22 decision making and purchase.

23 The pharmacist fulfills an essential role  
24 in the use of medications, helping consumers make  
25 their medications work. While the FDA ensures the

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1 safety and effectiveness and availability of available  
2 products, manufacturers ensure the production of  
3 quality, contaminant-free products, and physicians and  
4 other prescribers diagnose and direct consumer  
5 interaction within today's health care system,  
6 pharmacists work with consumers to make the best use  
7 of the powerful technology we know as medications,  
8 whether classified as prescription medications, over-  
9 the-counter products or dietary supplements.

10 In my practice and in community pharmacies  
11 across the country, pharmacists serve as a bridge  
12 between consumers' self-care activities and  
13 interaction with the formal health care system. For  
14 example, we monitor interactions between OTC products,  
15 dietary supplements, and prescription medications, and  
16 for the development of adverse effects.

17 My comments today are based on the  
18 perspective of a pharmacist as a medication use  
19 manager. APHA has long supported activities and  
20 programs designed to assure the appropriate use of OTC  
21 medications for consumers' health care.

22 Examples include publishing the Handbook  
23 of Nonprescription Drugs for more than 25 years,  
24 conducting consumer hotlines for access to  
25 pharmacist's consultation about OTC products, and

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1 participation in the Partnership For Self-Care, an  
2 initiative designed to help consumers use OTC  
3 medications safely and effectively.

4 The APHA House of Delegates has advocated  
5 for appropriate labeling of OTC drug products since  
6 1978. APHA believes an important component of the  
7 pharmacist's professional responsibility includes  
8 providing consultation to support drug selection,  
9 dosing, and use of prescription and nonprescription  
10 medications and dietary supplements.

11 My comments today will focus on four of  
12 the many questions posed in the April 27 announcement  
13 of this meeting. Specifically, I will discuss the  
14 criteria FDA should consider in rendering decisions on  
15 OTC availability of drug products; a recommendation  
16 for assuring consumer understanding of OTC products  
17 through pharmacist directed research; risks posed by  
18 consumer confusion regarding brand name line  
19 extensions; and the current structure for marketing  
20 OTC products.

21 Regarding criteria: The number of  
22 products shifting from prescription only to OCT status  
23 has increased markedly over the past several years,  
24 providing consumers with many more choices for self-  
25 care. These products, however, are available in a

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1 myriad of environments, including environments that do  
2 not provide the consumer with convenient direct access  
3 to a health care professional.

4 This lack of access to a pharmacist places  
5 greater responsibility on the consumer for the  
6 interpretation and the understanding of drug labeling  
7 and appropriate use of medications. As such, the  
8 decisions determining what products should be  
9 available in this environment must be carefully  
10 considered.

11 The question of whether a product should  
12 be switched from prescription to OTC status must  
13 involve more than the traditional review of the  
14 clinical information and research information  
15 demonstrating the safety and effectiveness of the  
16 product.

17 While such information represents the core  
18 information for considering a transition to OTC  
19 status, APHA recommends that the FDA criteria include  
20 an assessment of the environments surrounding the use  
21 of the product in question, as well as the environment  
22 of the disease or the symptom at issue.

23 The product switch question must be  
24 animated by a comparative review of existing therapies  
25 in the self-care market, the degree of treatment

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1 sought in the existing self-care system, and the risks  
2 and benefits of increasing access to the product at  
3 issue. Let me explain.

4 A review of existing therapies in the  
5 self-care market is important to explore what products  
6 are being used for self-care in the current  
7 environment. If existing alternatives for self-care  
8 are less safe due to potential for interactions with  
9 other therapy or risk of negative side effects, the  
10 relative safety of the product in question for  
11 transition may increase, making transition to OTC  
12 status favorable. If, however, a broad array of safe  
13 and effective products with minimal side effects is  
14 available for self-care, transition would be less  
15 favorable.

16 If existing alternatives for self-care are  
17 limited to dietary supplements, other problems may  
18 exist. Numerous studies have documented problems with  
19 product content and relief of the active ingredient in  
20 dietary supplement products, and consumers in this  
21 scenario are limited to products whose content may not  
22 match the claims on the label. Again, the relative  
23 safety of the product in question for transition may  
24 increase.

25 Another component of a comparative

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1 analysis should be a review of the degree to which  
2 consumers are choosing self-care treatment for the  
3 particular disease or condition at issue. Assessment  
4 of the use of self-care treatment, such as OTC  
5 products, dietary supplements or other alternative  
6 therapies, could provide valuable information for the  
7 consumer's interest in self-care treatment for the  
8 condition at issue.

9           Such an assessment may provide information  
10 about how consumers use those products, including  
11 whether consumers seek health care advice when  
12 symptoms persist after using the available self-care  
13 treatment.

14           The risks and benefits associated with  
15 increasing access to the product must also be  
16 evaluated in this comparative analysis. Specifically,  
17 the FDA process should evaluate the use of the product  
18 in the prescription-only environment to assess  
19 prescribing patterns, etcetera, that may be consistent  
20 with increasing consumer driven use of the product.

21           The provision of the product by  
22 pharmacists under the purview of collaborative  
23 practice agreements, for example, may support the  
24 expanded availability of the product. Generally, a  
25 collaborative practice agreement is authorized by

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1 state law and allows pharmacists and physicians to  
2 develop a protocol detailing conditions under which a  
3 pharmacist will initiate or modify a patient's drug  
4 therapy.

5           Regarding assuring consumer understanding  
6 of OTC products: Consumer understanding of a proposed  
7 OTC product labeling is essential to support the  
8 transition from prescription only to over-the-counter  
9 status.

10           APHA supports methods to assess consumer  
11 understanding of proposed labeling that involves the  
12 site where most OTC products are purchased, the  
13 pharmacy, and the health care professional most  
14 accessible to respond to questions about OTC products,  
15 the pharmacist.

16           In a recent multi-center clinical trial,  
17 pharmacists acted as principal investigators to  
18 evaluate compliance and persistence by consumers self-  
19 selecting to receive a product being considered for  
20 transition to OTC status. In this study data was  
21 gathered at more than 50 pharmacies, gathered at a  
22 site where most OTC products are expected to be  
23 purchased, and overseen by the health care  
24 professional most likely to help consumers choose a  
25 product and answer questions about how to use the

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1 product most appropriately.

2 Studies such as this provide valuable  
3 information to support transition from prescription-  
4 only to OTC status. Pharmacists, if widely utilized  
5 in Phase IV and post-marketing surveillance clinical  
6 trials such as the one I've just described, can play  
7 a valuable role in assessing and influencing through  
8 pharmaceutical care, where appropriate, medication use  
9 in the uncontrolled real world setting of self-care  
10 and health care.

11 In this system, pharmacists will  
12 ultimately provide contributions to our knowledge base  
13 regarding the effectiveness of various medications in  
14 the population at large.

15 Regarding risks posed by consumer  
16 confusion resulting from brand name line extensions:  
17 AS APHA has expressed to the FDA many times,  
18 pharmacists continue to have significant concerns  
19 about the presence and proliferation of the use of the  
20 same brand name or minor variations of the same brand  
21 name to identify products with similar active  
22 ingredients.

23 Just as Kleenex is now a universal name  
24 for facial tissues, consumers and health care  
25 professionals correlate product brand names with

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1 active ingredients of OTC medications. Consumers, and  
2 perhaps even some health professionals, may also  
3 assume that a consistent brand name on an over-the-  
4 counter drug product refers to consistent active  
5 ingredients.

6 This is not the current situation, given  
7 the trend toward over-the-counter brand name line  
8 extensions. The APHA is concerned that this practice  
9 may cause significant confusion.

10 Recently, I was made aware of a cough and  
11 cold product where a children's suspension formulation  
12 is significantly different from the pediatric drop  
13 formulation. The parent, directed by her pediatrician  
14 to use the brand name product but with no specific  
15 direction as to which of that brand product to choose,  
16 presented at the pharmacy trying to choose among the  
17 products where different formulations -- many  
18 different formulations of active ingredients existed.

19 Interaction with the pharmacist helped  
20 this parent resolve the situation. But one must ask  
21 how many times this situation is repeated, and how  
22 much confusion could be prevented by avoiding or  
23 limiting the use of similar brand names for products  
24 with different active ingredients.

25 When choosing or recommending OTC therapy,

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1 consumers and health professionals are likely to see  
2 only the prominent brand name and assume that this  
3 conveys active ingredient consistency. Consideration  
4 of the risks of confusion with brand name line  
5 extensions must be a component of FDA's review of  
6 consumer understanding.

7           Reviewing product names and brand name  
8 line extensions fits within the concept I previously  
9 discussed, the comparative review in order to assess  
10 transition from prescription to OTC status. A brand  
11 name, considered in isolation, may appear clear and  
12 understandable, but when placed on a pharmacy shelf  
13 with five or 15 other products with similar names,  
14 clarity is lost or, more concerning, the clarity may  
15 be lost when consumers try to recall their OTC therapy  
16 when consulting with a pharmacist about appropriate  
17 medication use.

18           Without being able to accurately identify  
19 the active ingredients in a product, checks for drug  
20 interactions or other potential problems are severely  
21 limited.

22           Finally, I will address the agency's  
23 question about the adequacy of the marketing structure  
24 for OTC products in the United States.

25           Generally, FDA's existing structure for

1 marketing both prescription and OTC products could be  
2 improved by an expanded recognition of the role of the  
3 pharmacist in ensuring appropriate medication use.

4 We are each aware of the steadily mounting  
5 evidence of morbidity and mortality attributable to  
6 underuse or misuse of prescription pharmaceuticals.  
7 This evidence has recently spilled over from its  
8 historical confinement in the pages of medical  
9 journals to play out in the lay media.

10 The media, with the public not far behind,  
11 are demanding more accountability of manufacturers,  
12 physicians and pharmacists. With prescription  
13 medications, part of the problem is the fact that  
14 health professionals are, unfortunately, being pushed  
15 by economic pressures into spending less time with  
16 each patient.

17 With OTC products, consumers must navigate  
18 the self-care system without the assistance of a  
19 health care provider unless they choose to ask for  
20 assistance. These marketplace trends make it  
21 difficult for providers, pharmacists -- prescribers,  
22 pharmacists and consumers alike to remain fully alert  
23 to the risks of every drug they prescribe and dispense  
24 and, in the consumer situation, purchase and use.

25 The FDA could help this situation

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1 considerably by enhancing the use of the pharmacist in  
2 managing medication use. Pharmacist consultation can  
3 be valuable in ensuring appropriate medication use,  
4 reducing adverse events, and ensuring consumer  
5 persistence and compliance with therapy.

6 Additionally, pharmacists can be valuable  
7 sources of information about medication use in real  
8 life, providing additional information about the use  
9 of prescription and OTC medications and dietary  
10 supplements.

11 As I described earlier, pharmacists'  
12 participation in research activities and in the  
13 community pharmacy can provide valuable information  
14 about consumer comprehension of labeling and the  
15 appropriateness of medication use, without the  
16 traditional health care professional intervention  
17 involved in the prescription medication use system.

18 Should the agency be presented with a  
19 situation where the appropriateness of OTC  
20 classification is questionable, however, the use of a  
21 system of marketing products through pharmacists  
22 should be considered. Such availability would expand  
23 access beyond the traditional system, while  
24 maintaining health professional interaction.

25 Additionally, data gathered from the

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1 experience of expanded access through pharmacists  
2 could be used to support the transition from  
3 prescription to full OTC availability.

4 It is important to recognize that APHA is  
5 not asserting that every product considered for switch  
6 to OTC status must flow into a transition class.  
7 Rather, APHA is recommending an alternative  
8 distribution system for use when the data are  
9 insufficient to support a transition to full OTC  
10 status, but expanded access to the product is  
11 necessary to support quality self-care.

12 Over-the-counter medications are a  
13 valuable part of consumer self-care and our health  
14 care system. The FDA must assure that OTC products  
15 are accompanied by labeling to support appropriate use  
16 and coordination with the health care delivery system.

17 The believe that over-the-counter drug  
18 products are helpful is true, but the belief that they  
19 are risk free is dangerous. The FDA's hearing today  
20 about the agency's approach to regulating OTC products  
21 is a vital step in assuring quality OTC products for  
22 consumers' use in self-care and pharmacists'  
23 interaction as a bridge between self-care and health  
24 care.

25 Thank you for your consideration of the

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1 views of America's pharmacists, and I would be happy  
2 to entertain any questions you may have.

3 MODERATOR DeLAP: Thank you. Questions?  
4 Dr. Jenkins?

5 DR. JENKINS: One of the points you made  
6 at the end of your talk seems to suggest that you are  
7 in favor of a third mechanism, the so called behind-  
8 the-counter availability of products. Yet we heard  
9 earlier about other views that that system doesn't  
10 work and that other countries are moving away from  
11 that system, and there's GAO report that did not seem  
12 to favor that system.

13 Can you comment on your thoughts about  
14 those other comments?

15 MS. CHATER: As a community pharmacist, I  
16 do firmly believe that there is clearly a role for  
17 pharmacist activity in this area. I think that a  
18 pharmacist is very well positioned to address the  
19 individual patient needs and balance that with the  
20 value, the use of a particular medication. So I am in  
21 favor.

22 DR. JENKINS: Could you maybe give some  
23 examples of -- Part of the questions we had in the  
24 Federal Register notice were particular drugs, classes  
25 or illnesses that might be appropriate. Could you

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1 give some examples of where you think that behind-the-  
2 counter would be an appropriate mechanism to move  
3 things over-the-counter, such as asthma,  
4 hypercholesterolemia, chronic conditions?

5 MS. CHATER: Well, there are a variety of  
6 examples I could offer, but for example, if a  
7 pharmacist is aware of a patient's medical history,  
8 there are products available that could cause concern  
9 in an absolute OTC switch, but would be appropriate  
10 for that individual patient.

11 For example, if there is a collaborative  
12 practice arrangement in place, a pharmacist with a  
13 previously arranged relationship with a physician  
14 could be able to assess that patient's needs and  
15 address those appropriately.

16 DR. JENKINS: Just one final question:  
17 Can you clarify? Do you practice in an independent  
18 pharmacy or a chain pharmacy, and can you correlate  
19 how you think that impacts on the ability to do these  
20 counseling sessions and some of the interactions with  
21 patients that you are suggesting pharmacists can do?

22 MS. CHATER: Yes. I practice in a  
23 regional chain. Kerr Drug is a regional chain in  
24 North and South Carolina of about 150 pharmacies.

25 Heretofore, we have made substantial

1 efforts in evaluating processes such as work flow,  
2 building efficiencies into our dispensing process to  
3 allow our pharmacists more time to provide direct care  
4 with patients. That is a system for us that is  
5 working and growing.

6 We actually have pharmaceutical care  
7 centers within some of our stores where that direct  
8 patient care is provided in the setting that's a  
9 little bit less hurried and more beneficial to the  
10 patient than has been in the past.

11 By the way, we find that patients remark  
12 consistently that receiving care in an environment  
13 like that is a very non-threatening way to receive  
14 care, and patients seem to be very, very much in favor  
15 of the services that we are providing.

16 MODERATOR DeLAP: Okay. Well, thank you  
17 very much, and we'll move on then to the National  
18 Community Pharmacists Association, Doug Hoey, Vice  
19 President.

20 MR. HOEY: Good afternoon. My name is  
21 Douglas Hoey, and this is my colleague, Boyd Ennis.  
22 We are pharmacists on the staff of the National  
23 Community Pharmacists Association, and on behalf of  
24 NCPA we would like to thank the FDA for allowing us to  
25 comment on this issue that is so important to public

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1 safety.

2 NCPA represents the 25,000 independent  
3 community pharmacies in the United States and the  
4 60,000 community pharmacists who practice in those  
5 pharmacies.

6 The FDA posed several questions for  
7 feedback in the April 27 Federal Register announcing  
8 this hearing. My comments today will address three of  
9 these areas mentioned: Public safety; a potential  
10 solution; and initiating product switches from Rx to  
11 OTC status. NCPA will also file more written comments  
12 and supporting documents prior to the August 25  
13 deadline.

14 All of us here have patient safety as our  
15 highest priority. Patient medication safety is  
16 perhaps more complex than ever before, because there  
17 are more medications, both prescription and OTC,  
18 available to consumers than ever before.

19 At the same time, patients have access to  
20 more information and are more interested in being  
21 involved with their own health care decisions  
22 affecting them and their family than ever before.

23 Although the FDA's recent regulation  
24 providing easier to read labeling will help patients  
25 better understand the actions and side effects of

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1 medications they are taking, in the pharmacy I still  
2 see a considerable amount of confusion that sometimes  
3 exists when it comes to taking OTC medications.

4 Illiteracy and difficulty reading English  
5 contributes to the confusion. According to  
6 information from the National Institute for Literacy,  
7 nearly one-third of Americans need a stronger  
8 foundation of basic reading skills.

9 This lack of universal understanding about  
10 medications becomes even more important as the FDA  
11 begins to consider medications used for chronic  
12 conditions for which patients have no immediate  
13 symptoms. For example, the class of drugs featured in  
14 yesterday's USA Today, today's New York Times,  
15 yesterday's evening news, on the morning shows this  
16 morning, interact with drugs from at least 15  
17 categories of medications, including some OTC vitamins  
18 and some OTC products that are currently on the  
19 market.

20 I mention those news stories only to raise  
21 the awareness of the potential for drug or food  
22 interactions. These potential interactions make it  
23 imperative that ready and accessible expert health  
24 care advice be available to patients to provide  
25 information about their medicine and help them to make

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1 a rational selection of care.

2 One of the questions we would like to  
3 address is: How can FDA be assured of consumer  
4 understanding?

5 Consumers need both oral and written  
6 information to ensure understanding about the  
7 medications they wish to take. Pharmacists are an  
8 excellent source of this information. According to a  
9 1999 FDA survey, 87 percent of patients are receiving  
10 written information about their medications from  
11 pharmacists.

12 With the explosion of Direct to Consumer  
13 advertising, it seems more appropriate than ever that  
14 access to a medicine expert, the pharmacist, could  
15 provide more safe and effective care. Additionally,  
16 pharmacists were voted the most trusted professional  
17 in the United States in Gallup poll surveys for 11  
18 straight years, and are the most accessible health  
19 care professional.

20 Pharmacists have a minimum of six years  
21 education. If a patient comes to the pharmacy where  
22 they also pick up their prescription medicine, the  
23 pharmacist has the advantage of having the patient  
24 profile readily available. This knowledge and  
25 information allows the pharmacist to assist the

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1 patient in making a rational selection for their  
2 condition. It also helps to eliminate the risk of  
3 duplicate therapies or therapies that conflict with a  
4 regimen the patient is already taking.

5 NCPA supports a transitional category of  
6 prescription drugs. This method seems to offer the  
7 best of all worlds by offering a bridge between the  
8 prescription and OTC categories.

9 Prescription drugs in a transitional  
10 category provides the FDA with the ability to assess  
11 the use and safety of the drug in an environment  
12 similar to OTC status, but one that would provide the  
13 safety elements of the patient conferring with a  
14 licensed health care professional.

15 The transitional category we are  
16 suggesting would be for an interim period of, say,  
17 three or four years, during which time the public  
18 health experience with the drug as an OTC candidate  
19 could be evaluated. This extra time allows the agency  
20 the flexibility to assess the drug and allow it to go  
21 OTC or, if safety concerns warrant, return the drug to  
22 Rx status, as it did with Metaproterenol in 1983.

23 To add to the FDA's collection of data,  
24 perhaps a reporting mechanism specific to this  
25 transitional category might be initiated.

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1 Approaches similar to the transitional  
2 category have already been successfully implemented in  
3 other countries. Many countries in Europe have  
4 employed a third category of medications for years.  
5 At a symposium on Capitol Hill in 1991, a panel of  
6 pharmacy leaders from Australia, Canada, Great  
7 Britain, and the Netherlands described how a  
8 transitional category of drugs has worked in their  
9 countries.

10 Robert Davies, the Executive Director of  
11 the Pharmacy Guild of Australia, said: "We believe  
12 our system of graduated drug control provides the  
13 greatest flexibility in balancing conflicting  
14 interests of protecting public health and providing  
15 drugs at a reasonable level of convenience."

16 Furthermore, an additional category of  
17 drugs has been in place in U.S. pharmacies for  
18 decades. The Controlled Substance Act allows for a  
19 fifth schedule of controlled drugs or a C-5 category.  
20 Drugs like Robitussin AC, Donnagel PG, and terpin  
21 hydrate with codeine, are sold only under a  
22 pharmacist's supervision or by prescription.

23 The advantages of this transitional  
24 category of prescription to OTC status could be:  
25 Drugs that might be abused could be identified and

1 controlled; reduced medication errors, duplicate  
2 therapies, or inappropriate therapies; enhanced  
3 compliance, particularly for medications taken for  
4 chronic conditions; and it also allows the FDA the  
5 ability to further evaluate patient safety and provide  
6 flexibility in recalling the drug, if necessary.

7 Who should initiate product category  
8 switches? Regarding this issue, we would make the  
9 following observation: There should be a formal  
10 mechanism where representatives from the manufacturer,  
11 health care professionals, FDA, and consumers can  
12 review prescription products on an ongoing basis to  
13 determine their potential for OTC status.

14 If the OTC Advisory Committee has the  
15 proper composition, structure, and authority to do  
16 this, they may be an appropriate group to perform this  
17 function. If it is not the appropriate group, then  
18 another committee could be formed that could be a link  
19 between public and private interests.

20 Again, NCPA appreciates the opportunity to  
21 discuss the importance of patient access and patient  
22 safety, as these potent medications are contemplated  
23 to be considered for OTC status. We hope the FDA will  
24 strongly consider this concept of a transitional  
25 category to act as a safety link between prescription

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1 and OTC status. Thank you. Can I answer any  
2 questions?

3 MODERATOR DeLAP: Questions? Well, I  
4 guess you covered it all in your comments. Thank you  
5 very much.

6 We'll move on to -- We have two more  
7 sessions, and then it will be lunch break. The next  
8 is Becton, Dickinson and Company, Anna Longwell,  
9 Director of Corporate Regulatory Affairs.

10 MS. LONGWELL: Well, most of you probably  
11 haven't heard of it. It's a publicly traded New York  
12 Stock Exchange medical supply company, and it's got a  
13 global market with about 50 percent U.S. sales, and it  
14 serves both the consumer and the hospital supply.

15 Our diabetes care segment of our business,  
16 for example, provides first aid alcohol wipes to  
17 consumers in a panoply of diabetes care products. We  
18 are also a hospital supply company who supplies a  
19 great deal of business-to-business antimicrobials,  
20 skin preps, surgical scrubs, etcetera. So that's our  
21 interest in OTCs.

22 We have monograph products. We have NDA  
23 products, and we have NDA prescription products that  
24 could be switched. So we've got the whole thing.

25 In terms of criteria for OTC availability,

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1 we'd like the FDA to consider the intended user. We  
2 are dealing now with the fact that we have two very  
3 different sets of customers, our consumers who are  
4 going into Long's and buying things, and our  
5 professional users.

6 The risk assessment is different for each  
7 of those and needs to be considered differently. In  
8 fact, in the tfm for antimicrobial products, you will  
9 see that they are broken out separately.

10 A common practice with cosmetics is to  
11 define quite differently those cosmetics that are  
12 intended for professional users as opposed to those  
13 cosmetics that are intended simply for everybody who  
14 is just buying them at the cosmetic counter.

15 With nonprescription IVD devices, there is  
16 a standard that is applied differently to products  
17 that are designed for professionals and products that  
18 are designed for consumers. Why don't we do this for  
19 these products?

20 Okay. The other issue was consideration  
21 of public health risks in prescription to OTC switch.  
22 I have to say that I really think that, if FDA is  
23 going to proceed with consideration of public health  
24 risks in determination of product safety, they are  
25 going to have to take Brown and Williamson into

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1 account in some way.

2 This is -- Nobody wants to expand on a  
3 Supreme Court decision that's so fresh the ink is  
4 hardly dried, but certainly, this was a component in  
5 the Supreme Court decision, and it was germane to the  
6 decision made, and it was a majority. However, I do  
7 think that public health is, in public opinion, part  
8 of the health consideration. That is, I think the  
9 American public expects public health to be considered  
10 in any public health -- in any health safety  
11 determination, and BD agrees with that.

12 We think it is a necessary component of  
13 the decision whether a product is safe. However, our  
14 concern is that FDA itself probably may not have the  
15 statutory authority and doesn't really have the  
16 expertise that other parts of the government have in  
17 determining public health issues.

18 Public health assessments have to be done  
19 by experts, and it's a different discipline than  
20 product evaluation. It really is. It requires a  
21 different panoply of expertise. So our concern is  
22 more with FDA expertise, and we believe that FDA will  
23 have to go back, look at the Supreme Court decision,  
24 and decide what its impact is on their ability,  
25 statutory ability, to use public health as a

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1 consideration.

2 Okay. We've been through this already.  
3 The criteria for OTC availability -- I just wanted to  
4 add a new one, which I think was added by the cosmetic  
5 people, too. Consider the intended user. Risk  
6 assessments are different.

7 There was another question about home IVDs  
8 and comprehension, and I did want to point out that  
9 DCLD, CDRH in general is dealing with educational  
10 efforts. However, they could do more. I realize  
11 nobody is here from there at the moment, but there is  
12 an international organization that's looking at  
13 criteria for home IVDs that are the kinds of IVDs that  
14 would be used to generate information that's used  
15 almost immediately to take a dose of a drug with a low  
16 therapeutic index.

17 These are products that really do require  
18 more concerted regulatory and standards making input.  
19 The current demands for the labeling is that it be  
20 understandable at the seventh grade level, and that is  
21 a demand now. But -- Yes?

22 DR. KWEDER: I'm sorry. At the risk of  
23 sounding ignorant, I have no idea what IVD stands for.  
24 Could you --

25 MS. LONGWELL: Oh, I beg your pardon.

1 DR. KWEDER: I'm sure there are many in  
2 the audience who don't either.

3 MS. LONGWELL: I'm sorry. In vitro  
4 diagnostics. There was a question about home in vitro  
5 diagnostics that FDA had put into their set of  
6 questions, and it's true that there is a concern about  
7 especially the home in vitro diagnostics that produce  
8 a value that a consumer will use immediately to self-  
9 administer a drug with a narrow therapeutic index.

10 So that there is one area of IVDs that is  
11 even of international concern, but we believe that  
12 DCLD is part of the agency that should be dealing with  
13 this, and not ODE.

14 I'm sorry. I thought everybody here was  
15 totally familiar with all of the initials in the  
16 world. Okay.

17 On this, this is one area where I think  
18 FDA, because individual companies really can't do the  
19 kind of comparative analysis that perhaps an  
20 overbranching organization could, if there really are  
21 therapies for the same condition, certainly a consumer  
22 cannot go read the labels of the OTCs and decide, oh,  
23 well, maybe I should be talking to my doctor about the  
24 prescription drugs that are available. This is  
25 impossible.

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1           That's why I think that's where FDA should  
2 be looking at educating consumers better about the  
3 different therapies. The other thing is perhaps some  
4 of the professional Websites could do it, too.  
5 Individual manufacturers can describe their product  
6 very well. It's a little more difficult to develop  
7 comparative tables, and it's not something that  
8 everybody wants to do anyway.

9           Okay. You're marketing OTCs. We have  
10 global marketing experience. We kind of like --  
11 Unlike the rest of the members of our manufacturing  
12 community, we kind of like the idea of the third class  
13 of OTC.

14           It makes more products OTC. It is a  
15 different risk/benefit. Our disadvantages are we  
16 think FDA now has two classes, the professional use  
17 and the consumer use. They're treating them as one at  
18 the moment. We're worried that, because it's so  
19 onerous to maintain the regulatory structure to keep  
20 two or three separate regulatory categories intact,  
21 that FDA would probably have difficulty managing  
22 another regulatory paradigm.

23           On Rx to OTC, we'd like to see more  
24 transparent procedures, and I think you've already  
25 heard that from the industry. So I don't think that

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1 I'm going to go into it very much, except to say that  
2 we'd like to see internal guidance, too.

3 That is to say, if you are going to take -  
4 - for two things. If you are going to take an Rx to  
5 OTC switch and consider maybe turning that into a  
6 petition to amend a monograph, we'd like to see  
7 internal guidance on that. We would also like to see  
8 internal guidance on criteria for FDA initiated  
9 switches.

10 FDA has been very good about producing  
11 internal guidances that are available to everybody.  
12 We would just like to see a few more of them.

13 This is something nobody has talked about  
14 yet. Maybe it's kind of a hot topic, but we really  
15 think some of these products have been made for a long  
16 time. Notwithstanding that we want to put in new  
17 APIs, we have some products that we have been cooking  
18 now for at least 15 years, almost exactly the same  
19 way.

20 We think that parametric release is  
21 something that could be done with the well  
22 characterized process, given rationales for validation  
23 of vendor's C of A's and review and acceptance of non-  
24 USP standard methods. Once again, this is being done  
25 in other branches of FDA. Why can't it be done here?

1           There are both U.S. and international  
2 methods that may very well be acceptable without  
3 extensive validation in the quality assurance lab.

4           Okay, monograph: My only comment is it  
5 really is kind of a disgrace. I will say that I don't  
6 think, you know, it's all FDA's fault, but Congress  
7 insisted in FDAMA, please finish the sunscreen  
8 monograph. They didn't just say please either. It's  
9 still not really finished. I mean, technically it is  
10 on the books. It's a final reg, but effectivity means  
11 something.

12           No regulation is better than something  
13 that's unenforceable or too vague, it's true. But my  
14 advice is to just give a timeline and stick to it.  
15 Try to do -- It's an embarrassment to the industry as  
16 well, I think, as to the agency.

17           My last point is that OTCs are important  
18 to U.S. health. People have said this already. I  
19 think, and perhaps some people here would agree with  
20 me, that it's often seen as a regulatory step-child.  
21 Prescription drugs are getting more expensive. We  
22 know that. Self-medication is getting more popular.

23           I'm from Silicon Valley. I teach food and  
24 drug law at the Santa Clara School of Law, and I will  
25 say that this is going to be a very big issue. You

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1 people should be spending more time looking at your  
2 Website, improving it, making it more user friendly,  
3 looking at those quack med.com sites that are out  
4 there that are giving out advice that is totally  
5 hopeless.

6 Perhaps you ought to consider links to  
7 some of the reputable professional organizations and  
8 what they are saying about drug use, especially OTC  
9 use. This is just the quality of the information on  
10 the Internet. It ranges from excellent to, you know,  
11 why isn't somebody coming after these guys.

12 Anyway, BD wants to thank FDA for holding  
13 the meeting and for paying more attention to this  
14 important subject. I hope that this is going to be  
15 the beginning of a concerted effort to improve the  
16 monograph process and to spend more time making the  
17 process as it exists more transparent and more rapid.  
18 Thank you. I'll answer any questions you have, if you  
19 have any.

20 MODERATOR DeLAP: Well, thank you for your  
21 comments. You've obviously put a lot of thought into  
22 this, and I appreciate it. Do we have questions?  
23 Well, if not, we'll move on to the American College of  
24 Obstetricians and Gynecologists, Dr. Michael Greene.

25 DR. GREENE: Thank you. I will be brief.

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1 I notice there are fewer questions as we get closer to  
2 lunch.

3 My name is Dr. Michael Greene. I am a  
4 Fellow of the American College of Obstetricians and  
5 Gynecologists, and I'm appearing today on behalf of  
6 the College to present the College's concerns  
7 regarding reclassifying prescription drugs to over-  
8 the-counter status.

9 My relationship to the College is as a  
10 member and an unpaid volunteer in this assignment  
11 today. My day job is Director of Maternal-Fetal  
12 Medicine, Massachusetts General Hospital and Associate  
13 Professor of Obstetrics/Gynecology and Reproductive  
14 Biology at Harvard Medical School.

15 My other paid position is as an associate  
16 editor of The New England Journal of Medicine. I also  
17 serve as Chair of the FDA's Advisory Committee on  
18 Reproductive and Neurologic Drugs.

19 I will not speak today either in favor of  
20 or in opposition to any specific product or products.  
21 I have no financial interests or potential conflicts  
22 to disclose to the agency.

23 The College thanks the agency for the  
24 opportunity to be heard on this issue. The College's  
25 mission is to improve the health care of women. We

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1 pursue that mission through a combination of education  
2 and advocacy.

3 Prior to the epidemic of thalidomide  
4 babies in the 1950s and Sixties, there was little  
5 public or professional awareness or concern about  
6 human teratogenic risks. This disaster coupled with  
7 the heart wrenching photographs from Japan of the  
8 devastating effects of methyl mercury poisoning in  
9 Mitamota Bay raised both the lay and professional  
10 consciousness about the vulnerability of the  
11 developing human fetus.

12 The 1960s saw the development of the  
13 Goldenthal guidelines requiring specific and detailed  
14 animal reproductive safety testing for new compounds  
15 which were designed to prevent another thalidomide  
16 epidemic. Women were advised to avoid any and all  
17 unnecessary drug and environmental exposures during  
18 pregnancy, and to check with their doctors prior to  
19 taking any medications.

20 This educational campaign seemed to be  
21 successful. Hypervitaminosis A was one of the  
22 original experimental animal teratogens in the 1950s.  
23 Thus, when the potent synthetic congener Vitamin A,  
24 isotretinoin, was introduced, it was anticipated that  
25 it would have the potential to be a dangerous human

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1           teratogen.

2                         It was hoped that the general education of  
3 both physicians and patients regarding potential  
4 teratogenic risks and the manufacturer's extensive  
5 efforts to avoid exposures in pregnant women would  
6 prevent fetal injuries. Unfortunately, it was not  
7 long after the introduction of isotretinoin that  
8 reports of severe consequences of fetal exposures  
9 began to pour into the manufacturer and the Food and  
10 Drug Administration.

11                        There are several reasons why women remain  
12 vulnerable to teratogenic exposures. First, it is  
13 generally acknowledged that 50 percent of all  
14 pregnancies in the United States are unplanned. Some  
15 pregnancies represent failures of appropriate and  
16 conscientiously applied contraceptive measures. More  
17 commonly, however, they result from failure to take  
18 appropriate contraceptive measures.

19                        In many of these cases, women may not even  
20 recognize that they are pregnant until they are well  
21 into the first trimester. By that time, much of the  
22 critical period of organogenesis has passed. Many  
23 potential teratogenic exposures occur under these  
24 circumstances.

25                        The potential for adverse fetal

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1 consequences of drug exposure also extends well beyond  
2 the first trimester, as we have learned with the  
3 angiotensin converting enzyme inhibitors. Dr. Allan  
4 Mitchell of the Sloan Epidemiology Unit at Boston  
5 University has studied the epidemiology of drug  
6 exposures during pregnancy quite extensively.

7 He has shown that, when women are  
8 questioned regarding drug use during pregnancy, they  
9 frequently fail to report the use of over-the-counter  
10 preparations. When questioned in more detail about  
11 this, they frequently respond that they "did not  
12 consider over-the-counter preparations to be drugs."

13 Similarly, women will frequently be  
14 reticent to take prescription drugs due to safety  
15 concerns, yet take over-the-counter drugs without a  
16 second thought. This casual regard for over-the-  
17 counter drugs makes it all the more important that  
18 they be safe for use during pregnancy.

19 Drug safety during pregnancy goes beyond  
20 concerns about teratogenicity and developmental  
21 toxicity. The liver and kidneys are both more  
22 sensitive to toxins when pregnant. This lesson was  
23 learned when pregnant women suffered fatty  
24 degeneration of the liver and renal failure when given  
25 large doses intravenous tetracycline to treat

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1 pyelonephritis in the 1950s.

2           Although of less consequence, women still  
3 occasionally develop enterohepatic cholestasis due to  
4 exposure to erythromycin estilate. On March 30 of  
5 this year I participated as an FDA panel member in a  
6 public meeting regarding safety issues surrounding  
7 dietary supplement use during pregnancy which were  
8 raised by the Dietary Supplements Health and Education  
9 Act, DSHEA.

10           During that meeting, a public panel member  
11 presented the results of her research among consumers,  
12 the lay public. She found that consumers were  
13 generally not aware of the individual components and  
14 active ingredients in most products. She found that  
15 most women assumed that, if a product -- in this case,  
16 dietary supplements -- was available for sale over-  
17 the-counter, it was safe for any and everyone.

18           When challenged, women responded that they  
19 were confident that if a product was not safe for  
20 everyone, including pregnant women, quote, "they would  
21 not permit it to be sold over-the-counter." The FDA  
22 is "they."

23           The irony in that case was that the  
24 restrictions of DSHEA specifically prevented the FDA  
25 from regulating the sale of those products. In the

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1 case of over-the-counter preparations, the FDA has the  
2 ability to regulate these products.

3 The general assumptions of the safety of  
4 over-the-counter preparations and the degree of  
5 confidence placed in the FDA to safeguard the public  
6 safety places a heavy burden of responsibility upon  
7 the agency. As you are also aware, the agency cannot  
8 count upon the assistance of a, quote, "learned  
9 intermediary" to help consumers assess the relative  
10 safety risks and therapeutic benefits of a drug  
11 purchased over the counter in a supermarket.

12 Although consumers are ready to accept the  
13 idea that over-the-counter remedies may not be  
14 perfectly effective, they are not prepared to accept  
15 the idea that they are not safe.

16 The American College of Obstetricians and  
17 Gynecologists urges the FDA to make a rigorous  
18 assessment of reproductive toxicity safety in its  
19 broadest sense a routine and mandatory requirement for  
20 drugs being considered for over-the-counter sale. The  
21 burden of proof of safety must be high.

22 American women expect the FDA to protect  
23 them and their fetuses from risks due to over-the-  
24 counter drugs. We trust that you will not let them  
25 down. Thank you.

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1 MODERATOR DeLAP: Thank you for your very  
2 eloquent comments. Do we have questions?

3 DR. HOUN: In looking at safety for  
4 pregnant women, it's hard to do controlled studies.  
5 So are you saying looking at epidemiologic data to  
6 make that assessment?

7 DR. GREENE: I think you're absolutely  
8 correct and, as we all know, when a drug is introduced  
9 the number of persons that have been exposed to it is  
10 relatively small, and usually pregnant women have been  
11 systematically excluded from that small number.

12 So there is frequently very little  
13 information, controlled or scientifically useful  
14 information, to base these decisions upon. I suppose  
15 we would have to advocate that any and all available  
16 information that could be useful to address the issue  
17 be reviewed.

18 DR. KWEDER: To follow up on that, Dr.  
19 Greene, you made the comment that the liver and kidney  
20 have unique sensitivities in the pregnant woman. Do  
21 you think that those considerations should be factored  
22 into the kinds of data that might be considered in  
23 assessing an Rx to OTC switch?

24 DR. GREENE: Absolutely, and that's what  
25 I meant by a broader assessment of reproductive

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1 toxicity, not just looking narrowly at fetal or  
2 developmental effects.

3 MODERATOR DeLAP: If there are no further  
4 questions, thank you very much.

5 We do have one or two announcements that  
6 I will let Dr. Titus make.

7 DR. TITUS: While we can't invite all of  
8 you to lunch, the panel and DAC members have reserved  
9 seats in the cafeteria so that you can get a quick  
10 lunch, because we are coming back and reconvening at  
11 two o'clock.

12 We have an announcement for Susan Winkler.  
13 There is a FAX at the desk for you, at our desk out in  
14 the hall.

15 MODERATOR DeLAP: See you at two.

16 (Whereupon, the foregoing matter went off  
17 the record at 1:09 p.m.)

18  
19  
20  
21  
22  
23  
24  
25

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

(2:08 p.m.)

1  
2  
3 MODERATOR DeLAP: Okay. We are going to  
4 start with a couple of announcements from Dr. Titus.

5 DR. TITUS: Many of you have been asking  
6 us how soon the information from the meeting, the  
7 transcript, gets posted. In approximately two weeks  
8 after the meeting, it will get posted, and we've  
9 provided at the table out front this yellow flier  
10 which is your way to access how to find it on docket.

11 Then the second thing we want you to be  
12 thinking about is tomorrow afternoon, assuming that we  
13 stay on schedule, from 2:30 to whenever the meeting  
14 ends, we have an open public hearing scheduled. We  
15 are encouraging you to fill out a form that we also  
16 have left at the table indicating if you are  
17 interested in participating in the open public hearing  
18 tomorrow.

19 Our first priority is to listen to people  
20 from whom we haven't heard, obviously, but we will  
21 also consider people who have presented today if they  
22 want to add more things. So we're encouraging you to  
23 fill out the form and indicate what you would speak to  
24 us about, and you should plan on at most something  
25 along the lines of five minutes. The sooner you turn

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1 them in, the easier it would be for us to figure out  
2 what was going to happen tomorrow afternoon.

3 We will post a list probably sometime  
4 after lunch tomorrow indicating who is speaking at the  
5 final open public hearing session.

6 MODERATOR DeLAP: Very well. Our first  
7 speaker for the afternoon session is Dr. Sidney Wolfe,  
8 representing the Public Citizen's Health Research  
9 Group. Dr. Wolfe.

10 DR. WOLFE: The speaker after me needs to  
11 catch a plane. So I have -- I wouldn't call it  
12 gracious, because that's not the adjective to describe  
13 it. I'm switching places with her.

14 MODERATOR DeLAP: Thank you, Dr. Wolfe.  
15 So then the first speaker is Dr. Chao of MedImpact.

16 DR. CHAO: Good afternoon. First of all,  
17 I want to thank Dr. Wolfe for his graciously letting  
18 me speak before him so that I can catch a flight, and  
19 also thank you, Dr. Titus.

20 Good afternoon, everyone. It's always a  
21 challenge to be the first speaker after lunch. So I  
22 will keep my remarks very brief so that you can fall  
23 asleep on the next speaker. That serves Dr. Wolfe  
24 right for letting me speak first, I guess.

25 I'm Schumarry Chao. I am here on behalf

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1 of MedImpact, which is a pharmacy management company  
2 who also deals with information from the pharmacy data  
3 in looking and managing care.

4 My other day job is as the clinical  
5 professor of emergency medicine and the clinical  
6 professor in pharmaco-economics in the School of  
7 Pharmacy at University of Southern California. On a  
8 voluntary basis, I'm on the Board of Emergency  
9 Medicine in terms of Board of Examiners, as well as on  
10 the Board of Health Care Policy at the University of  
11 Southern California in the School of Public  
12 Administration.

13 My remarks today really are to raise the  
14 concerns that I see with the potential of the  
15 conversion of prescription drugs en masse to the over-  
16 the-counter status. As the medical officer and the  
17 Chief Medical Officer at MedImpact, I oversee the  
18 medical aspects of pharmacy benefit management and  
19 clinical interventions for millions of members and  
20 consumers.

21 As a prescription benefit manager, we  
22 adjudicate claims real time. In that role, we capture  
23 complete longitudinal drug history on each of our  
24 members regarding how many -- regardless of how many  
25 different physicians prescribe medications for that

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1 patient and regardless of how many pharmacies that  
2 patient may access in the dispensing of that  
3 medication.

4 This information is invaluable in that at  
5 the time of prescribing and dispensing, the physician  
6 and pharmacies are able to be alerted to drug  
7 interactions so that we can prevent the medical  
8 problems that can result from the adverse reactions.

9 For example, combinations of certain  
10 allergy medications and antibiotics or antifungals can  
11 have serious implications on the cardiovascular  
12 system. In addition, for example, medications which  
13 are very efficacious in the treatment of asthma can  
14 have serious conflicts if the patient happens to be a  
15 hypertensive.

16 According to our data, physicians or  
17 pharmacists have been able to avoid an adverse event  
18 in about 15 percent of the time due to our  
19 intervention. If these therapeutic classes are  
20 converted to OTCs, we will no longer be able to  
21 capture that information, nor will we have the  
22 opportunity to be able to intervene real time to  
23 prevent these adverse reactions.

24 As we are all familiar with the recent  
25 results which were released by the National Institute

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1 of Health regarding the number of iatrogenic deaths  
2 per year, up to 100,000, and the majority of which are  
3 due to drug adverse reactions, I think that with the  
4 conversion en masse to OTCs we can only see those  
5 numbers increase logarithmically.

6 In addition to the alerts of drug  
7 interactions, the longitudinal drug history also  
8 provides physicians with information on patient  
9 compliance, which is key in the management of chronic  
10 diseases, as well as that it also alerts the doctor as  
11 to other patient diagnoses which the doctor may not  
12 have been aware of, if he's only treating that patient  
13 for a specific one particular complaint.

14 According to our data, up to 30 percent of  
15 the time physicians act on that information to better  
16 manage the patient, thereby alerting the patient of  
17 the importance of compliance or changing their  
18 therapies based on their knowledge of other diagnoses.  
19 Again, with the conversion to the OTCs, that  
20 opportunity will be lost.

21 Finally, the aggregation of the pharmacy  
22 claims data, which to date is still the best clinical  
23 data that we really have, with other pieces of data,  
24 including medical claims data, lab, etcetera, really  
25 provides us with the best opportunity to the future --

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1 for the future of evidence based managed care.

2 Analysis of this data can provide  
3 insights as to the relative efficacy and cost  
4 effectiveness of alternative therapies on major  
5 disease states. As you can see, I'm a typical doctor.  
6 I can't read my own handwriting. This opportunity  
7 also will be lost in the event that we actually lose  
8 access to that claims data.

9 Now as an emergency physician for the past  
10 25 years, and also as one of the key architects of the  
11 emergency medical system in L.A. County in the 1970s,  
12 I've always been a strong advocate of having  
13 appropriate population access to the appropriate care  
14 based on medical necessity, not based on ability to  
15 pay.

16 It is ironic today that in Congress we are  
17 having a debate in terms of promoting access to  
18 affordable drugs on the Hill with the expansion of  
19 prescription benefits for Medicare at the same time as  
20 we are looking at conversion of these drugs, the  
21 prescription drugs, on major therapeutic classes to  
22 OTCs. We are, in essence, changing the benefit design  
23 to 100 percent co-pay for the patient, and we are  
24 basically looking at allocating drugs and access to  
25 these drugs based on ability to pay, not based on

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1 medical necessity.

2 From my perspective, that raises some  
3 really serious concerns. As a physician, if we are  
4 looking that we think that this is the best line of  
5 therapy -- and often drugs are the first line of  
6 therapy, because of their cost, effectiveness as well  
7 as of their noninvasive nature.

8 Now if we actually lower that access  
9 because we are fooling ourselves, saying that we are  
10 opening up access, but if the patient can't afford to  
11 buy their drugs, they basically have no access. One  
12 is they will be denied that access to care.

13 Secondly, in all likelihood, health care  
14 costs will go up, because we will be shifting to  
15 second and third line of therapies, because those  
16 therapies are really covered by insurance.

17 Lastly, I'll reserve my comments as a  
18 practicing physician. In the emergency room, if I  
19 were to ask a patient what drugs they are on, in all  
20 likelihood they would even forget to mention that they  
21 were on OTCs. The reason for that is most consumers  
22 perceive OTCs as innocuous. They are harmless. They  
23 are totally safe. Otherwise, they wouldn't be so  
24 openly accessible.

25 They don't even bother to mention that.

1 Now when we don't have the physician oversight because  
2 of lack of prescription, in addition, based on the  
3 1992 report by the GAO office, we also find that the  
4 OTCs have much less oversight from the FDA than  
5 prescription drugs.

6 So as we take a look at this whole issue  
7 from all the different perspectives of a pharmacy  
8 manager, as an academician and a researcher, as a  
9 health care policy adviser and as a practicing  
10 physician, I raise the concerns that conversion to  
11 OTCs of major therapeutic classes will have negative  
12 impact on patient care.

13 Access to commonly accepted first lines of  
14 therapy only on the basis of ability to pay, which is  
15 what this really means, with no means really for  
16 clinical monitoring nor intervention go against the  
17 very principle of managing care, which is to promote  
18 access to the appropriate care for the appropriate  
19 patient. Thank you.

20 MODERATOR DeLAP: Well, thank you very  
21 much. I think we did have some discussion this  
22 morning about the ramifications of changing  
23 availability and what that meant as far as adverse  
24 experience reporting.

25 I think that is an issue that we have to

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1 consider. The reporting, of course, is quite  
2 different for an NDA kind of drug than for a drug  
3 that's marketed under a monograph. And even when  
4 products are marketed OTC under an NDA, I think we  
5 have to be secure that we are still getting the  
6 adverse experience reporting that we need to get.

7 In that regard, your comment about having  
8 the claims data to try and make associations and  
9 epistudies and that sort of thing is something that,  
10 I guess, you lose if you go into the OTC setting, even  
11 with an NDA drug.

12 Are there other comments or thoughts from  
13 the panel? Dr. Temple?

14 DR. TEMPLE: You made a number of points  
15 about how there were disadvantages to self-care, that  
16 you can't monitor for interactions, and you can't get  
17 a history of allergy and all the kinds of things.  
18 That's certainly true, and you can imagine that we've  
19 put those elements into discussions of this.

20 One of the arguments that people have used  
21 strongly for the availability of certain chronic  
22 medicines, notably antihypertensives or lipid lowering  
23 drugs, is that the current system, for better or  
24 worse, fails to treat a large fraction of people who  
25 need treatment. And while recognizing the

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1 disadvantages you cite, they say that's worth -- that  
2 makes it all worth it, because so many more people  
3 could be treated this way.

4 Do you have any response to that line of  
5 argument?

6 DR. CHAO: I guess I'm a little puzzled in  
7 terms of that line of argument. They would have a  
8 larger number of people because they would have open  
9 access. Is that the argument?

10 DR. TEMPLE: I think the idea is that the  
11 promotion would be so unbelievable that everybody  
12 would now know, whereas now the companies are helpless  
13 and can't promote their products.

14 DR. CHAO: Well, I think that anyone who  
15 thinks the pharmaceutical companies have been, you  
16 know, slouching in the area of directed consumer  
17 marketing hasn't been watching TV very often, because  
18 in my perception it doesn't seem to matter whether  
19 it's an over-the-counter or a prescription drug in  
20 terms of the raising of awareness of the consumers to  
21 particular drug classes and their benefits to those  
22 consumers. However, I think as you raise the issue of  
23 access, I totally am supporting access.

24 The question that I raise is the  
25 appropriate access and the monitoring of that, because

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1 there is a perception, as I mentioned before, that  
2 with the advertising people are looking at it in the  
3 same category of a number of other consumer products  
4 where consumers can really choose at will as to  
5 whatever they find sexy on the ads, that they would  
6 then go and access those type of products.

7           You know, if drugs are innocuous, they  
8 wouldn't have any therapeutic effects. If by having  
9 therapeutic effects they are not innocuous and,  
10 therefore, really do have downsides as well as  
11 upsides, and I think that, regardless of all of the  
12 things that we're talking about of Internet and the  
13 patient education, patients are a long ways away from  
14 knowing enough about this to be able to self-medicate  
15 appropriately as to not create as much the downside as  
16 much as the upside.

17           In fact, as I showed in my data, even  
18 physicians who, hopefully, through medical school and  
19 medical training would have more knowledge, we are  
20 intervening in up to 15 percent of the time, because  
21 they are not able to keep in their head all of the  
22 drug interactions.

23           To be able think that individual consumers  
24 accessing information ad lib, whether it's on the Web  
25 or on TV or on radio, especially given that OTCs are

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1 not as heavily regulated in their advertising as  
2 prescription drugs, I think that we are really setting  
3 ourselves up for a major disaster.

4 MODERATOR DeLAP: Well, thanks very much  
5 for your comments, and I guess we can let you go and  
6 get your plane then, and we can --

7 DR. CHAO: Thanks again, Dr. Wolfe. I  
8 think they are still awake.

9 MODERATOR DeLAP: We can hear from the  
10 long awaited Dr. Wolfe.

11 DR. WOLFE: We have been watching this  
12 process for 29 years or whatever of the switching  
13 slowly of certain drugs from prescription to over-the-  
14 counter status, and in many of the instances, such as  
15 the analgesics, we have thought it was a good idea.

16 Really, only twice prior to now have we  
17 attempted to intervene to stop switches, in one case  
18 a drug that had already been switched. In other  
19 words, it was pending to be switched.

20 I will mention those in the context of  
21 some principles that we have used over the years and  
22 will continue to use when we review possible switches  
23 from prescription to over-the-counter status. I think  
24 that these are principles that could be helpful to  
25 other people. They are principles that, I'm sure, a

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