

UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

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PUBLIC HEARING

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TUESDAY,

NOVEMBER 1, 2005

The Public Hearing was held in the Lower Level Boardroom of the National Transportation Safety Board at 429 L'Enfant Plaza, Southwest, Washington, D.C. at 9:00 a.m., Tom Abrams, presiding.

PRESENT:

TOM ABRAMS, Chair
KATHRYN AIKIN
RACHEL BEHRMAN
GLENN BYRD
KRISTIN DAVIS
SCOTT GOTTLIEB
MARTINE HARTOGENSIS
MELISSA MONCAVAGE
NANCY OSTROVE
ROBERT TEMPLE
DEBORAH WOLF

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ALSO PRESENT:

ROSE CUNNINGHAM
JANET WOODCOCK, Deputy Commissioner of Operations, FDA
SHARON ALLISON-OTTEY
RUTH DAY
LEWIS GLINERT
JOHN KAMP
ANDREW KLEIT
J. PATRICK KELLY
ABBY MEHTA
MICHELE SPENCE
CHRISTINE WINNICKI
JAMES GARDNER
GAIL JAVITT
WILLIAM PERSON
CAROLE ROGIN
MARLENE TANDY
REBECCA BURKHOLDER
LEE HAMMOND
GARY STEIN
LISA VAN SYCKEL
DIANA ZUCKERMAN

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P R O C E E D I N G S

9:01 A.M.

MS. CUNNINGHAM: Good morning, everyone. Anyone still out in the lobby, please come forward. We had over 500 people signed up. It doesn't look like we have 500 people here yet, but they'll be dribbling in and out and in part today and then tomorrow, different people.

If you are one of our panel members on Panel 2, please see me as soon as possible. I want to make sure you're all here, because you'll be coming up as soon as we have a break.

We're going to begin. I've been asked to remind people to please turn off your blackberries. It interferes with the audio. We have wireless mikes that are going to be used and it picks up static.

So with that the restrooms are out front. There are restaurants in the complex. Everybody is given 12 minutes. Please stick to the time because we have a very ambitious schedule and lots of people talking.

With that, I'm turning it over to Tom Abrams who is the Director of our DDMAC.

MR. ABRAMS: Good morning and welcome to FDA's public hearing on consumer-directed promotion of

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1 regulated medical products or direct-to-consumer
2 promotion, also known as DTC.

3 I am Tom Abrams, Director of DDMAC, the
4 Division of Drug Marketing, Advertising and
5 Communications in CDER, the Center for Drug Evaluation
6 and Research. And I will serve as the presiding
7 officer for this hearing.

8 It would be an understatement to say that
9 much has happened in consumer-directed promotions
10 since the first DTC ads appeared in the early 1980s.
11 There's also much interest in this area, illustrated
12 by we have a full registration and we will have a full
13 attendees today. I know people are coming in later
14 from the Metro.

15 The Agency, the industry and other members
16 of the public have gained much experience with
17 consumer-directed promotion, so we believe it's a good
18 time at this point to take a step back and to evaluate
19 what regulatory issues should be addressed in FDA's
20 activities.

21 This hearing today is intended to provide
22 an opportunity for broad public comment concerning
23 consumer-directed promotion of medical products,
24 including human and animal prescription drugs,
25 vaccines, blood products and medical devices.

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1 I would like to introduce the FDA Panel at
2 this point. Starting from my left is Kathryn Aikin,
3 Social Science Analyst in DDMAC. To my immediate left
4 is Robert Temple, the Director of the Office of
5 Medical Policy in CDER. To my right is Rachel
6 Behrman, Deputy Director of Office of Medical Policy.

7 And Scott Gottlieb, the Deputy Commissioner for
8 Policy for the Food and Drug Administration.

9 Going down to the Panel on the floor,
10 closet to the front of the room is Deborah Wolf,
11 Regulatory Counsel in the Office of Compliance for the
12 Center of Devices and Radiology Health. Next to
13 Deborah is Nancy Ostrove. Nancy is Senior Advisor for
14 Risk Communication in the Office of Planning of the
15 Office of the Commissioner. Melissa Moncavage is the
16 leader of the DTC Review Group in DDMAC. Martine
17 Hartogenesis is Promotion and Advertising Liaison in
18 the Center for Veterinarian Medicine. Glenn Byrd is
19 the Chief of the Advertising and Promotional Labeling
20 Review Branch in the Center for Biologics Evaluation
21 and Research. And finally, Kristin Davis who is
22 Acting Deputy Director in DDMAC.

23 We have 38 speakers in this hearing, so to
24 provide a most productive meeting, let me just go over
25 some of the ground rules. First, this meeting is

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1 informal. The rules of evidence do not apply. No
2 participant may interrupt the presentation of another
3 participant. Only FDA panel members will be allowed
4 to question any person during the presentation or at
5 the end of the presentation.

6 If time permits after the FDA Panel has
7 completed its questioning of each panel session,
8 public comments will be taken from the floor. We will
9 open it to the floor at that point.

10 Public hearings under part 15 are subject
11 to FDA policy and procedure for electronic media
12 coverage of FDA public administrative proceeding.
13 Representatives of the electronic media may be
14 permitted, subject to certain limitations to
15 videotape, film or otherwise record FDA's public
16 administrative proceeding, including the presentations
17 of the speakers today.

18 This meeting will be transcribed and
19 copies of the transcript may be ordered through the
20 dockets or accessed on the internet.

21 Each speaker will be given 12 minutes to
22 present their information and the FDA Panel Members
23 will have up to 8 minutes to ask questions, so we'll
24 have the speaker for 12 minutes or under and then FDA
25 will open up with questions. After all the speakers

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1 are done on the panel, we will open it up to the floor
2 for comments, if time permits.

3 Given the full agenda today, we request
4 that each speaker keep their presentations to 12
5 minutes, so we will have time to hear from all the
6 speakers. We thank you for your interest and
7 participation today. We look forward to a very
8 productive meeting.

9 Now I would like to introduce Janet
10 Woodcock, the Deputy Commissioner for Operations of
11 the Food and Drug Administration.

12 Dr. Woodcock?

13 MS. WOODCOCK: Thanks, Tom. And good
14 morning to all of you and thank you for participating
15 in this hearing. As you're aware, the subject of
16 consumer-directed advertisement of prescription
17 products also called consumer-directed promotion or
18 DTC, generates great interest from diverse groups and
19 I expect we will have a lively set of presentations
20 over the next several days.

21 Before we get started hearing the
22 testimony it may be useful to review some basics about
23 the DTC and how it evolved to where we are today with
24 this form of promotion.

25 First, there are no laws or regulations

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1 that prohibit promotion directly to the consumer. FDA
2 often gets questions about this and this basic fact.
3 Second, the regulations focus on the content and not
4 the extent of promotion. Therefore, as a result, it's
5 legal for companies to promote directly to consumers,
6 and additionally, of course, there is no legal limit
7 on the amount of money a company can choose to spend
8 on direct-to-consumer advertising.

9 FDA regulates the content of the promotion
10 to ensure it's truthful, balanced and not misleading.

11 Regulation of promotion in this manner is important
12 because of the impact of prescription drugs and
13 restricted devices may be different from other
14 products because of their potential risks inherent in
15 their use or misuse.

16 Therefore, it is critical from a public
17 health standpoint that ads are truthful, balanced and
18 not misleading. Balanced, in this context, means
19 having a candid representation of the risks associated
20 with the use of the product presented in the
21 advertisement, along with the representations of the
22 benefits, the potential benefit.

23 Prior to the early 1980s, prescription
24 products were not promoted to consumers and patients.

25 In fact, as we've discussed before in this setting, a

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1 long time ago, it was viewed that it was not very
2 helpful for patients or consumers to actually know
3 what was wrong with them. However, that changed in
4 society and in the early 1980s, a few companies began
5 advertising two products to consumers. One was an
6 arthritis drug and the other was a pneumonia vaccine.

7 Because there was no experience with direct consumer
8 promotion, up to this point many parties expressed
9 concerns about the possible impact on the public
10 health.

11 To allow time to evaluate and make this
12 assessment, FDA issued a policy statement on September
13 2, 1983, asking industry for a voluntary moratorium on
14 direct-to-consumer. The industry complied with this
15 request, giving the Agency time needed to study
16 whether current regulations which had been developed
17 in the 1960s for promotion directed to health care
18 professionals provided sufficient safeguards to
19 protect consumers when applied to DTC.

20 This also gave the Agency time for a
21 dialogue among the affected stakeholders, consumers,
22 health care professionals, industry and for interested
23 parties to conduct research on DTC. After meetings,
24 research and discussion, FDA lifted its request for
25 the voluntary moratorium in 1985, stating that the

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1 regulations provide sufficient safeguards to protect
2 consumers.

3 Since that time, FDA has held several
4 meetings and issued a number of guidances. However,
5 as Tom said, a lot has changed, especially in the past
6 decade in DTC and we believe it's time to obtain
7 additional input to guide our overall policy
8 development.

9 We also want to note that DTC promotion
10 for medical devices has not received as much attention
11 previously because until recently there's not been a
12 significant amount of DTC device promotion, except in
13 very limited areas. However, this situation may be
14 changing and we seek input on this topic as well.

15 Today, we will hear thoughts of the
16 panelists concerning current DTC regulations and how
17 it might be improved or changed. Today, the FDA is
18 here to listen. We will be reviewing everything that
19 is presented during these proceedings and to the
20 docket to determine our next steps.

21 Once, again, we want to thank you for
22 taking the time to come today to assist us in this
23 endeavor and we also look forward to the written
24 comments that might be submitted to the docket. Thank
25 you very much.

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1 MR. ABRAMS: Thank you, Dr. Woodcock.
2 Let's review the agenda and then we'll begin. We will
3 have four panels today and four panels tomorrow. We
4 will have two panels this morning with a break in
5 between those and then break for lunch, come back and
6 have two additional panels with a break between the
7 two panels.

8 So we will begin with the first panel.
9 Each panel member will come up and present and then
10 FDA's Panel will pose some questions. The next panel
11 member will come up and present and FDA will have an
12 option to pose questions to that panel member. And
13 then, as I mentioned, if time permits, after the panel
14 has completed its presentations and FDA panel has
15 completed its questioning, we will open it up to
16 comments from the floor.

17 I'd like to begin with the first speaker,
18 Sharon Allison-Ottey.

19 MS. ALLISON-OTTEY: Good morning. First,
20 I want to thank the FDA and DDMAC, Mr. Abrams, and the
21 entire Panel for number one, having the hearing and
22 opening up an opportunity to present this data, but
23 also for having the interest of Americans at heart.

24 I'm going to present some brief summary
25 research that was actually commissioned by Pfizer,

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1 they commissioned Ipsos, which is an international
2 market research firm and in a few slides you'll
3 understand why I'm presenting on behalf of the key
4 opinion leaders and experts in health literacy and
5 some consumer advocacy groups that were asked to
6 participate with guidance on this.

7 This project's research objectives were to
8 determine if alternative versions of the brief summary
9 do a better job at conveying additional information
10 than the current brief summary, to communicate key
11 risks and benefits, to motivate and not necessarily
12 demotivate appropriate discussion with a position, and
13 to recommend potential alternatives to the current
14 brief summary with a huge focus on health literacy in
15 making sure that patients understand risks and
16 benefits.

17 The project kickoff and I think it has to
18 be noted that prior to any of the data, prior to any
19 of the research being done, Pfizer engaged public
20 health thought leaders such as members from the
21 National Consumers League, American Academy of Family
22 Physicians, COSHAR, which I represent, the National
23 Council on Aging, all of us whom have an inherent
24 interest in patient safety and in making sure that
25 communication is effective.

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1 Then the formats, the qualitative research
2 was completed and we moved forward with quantitative
3 research which I'll discuss.

4 The qualitative research was conducted in
5 September of 2004 and really the focus was to better
6 understand consumers' and physicians' reactions to
7 eight innovative or new alternatives to the current
8 brief summary. Interviews were conducted, about 60
9 minutes, with 27 consumers and 14 physicians. Based
10 on that study and that data, four innovative options
11 that were developed that may be able to help provide
12 consumers with more user-friendly information were
13 recommended.

14 One, empowerment, and you will see these
15 in a few minutes, the empowerment module which
16 provided information that was important about the
17 information on the two disease processes that were the
18 target of this data were high cholesterol and
19 migraine. So empowerment was to not only talk about
20 the disease process, but to talk about medication,
21 lifestyle changes that can empower the patient and
22 thus the term, to improve their own outcome.

23 "Fast Facts" which provided the pertinent
24 information in an easy-to-follow format allowing the
25 reader to do what most of us do and that is to quickly

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1 scan and read the sections that are most important.

2 The "Questions" format provided, again, a
3 Q and A approach as another way of getting information
4 to the patient or consumer. And then finally, the
5 "Safety Guide" which seemed to be actually highly
6 user-friendly. There were the blocks and different
7 things in the format that drew the eye to the safety
8 guidelines, risk and benefits.

9 These were combined with the existing
10 brief summary versions and prototypes of those
11 referenced by the 2004 FDA brief summary guidance to
12 create the quantitative tests matrix.

13 And you will see, I've talked about these.

14 These are just kind of an overview of the nine that
15 were utilized.

16 The methodology for the quantitative
17 research, a survey instrument was administered to at-
18 risk and diagnosed populations, patients or consumers
19 self-identified. There were 2100 actual participants
20 in the survey. Each alternative version of the brief
21 summary, including one version that was an ad only
22 with no brief summary, was tested. A fictitious
23 product name and that was at the name of the
24 recommendation of the FDA and I think it should be
25 noted, as it was noted here, that the FDA's input was

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1 requested and incorporated at several levels and
2 development of this research project.

3 The front page was the same for each of
4 the ads and each sale had 200 respondents with the
5 current brief summary having 300 respondents.

6 The interview process was somewhat simple.

7 The respondents were asked to read and review an ad,
8 i.e., that was a forced exposure. And then the
9 respondent was administered and interviewed, the
10 survey instrument.

11 Respondents were asked with aided recall,
12 i.e., is this product useful for high cholesterol,
13 high blood pressure, etcetera, etcetera, asked aided
14 recall of specific communication points. They were
15 questioned on their recall, again, of who the product
16 was for and who the product was not for, other things
17 you can see on the slide, what the side effects of the
18 medication are and how severe they are. They were
19 also asked about their reaction to the ad and in the
20 upcoming slides you will see affect. Affect
21 descriptors are were the ads useful? Was it
22 informative? Did it appear cluttered? Was it easy to
23 read? Was it hard to understand?

24 They were also asked about actions they
25 may or may not take as a result of seeing the ad.

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1 Would you speak to your physician? Would you look for
2 more information? Would you call a 1-800 number?

3 There were additional questions about
4 health as well as demographics. And you can see,
5 again, the N for this is 2100. The respondents of the
6 study were balanced to match the sufferer/at risk
7 universe and the demographics are similar to what we
8 see in this country.

9 Many of you know, before I was here in
10 2004 presenting data for minority communities, and it
11 is interesting to note that there is a good
12 representation across the board for this study.

13 Analysis. Each version of the back page
14 has been analyzed based on the following dimensions:
15 one, aided recall; two, prompt discussion; and three,
16 the affect, which I discussed. The analysis that
17 determines the degree of effectiveness on the back
18 page version by dimension or component of dimension is
19 based on a two step test, one, which alternative
20 version is better than the control. And remember, the
21 control is the current brief summary. And two, if the
22 alternative version passes that step and it's better
23 than the control, among those that move forward which
24 is best?

25 I talked about affect and I briefly just

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1 wanted to go over this when we look at the scoring.
2 The question items that comprise the affect scale you
3 can see on the left. The desired answer is the next
4 column and the sample respond, the actual answer. If
5 the respondent answered or gave the desired answer
6 they received a one on a scale of seven factors and
7 this was extrapolated out to a scale of 100. And
8 those are the data that you will see now.

9 Key learnings. Before looking at the
10 final slides are one, the added self is an integral
11 part of risk communication. Consumers do receive
12 information about side effects and other important
13 information from the ad alone which was demonstrated
14 by the ad sale only. But two, the brief summary, as
15 we all know, matters. And ad with a brief summary is
16 much more effective at conveying side effect
17 information compared to having an ad only with no
18 brief summary at all. Three, the brief summary can
19 definitely be improved. The current brief summary is
20 clearly inferior at communicating information,
21 compared to all of the other alternative measures that
22 were tested. Four, there are several appealing
23 alternatives to the current brief summary. On the
24 crucial dimension of recall and severity of side
25 effects and thus patient safety, three of the

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1 alternative versions proved superior to other versions
2 tested within both therapeutic areas and remember that
3 the therapeutic areas are migraine and high
4 cholesterol.

5 And importantly, risk communication and
6 motivation are not incompatible. Each of the versions
7 as motivation scores that are no worse than an ad
8 paired with the current brief summary.

9 This is a performance survey and you will
10 be able to see better for the essence of time. Here,
11 look at the yellow portions which indicate -- the
12 following table indicates the shaded cell, those
13 versions perform significantly better than control on
14 the dimensions tested. You will see that the yellow
15 indicates the cholesterol module, the migraine module
16 is the hatch marks and you can see the ones that
17 perform better for both migraine and cholesterol.
18 Clearly, the brief summary has room for improvement.

19 And finally, the performance funnel.
20 Number one, the ad only and this is who is the winner?

21 So you start with the ad only which performed the
22 most poorly. I don't think that's a word, but
23 performed poorly. It does not do better than control
24 on side effect communication although, as I said
25 before, some side effect communication was -- some

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1 side effect information was conveyed, based on this
2 study. Then you move down and you see that the next
3 ads do better than control on side effect
4 communication for one indication, but not for both.
5 And then finally, the winners are fast facts,
6 questions and the safety guide. These three
7 prototypes all do better than control on side effect
8 communication for both indications.

9 The most exciting phrase to hear in
10 science is the one that heralds new discovery -- it is
11 not "Eureka", but "that's funny." In that light, I
12 believe that this data shows that. If we keep it
13 simple, but effective with an eye on safety, but the
14 ability to effectively communicate in a way that
15 patients/consumers can understand, we can achieve our
16 goals of making sure that side effects, risks,
17 indications and all of the information is
18 communicated. But we must speak the language of the
19 patient.

20 Thank you.

21 MR. ABRAMS: Thank you, Dr. Allison-Ottey.

22 We will open it up to questions at this point from
23 the FDA Panel.

24 Dr. Aikin?

25 MS. AIKIN: Thank you for your

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1 presentation. It was very interesting. I do have a
2 question for you. You mentioned that the new versions
3 of the ads scored no worse in terms of motivation than
4 the control ad, whereas I would have expected an ad or
5 rather a brief summary that's more accessible to score
6 better in terms of motivation.

7 Do you have any insight as to why it
8 didn't score any better?

9 MS. ALLISON-OTTEY: Well, in some areas,
10 it actually did score better. But I think --
11 remember, the front of the ad stays the same. And is
12 it that the front of the ad is the motivator? And
13 then on the back you have information that talks about
14 side effects and risks and those things and I think
15 there's a balance in that.

16 MS. AIKIN: So were you simply -- were
17 they simply measuring motivation in terms of
18 motivation to read the front of the ad?

19 MS. ALLISON-OTTEY: It was motivation to
20 speak to the physician; motivation to not speak to the
21 physician; motivation to dial a 1-800 number. So it
22 was the motivation to take action.

23 MS. AIKIN: Okay, thank you.

24 MR. ABRAMS: Dr. Temple?

25 DR. TEMPLE: One of your formats, if I can

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1 remember the name, is empowerment?

2 MS. ALLISON-OTTEY: Yes.

3 DR. TEMPLE: If I understand you, that
4 didn't make any special effort to communicate side
5 effects. It really, to some extent, has a different
6 purpose. It's about why you might want to use the
7 drug. So I take it you don't think that its failure
8 to communicate side effects is either here nor there,
9 as to whether that might be a useful thing to do. It
10 seems to have a different function.

11 MS. ALLISON-OTTEY: It does have a
12 different function, but side effects were noted. And
13 so it actually did not fare any worse than the current
14 brief summary on communicating those side effects.

15 DR. TEMPLE: So telling people about the
16 disease didn't help them understand side effects,
17 particularly, but one might not have expected it to.
18 Okay.

19 DR. TEMPLE: Dr. Ostrove?

20 MS. OSTROVE: And if you don't have the
21 information with you, I certainly understand. You
22 said that one of the affects that you asked about
23 according to this was whether the ad or the
24 information was scary or frightening. Can you say
25 anything about the results of those?

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1 MS. ALLISON-OTTEY: I think because of the
2 ambiguity, we took out some of that information
3 because how is that interpreted? And so I'd rather
4 send you something on that. I'm not prepared to
5 really comment.

6 MS. OSTROVE: That would be great, thank
7 you.

8 MR. ABRAMS: Dr. Behrman.

9 MS. BEHRMAN: This may be along the lines
10 of what Nancy was asking about, but when you say risk
11 communication and motivation are not incompatible, are
12 you essentially trying to address the question of
13 whether the risk information in the ad discourages
14 people from seeking -- seeing a physician or seeking
15 help from addressing the matter. Was that what that
16 point was trying to get at?

17 MS. ALLISON-OTTEY: Yes, exactly.

18 MR. ABRAMS: A question. Will you be
19 submitting to the docket this detailed information? I
20 know you were only given a short time.

21 MS. ALLISON-OTTEY: We certainly can.

22 MR. ABRAMS: We would appreciate that.
23 Okay, Dr. Allison-Ottey, we appreciate that. Dr.
24 Allison-Ottey is from the COSHAR Foundation.

25 Our next speaker is Ruth Day from Duke

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1 University.

2 MS. DAY: Good morning. The topic is
3 comprehension of benefits versus risks, is their fair
4 balance in DTC? First question, how do people
5 understand risk information? The answer is with great
6 difficulty. There are a lot of reasons for this,
7 including heavy information load, complex technical
8 information and so forth, but today we're going to
9 focus on cognitive inaccessibility. Cognitive
10 accessibility is the ease with which people can find,
11 understand, remember and use drug information and
12 hopefully in a safe and effective manner. Cognitive
13 inaccessibility occurs when people have trouble with
14 any of these processes.

15 In our research lab, we study a wide
16 variety of types of information about drugs. Today,
17 I'll be focusing on TV ads for prescription drugs and
18 their implications for print ads as well.

19 The basic approach in our research is to
20 perform cognitive analyses on the materials first. We
21 obtain quantitative measures. We calculate cognitive
22 accessibility and compare it for both benefits versus
23 risks. Then we develop enhanced displays of the same
24 information based on cognitive principles and then
25 perform cognitive experiments in the laboratory to

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1 test the effects on attention, comprehension, memory,
2 problem solving, decision making behavior and
3 ultimately health outcomes.

4 All of this is based on a variety of
5 cognitive principles, some of which I'll discuss
6 today. So let's consider some TV ads.

7 This research spans a wide range from the
8 Year 2000 to 2005 and let's see what a typical
9 experiment is like. People will see an ad or three
10 ads and then we will test them on benefits versus
11 risks and one type of question is what is it for, the
12 indication. And as you can see, people typically do
13 quite well on this type of question. Generally, about
14 80 percent correct across a variety of different ads.

15 However, when you ask what are the side effects, they
16 have great difficulty, only about 20 percent overall.

17 So those are the averages over various drugs. About
18 80 percent for things in the benefits category; about
19 20 percent in the risks category, especially the side
20 effects.

21 So we might ask why is this so hard? And
22 there are many answers and let's start by looking at
23 an actual script of what is said during an ad. One
24 factor is readability. Now readability is not the
25 same thing as comprehensibility. However, it's easy

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1 to measure and has predicted value and therefore we
2 use it as a quick proxy for comprehensibility. In the
3 2001 sample, here were the ads that we looked at. And
4 we plotted what grade level people would need in order
5 to understand the benefits versus the side effects.
6 For benefits, it was slightly over the sixth grade
7 level. Side effects, ninth grade level. And as you
8 can see, this is a good three grade levels higher.

9 In 2005, has anything changed? Here are
10 the ads we looked at most recently. And readability
11 still is showing the same pattern, but now there's
12 only a two grade level difference involved here. And
13 by the way, side effects are comparable to all risks
14 in general when you combine them together. So these
15 are averages across many different drug ads. Let's
16 now look at each individual drug ad. In order to do
17 this, we're going to compute a different score. The
18 readability level for benefits minus side effects. If
19 there's no difference, the results will be around this
20 red line. And then we're going to plot grade levels
21 in addition that would be needed if benefits are
22 harder or side effects would be harder to understand
23 and there are the results. As you can see, most of
24 them are towards the side effects harder range.

25 Is this fair balance? I think we'd have

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1 to say no and what can we do about this? Well, we can
2 set some criteria. For example, we can decide that
3 plus or minus two grade levels is not very good or one
4 grade level, etcetera, but at least we have a
5 quantitative way to measure benefits versus risks.

6 Let's consider the location of the
7 information. Here's a speaker time line for the drug
8 ad for Allegra. You'll see yellow blocks here
9 indicating that someone was speaking and the straight
10 lines means that nobody was. So the first block says"
11 it's allergy season or Allegra season." The next,
12 "enjoy your world with nondrowsy Allegra for people 12
13 and older" and then a longer block.

14 Notice that the principle of chunking is
15 observed for the first two blocks, that is to say put
16 together what goes together and separate it from
17 everything else. But once the side effects are
18 uttered, there is no chunking after it. More
19 information just keeps coming which makes it hard to
20 mentally digest that information.

21 Another cognitive principle is called the
22 Serial Position Effect. When we see or hear a list of
23 items and then have to report them, we do better at
24 the beginning and the end of the list and have trouble
25 in the middle. So performance is best in the middle

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1 of the list and a little bit to the right.

2 What about the location of side effects?
3 And the 30 second ads they were in the middle and a
4 little bit to the right. Forty-five second ads, 60
5 seconds in the middle and a little bit to the right.
6 That was in 2001. Clearly, unfavorable location was
7 being used to place the side effects. What that was
8 then, this is now. Let's take a look. Now we're
9 plotting the same information, but now we put the
10 different durations of ads all into the same metric
11 and look at the percent of elapsed time, of total
12 time, when the side effects occur and there you can
13 see where they are. They're between 60 to 85 percent
14 of elapsed time and all risks between 50 and 85,
15 generally speaking, of total elapsed time. Again,
16 still unfavorable location today.

17 But you might say what does -- what effect
18 does location have on cognition? We need to have some
19 evidence. So therefore, we've produced a new TV ad
20 for a hypothetical drug called FluAide and the
21 structure and content is like that of typical ads.
22 The purpose is to vary specific factors and observe
23 the effects on cognition. So let's look at the first
24 experiment in this series, just the part where we ask
25 what were the side effects. There were many other

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1 experiments we do within this.

2 On a random basis, half the people heard
3 the side effects in a more favorable location versus
4 the unfavorable location. Its exact same visual and
5 auditory displays, they differ only in the location of
6 the side effects. We plot percent correct and we get
7 the typical results for the unfavorable location and a
8 nice increase for the favorable location, about 100
9 percent increase in people's knowledge of the side
10 effects.

11 There is still some people unable to
12 report any side effects at all, but as you can see,
13 nearly all of them are in the unfavorable condition
14 and this is an 800 percent difference.

15 Speed is important as well. We can plot
16 speed by the number of syllables per second, as
17 different portions of the ad are presented. Now let's
18 compare benefits versus side effects for two drugs for
19 the same indication. For Ambian, you can see that the
20 side effects went much faster than the benefits. And
21 for Lunesta about the same. Focusing just on the side
22 effects, there is a big difference between these two
23 ads and you might say so what? So the question is
24 does speed affect accuracy? And the answer is you
25 bet.

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1 So fast talk leads to lower knowledge.
2 Slower or normal talking speed leads to higher
3 knowledge. Another principle is about divided
4 attention and for this I will ask for some help from
5 the Nasonex bee, a very charming character. And in
6 these drug ads, the bee flies around. For the side
7 effects, he's flying most of the time around this
8 window. Watch his wings. I don't have time to show
9 you the video, so I'm going to simulate just a
10 portion. Fix your eyes on the wings and let's see
11 what happens. All right, his wings are moving around
12 quite a bit during the side effects. During the
13 benefits, at the end of the ad, his wings are not
14 going and in fact, he doesn't have any wings at all.
15 So we can now plot number of wing flaps per second for
16 benefits versus side effects and that's what we get,
17 clearly more during the side effects.

18 There is also an effect we can only
19 describe as wing flashes, where there may be flashes
20 from other parts of the body, but definitely when the
21 bee faces forward, there's some flashing effect here.

22 Now this may be a graphic artifact which I can
23 describe during the discussion, if you're interested,
24 but clearly more of it goes on during the side effects
25 than the benefits. So the effect of all these wing

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1 flaps and wing flashes and all these sparkly things
2 happening is to divide the viewers' attention,
3 watching these things rather than diverting attention
4 to the processing of the -- all of the different side
5 effects. This leads to decreased knowledge and their
6 comments that people say where they tell us there
7 weren't any side effects. And people actually argue
8 with us, there weren't any side effects and we have to
9 show it to them again in order to convince them that
10 there were.

11 There are a variety of speaker effects in
12 the typical ads. The side effects are spoken by a
13 narrator, a voice offscreen, but there are some new
14 approaches. For example, in this ad, the wife begins
15 talking about the side effects. The husband chimes in
16 and they talk back and forth about it. So we have
17 chunking, personalization and positive affect, feeling
18 positive about this by the way they look. This does
19 lead to increased knowledge, acceptance and comments
20 that well, these people seem okay with the side
21 effects. They must not be too bad.

22 Another example from Ortho Evra where a
23 doctor will mention there are risks. The patient says
24 "oh, how do I know I'm one of the people involved?"
25 And then the doctor answers. So again, there's

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1 chunking, personalization and notice how the
2 appearance of the patient changes from being very
3 attentive to having been afterwards being satisfied
4 with positive affect. Again, this leads to increased
5 knowledge, attentiveness and acceptance.

6 So why is it hard to get the risks? There
7 are many, many factors involved. I've just shown a
8 few. Let's move to conclusions.

9 There is currently a clear unfair balance
10 in cognitive accessibility of benefits versus risks in
11 these ads, weighted towards the benefits side. So
12 risk information is there. It's physically present,
13 but it's functionally absent. Physically present, but
14 functionally absent.

15 Before we have a rush to judgment,
16 however, we must beware and compare. We get similar
17 results from the ones I've showed you today, in
18 various other types of drug information, for
19 medication guides to the professional label. Risk
20 information is less accurate than benefit information,
21 excuse me, less accessible. Risk performance is
22 worse, but most importantly, risk performance
23 increases with enhanced cognitive accessibility.

24 Recommendations. To regulate or not to
25 regulate, that is the question on many minds today.

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1 Whether 'tis nobler in the mind to suffer the slings
2 and arrows of inaccessible risks or to take arms
3 against the sea of troubles and by opposing in them
4 and with apologies to William Shakespeare. Should
5 there be an end to DTC? There are many pros and many
6 cons and this research clearly shows that there's
7 an unfair balance of benefits versus risks, but it can
8 be improved. Better balance leads to improved
9 performance in perception, comprehension and memory
10 for risks. So I'm arguing for an evidence-based
11 approach for industry and regulatory sectors.

12 Sure, it's great to have a positive
13 treatment for benefits, but let's do that for risks as
14 well, so we'll be in fair balance.

15 In conclusion, risks generally go like
16 this, up over the head. We can get them into people's
17 heads so they understand and the way to do that is to
18 increase cognitive accessibility.

19 Thank you very much.

20 MR. ABRAMS: Thank you. You talked about
21 a concept of chunking and that seemed to be quite
22 beneficial as far as more effectively communicating
23 information that you want to convey. But it's not
24 being done often with certain information.

25 Any downside into chunking that you can

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1 think of, or more generally, any obstacles for people
2 not being able to do this or wanting to do it?

3 MS. DAY: I see no obstacles for doing it.

4 First of all, don't use speech compression. There
5 are sampling techniques where you can acoustically
6 take out parts of an utterance and you can still
7 understand what it says, but it goes very fast and so
8 on. I see no downsides to chunking. I suppose
9 industry might think well, when you chunk and pause,
10 put pauses in, that takes away from time from the
11 total ad, but I think there's ample time in a 60-
12 second ad to get everything in that's appropriate.

13 MR. ABRAMS: Dr. Temple?

14 DR. TEMPLE: Could you explain chunking?

15 MS. DAY: Chunking is the following: if I
16 give you a long list of information, let's take
17 something very simple, like a list of digits and I say
18 8, 5, 3, 4, 3, 2, 6, 1, 9, 7. These are typical
19 laboratory experiments and ask people what were those
20 numbers, people have difficulty remembering them.
21 However, if I presented them in this way, 8, 5, 4 --
22 3, 2, 6 -- 1, 9, 7, performance goes up dramatically.

23 So chunking is partly the clustering of like
24 information, not sprinkling it around in different
25 places, putting it together and then separating it

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1 from the surrounding information. This can be done in
2 time, when it is spoken. It can be done in space when
3 it is written and this principle got started in the
4 1950s by George Miller and it's been replicated and
5 found hundreds of times in the research literature
6 with various types of material.

7 DR. TEMPLE: One other question. I
8 understand why speeding up would give you adverse
9 effects. One of the most important features though
10 was location and I guess I ask we have some sense that
11 telling why you take a drug, so it automatically comes
12 first and you can't do anything unless you do that.
13 So is there some problem in this that you always are
14 going to hear somebody say I should take it first and
15 what do you do about it?

16 MS. DAY: Well, I did go into detail about
17 where we placed the side effects with a favorable
18 condition, but there is ample time to either give the
19 indication and/or say what the product name is before
20 going into the side effects. So you don't just start
21 out with side effects or adverse effects, that would
22 be ridiculous. Why would people listen to the rest of
23 it? But there is ample time within the time course of
24 a 60-second ad and even in briefer ads as well.

25 Dr. Gottlieb?

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1 MR. GOTTLIEB: Thank you. I enjoyed your
2 presentation. You mentioned the difference between
3 the grade level, the comprehension needed to
4 understand the risks versus the benefits of the
5 medication. Can you explain a little bit why -- is
6 there something inherent in the risk versus the side
7 effect information itself?

8 MS. DAY: Yes and no. If what you do is
9 put the side effects in a really long sentence, and if
10 any words in it are technical, then you will get a
11 boost in your readability score. Readability scores
12 have pros and cons. They're easy to calculate. There
13 are a variety of different measures. They really only
14 take into account the frequency of the words in the
15 language, whether they're high or low frequency or
16 high or low commonality and overall length.

17 However, there are people, when they
18 write, say medication guides or other kinds of things,
19 struggle to get the readability level in the sixth to
20 eighth grade range. You can do that, but you can
21 still have the information hard to understand.
22 There's ways to kind of cheat around it. And so if
23 you say for the side effects, one big long sentence is
24 automatically going to come up as a higher
25 readability, but there are ways to even make the

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1 sentence shorter and still have it difficult to
2 understand as well.

3 So in other presentations I've talked
4 about what the real measures of comprehensibility
5 should be, like the number of prepositions per
6 sentence, cohesion, syntactic complexity and so forth.

7 So there are ways to present all risk information and
8 have the readability and hence, comprehensibility be
9 comparable to benefits. That's used typically for
10 benefits.

11 MR. ABRAMS: Dr. Ostrove?

12 MS. OSTROVE: You've apparently done a lot
13 of studies. Typically, can you give us a sense of how
14 long it takes to do one of these cognitive studies
15 that you're reporting on?

16 MS. DAY: Yes. It depends on if you
17 test one on one or in a group situation. These are
18 carefully controlled studies where study time is
19 fixed, based on pilot study or we let people take as
20 long as they want and then we time how long that is
21 and so forth.

22 But one of the studies I presented today
23 was completed, it took time to design, prepare the
24 materials and so forth, but it was collected in two
25 days. And that was because we had small groups of

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1 people or medium sized people in a room at the same
2 time where they can't see what each other is doing and
3 an experimenter and an experienced experimenter
4 administers the test and the testing phase and there's
5 much more than I showed here today. There's a
6 perception and attention and comprehension and memory
7 components, but everything can be collected within a
8 half an hour, including instructions and the briefing,
9 telling them what it's about and getting their
10 feedback.

11 MR. ABRAMS: Dr. Aikin.

12 MS. AIKIN: I think you've made a really
13 good attempt to quantify fair balance which is
14 something that we struggle with a lot.

15 Have you asked your subjects or your
16 participants whether they think the ads are fairly
17 balanced? Not just in terms of benefits and risks,
18 separately, but overall?

19 MS. DAY: Not in a formal way. I don't
20 think they understand the concept. I have asked it
21 informally sometimes. So do you think this is a
22 balanced ad and they get this kind of deer in the
23 headlights look and say what do you mean? And then
24 I'll say, well, did you get the benefits and the risks
25 equally well? And you get a wide variety of responses

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1 and I don't have enough formally collected to comment
2 thoroughly, but some people have the attitude, well,
3 those side effects, they just have to throw those in
4 as if there's just some requirement and they don't
5 need to pay much attention to them.

6 Sometimes they say oh, there were side
7 effects? Or they talk about other things. I don't
8 think they quite get that concept and that's why I
9 like some of these newer ads where they're directly --
10 the adverse events are directly shown by the patients
11 interacting with each other or with a physician or
12 somebody else, or speaking them. Have a patient talk
13 about the side effects and look like he or she is
14 accepting them and knowing about it anyway, I think is
15 quite remarkable. But I will follow up on that, Dr.
16 Aikin.

17 MR. ABRAMS: To FDA sitting on a panel, it
18 doesn't seem to be a real difficult concept to
19 understand your need to have balance, risk information
20 is real, real important.

21 Do you have any suggestion for FDA how we
22 can better convey this concept so people can
23 understand it?

24 MS. DAY: Well, of course, this would be
25 in some guidance to be developed, I guess. I would

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1 show what the consequences are of having an unfair
2 balance in the cognitive accessibility of the
3 information. I think generally most of us when we
4 hear fair balance, we mean what is the information in
5 the ad? Are there the benefits and are there the
6 risks? And then what I would do is say hey, the risks
7 can be there, but they can be functionally absent.
8 That is to say, you could put them in the least
9 favorable location. You can put other sparkly things
10 going on so people won't listen to them. You can do
11 X, Y and Z and so forth, and they're going to
12 functionally absent.

13 So whatever you're doing to enhance the
14 benefits, do that also to enhance the risks so we will
15 then have good, cognitive accessibility and be in fair
16 balance on that.

17 MR. ABRAMS: Dr. Day, thank you.

18 MS. DAY: Thank you.

19 MR. ABRAMS: I have a request for all the
20 speakers and anybody else who has done research in
21 this area, to submit to the docket, to make it
22 publicly available if you're comfortable doing so.
23 FDA is a data-driven agency, obviously, and we like
24 data. We use data to drive our policy development.
25 So any data you have, please submit if you're

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1 comfortable doing so, to the docket to all parties, so
2 public and the Agency can have access to it.

3 Our next speaker is Lewis Glinert from
4 Dartmouth College.

5 MR. GLINERT: My submission today is a
6 response in a spirit of linguistics and communication
7 science to the FDA's repeated calls for hard research
8 on the communicative workings of televised drug
9 advertising.

10 Among the public's main -- many concerns
11 about televised drug advertising, the provision of
12 risk information stands out, as we know. How do we
13 get people to act on risk information is, of course, a
14 communications according to the Holy Grail. But when
15 people don't even believe they're being adequately
16 warned as FDA research of 2002 and Prevention
17 Magazine's 1998 survey brought out so clearly, you
18 have a problem of an entire different order.

19 Research of Louis Morris and others in the
20 1980s on the formatting of ads whether the position of
21 risk information, whether it should be visual or audio
22 or both, how much of it there should be was used by
23 FDA, rightly or wrongly, to justify the type of ads we
24 watch today. However, the fair balance between
25 benefit and risk information enshrined in FDA guidance

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1 has neither been rigorously operationalized nor
2 empirically demonstrated. No practical procedure
3 exists for easily judging fair balance, nor for
4 proving it holistically although they have made many
5 strides towards this goal. As a result, FDA has found
6 itself reacting to events rather than guiding them.

7 My submission today relies in part on
8 collaboration with John Schommer, Professor of
9 Pharmaceutical Care and Health Systems at the
10 University of Minnesota, who unfortunately cannot be
11 here today. We are engaged in revisiting the key
12 issue of the formatting of TV ads and its
13 communicative effect which leads us to question some
14 of the working assumptions in common drug advertising
15 regulations.

16 In a recent paper, advertisement format
17 and the provision of risk information about
18 prescription drug products, we examined ways to
19 include the required risk messages in TV prescription
20 drug ads. We took two ads, one for lower-risk and one
21 for higher-risk medication and using male and female
22 voice over artists, we produced two alternative male
23 and female versions of the ads with the risk
24 information shifted to the end and supplemented by a
25 risk messaging caption.

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1 For the higher-risk medication, we found
2 that placing the risk information at the end of the
3 ad, with captions, had the following effects: (1) it
4 significantly improved the students' short-term memory
5 of general and specific side effect information, but
6 without the medication appearing to be more risky.
7 Two, it created the perception that the advertisement
8 was more informative. Three, it produced feelings of
9 distraction. Four, it produced feelings of
10 information overload such as bewilderment and finding
11 it hard to follow. However, little effect was found
12 with the advertisement for the lower risk medication
13 and medication being taken by many of the students,
14 perhaps because they simply didn't care to pay much
15 attention to the risk message.

16 On the other hand, the female voice over
17 had considerably more effect than the male voice over
18 which intrigued us. At the moment, we cannot be sure
19 why.

20 While our experiment was restricted to a
21 group of first-year pharmacy students, most of them
22 female, we believe that it points the ways of
23 improving risk information in drug advertising. We
24 hope to extend our work to a broader population.

25 In addition, and in our view of great

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1 importance, there is an urgent need to study the
2 response of the elderly, the semi-literate and other
3 vulnerable groups. The elderly, for example, have
4 been shown to have difficulty with rapid or
5 disorganized text and with elaborate inferencing. And
6 even at the best of times, TV ads, like any spoken
7 message, cannot offer the viewer the same opportunity
8 for scrutiny as the printed ad can.

9 In clinical studies of communication,
10 whether they're surveys or focus groups or
11 experimental manipulations, are notoriously difficult
12 and expensive to construct. Often the setting is
13 artificial. Nor do they easily robust or general
14 conclusions. If we are to conduct the kind of case by
15 case studies that Morris pinpointed in the major
16 review published in 1998, one of the most promising
17 and practical avenues is linguistics and discourse
18 analysis.

19 Linguistics studies linguistic structures,
20 sounds, words, syntax and the meaning they create.
21 Discourse analysis opens the lens still further to
22 look for patterns in whole specters of text and to see
23 how they relate to the situation through the speakers
24 and addressees, how they relate socially, what they
25 are doing culturally and what other systems of

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1 communication are being used, visuals, body language
2 and so on. Discourse analysis, in other words, is
3 holistic.

4 Linguistics and discourse analysis are not
5 in and of themselves a way of empirically predicting
6 quite how readers or listeners will understand the
7 text. But they can call upon massive databases of
8 verbal behavior and on the analyst's own well-honed
9 intuitions, in order to anticipate what a text might
10 mean.

11 Equally important, however, discourse
12 analysis alerts us to a complex and often daunting web
13 of meaning. Behind the disembodied semantics of a
14 sentence is what is called pragmatics. The use we
15 make of the sentence in context, the associations in a
16 phrase like "ask your doctor" -- ask has more than one
17 meaning. The tone of voice, the suggestivities, the
18 strategic ambiguities including all kinds of
19 innuendoes for which we would not be wished to be held
20 strictly accountable.

21 All of this is part of language and so
22 when a trial (9:58:21) assesses what something means
23 to the ordinary man or woman, something of this web of
24 meaning and pragmatics will generally be taken into
25 account, but not enough. It takes trained analysts to

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1 disentangle such meanings and then to point the way to
2 empirical investigation of key phenomena.

3 The two most challenging and sophisticated
4 types of text for analysis of meaning are the poem and
5 the advertisement. Few of us often portray
6 advertising as being either informational or
7 persuasive. However, discourse analysis sees
8 advertising based differently. Consumers should not
9 expect to find any logic in an ad. Guy Cook, in his
10 book, The Discourse of Advertising, has argued that an
11 intrinsic playfulness and creativity in advertising is
12 inherently playing with words. And extraordinary
13 creativity constantly seeking to surprise and to
14 reinvent the rules of the game.

15 We now face this in a particularly potent
16 form. The post-modern ironic or retro advertising
17 where the words are becoming less and less important
18 and the image is saying it all, the consumer will try
19 to play along to various degrees.

20 What then of literalism, the popular
21 belief that a sentence has a literal meaning, quite
22 independent from its implied meaning? This belief in
23 literalism is inconsonant with the way ordinary people
24 actually understand language. With far reaching
25 implications of a study of advertising, in the words

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1 of Dwight Ollinger, the president of the Language
2 Society of America, the most insidious of all concepts
3 of truth is that in literalness. Advertising
4 capitalizes on the legal protection that it affords.

5 I'm sorry, I'm having a little problem
6 here. I'm a Mac person, not a PC.

7 (Laughter.)

8 An example of what linguistic and
9 discourse analysis can bring to the evaluation of drug
10 ads, I micro-analyzed the text and visuals of several
11 ads using linguistic and discourse analytic
12 procedures. My research questioned what the ad was
13 seeking to do, how the wording and visual patterns
14 related, and what messages a viewer was likely to
15 derive.

16 Here are the main findings. One,
17 functionally, the advertisements were a bewildering
18 blend of promotion, information and aesthetics or
19 entertainment with many touches of post-modernist
20 irony. One celebrated campaign made a point of mixing
21 science with science fiction in its ads. Or again,
22 what does the viewer make of a finale, delivering a
23 final punch, but distorting some of the key medical
24 information delivered elsewhere in the ad. Is the
25 outcome a cognitive dissonance or will viewers perhaps

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1 draw upon the entire message in reaching that
2 conclusion and take this finale as merely a total
3 flourish. And this is the kind of finale in breach of
4 FDA guidance of fair balance.

5 Two, risk messages frequently competed
6 with upbeat music and visuals and with these words of
7 course, having to process the warning caption "your
8 results may vary" together with an image of a beaming
9 woman and a quick line of string of superlatives, the
10 average viewer may well not consider the possibility
11 that for many people the effect may be less than a
12 complete cure.

13 Three, we found intense switching and
14 fusing of styles and here, the cognitive and
15 persuasive effect of this on people of a non-American
16 cultural background needs to be investigated urgently.

17 Four, strategic and linguistic ambivalence
18 was frequently used and thus running through
19 testimonials for an asthma medication was a tension
20 between absolute and relative claims of efficacy.
21 Three of the testimonials were cautiously couched,
22 gets out more, fewer symptoms. Doesn't have to use
23 his reserve inhaler as often. More nights of restful
24 sleep. Fewer asthma symptoms. However, the fourth
25 testimonial and the epilogue had an absolute ring, for

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1 day and for night, control of asthma symptoms. This
2 can be construed as a very small claim, toned down,
3 maybe by helps control, helps control asthma symptoms,
4 but it ends all day and all night. Again, sweeping
5 connotations.

6 Fifth, there was much variation and
7 ambivalence after the source of authority and the
8 identity of the addressee. For example, the
9 traditional advertising distinction between personal
10 and impersonal was sometimes ostentatiously flouted.
11 These results point to textual features that preserve
12 experimental or other empirical studies. I would
13 stress that one of the central issues in analyzing a
14 text in the communications terms is the relative
15 impact of its component elements.

16 Are we to consider the whole text in toto?

17 It is the nature of this kind of qualitative micro-
18 analysis to focus on the limited group of texts and
19 study them as organic wholes. Undoubtedly, large
20 scale studies are needed, using teams of analysts and
21 the results could then be compared with survey and
22 focus group responses.

23 Complex as it is, discourse analysis holds
24 out promise of providing a useful rapid evaluation of
25 advertising requiring either prior or post-factual

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1 approval. More generally, it can contribute to our
2 general understanding of how TV advertisements convey
3 meaning with respect to drug benefits and risks with
4 implications that advertisers, regulators and patient
5 education.

6 Thank you.

7 MR. ABRAMS: Thank you for your
8 presentation. Questions form the panel?

9 Dr. Behrman.

10 MS. BEHRMAN: Thank you. You touched on
11 two things that we struggle with a lot internally and
12 maybe you could help us think about how to approach
13 them or whether there are more data that will help us.

14 The first thing was cognitive dissonance which, if I
15 understand what you're saying, is distinct from or
16 broader than simply distraction.

17 And the second, you didn't use quite these
18 words, had to do with whether disclaimers can ever
19 correct a mis-impression or a strong impression. And
20 in both cases, we struggle with how to quantify the
21 impact and how to balance those.

22 Do you have any comments on those two
23 subjects? I think they're somewhat related.

24 MR. GLINERT: As I've said, linguistics is
25 a companion to empirical and quantitative studies of

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1 cognition. They're all within linguistics. Many very
2 sophisticated quantitative and qualitative techniques,
3 for example, in cognitive semantics and in the study
4 of gigantic databases.

5 In general, I would say that countless
6 thinking in linguistics is that language acts as a cue
7 for meaning. We can't find meaning located
8 intrinsically in text. It depends crucially on what
9 the reader chooses to focus on and therefore the job
10 of the linguist is to analyze the actual structures
11 and to point to where the public dissonance is like to
12 arise and should be examined.

13 Ultimately though I'd say that there is a
14 phenomenal variance between different speakers,
15 different listeners, different social settings,
16 different genres. The very question of whether a
17 viewer things they are being entertained or being
18 informed is critical and I guess they got many people
19 from non-American culture backgrounds might be more
20 liable to listen and pay attention to a text that is
21 written actually in a very academic and let's say less
22 comprehensible style because then the mark of an
23 authority is to speak in difficult terms. This does
24 raise a whole slew of questions.

25 MR. ABRAMS: Dr. Temple?

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1 DR. TEMPLE: Two things. At the beginning
2 of your talk, you noted one thing and I want to see
3 whether this is (inaudible- speaking from un-miked
4 location). He had done a time course of
5 comprehensibility that (inaudible- SFUL) material at
6 the end. Do you think that's what your initial
7 finding was? (inaudible- SFUL)

8 So it's the middle that's the worse. The
9 end and the beginning might be better.

10 MR. GLINERT: I don't see any
11 incompatibility between Dr. Day's findings. We were
12 looking specifically of what happens if you take the
13 materials and show them at the end. And one thing in
14 the back of our mind which still requires a lot of
15 study is whether it's part of the cognitive schema of
16 someone seeking information to look for it, put let's
17 say soberly and in a very organized fashion at the
18 end.

19 In other words, what are different types
20 of viewers really expecting when they watch a TV ad?
21 So we have some great fundamental questions and
22 clearly a whole range of different studies need to be
23 performed.

24 DR. TEMPLE: My second question is you've
25 noted a wide variety of linguistic tricks and

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1 properties and so on. Have you gotten yet to the
2 point of trying to study variations on these things
3 and how they actually communicate particular
4 information or is that sort of the next step?

5 MR. GLINERT: That is one of our goals.
6 There will be a fair amount of information about the
7 particular need area of ergonomics and human factors.

8 For example, Michael Vogelsberg at the University of,
9 I think it's South Carolina, has found that many
10 studies looking at the effect of particular
11 description terms. So, for example, he found that a
12 product, a food product, that says "no fat" was
13 understood as having less fat than a food product that
14 claimed "fat free". That's the kind of stuff that can
15 sen regulators into a tailspin. But, as I say, a
16 substantial amount of study of these individual items
17 has been conducted, and it does lead to very serious
18 concerns.

19 DR. TEMPLE: It would, in the end, though
20 be of interest to take an ad that has many of these
21 properties, you know, witticisms that get into the way
22 and all that stuff and see if you could amend the ad
23 in a series of steps to make it function better.

24 MR. GLINERT: Yes, yes. I would start
25 with that beautiful expression "ask your doctor".

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1 DR. TEMPLE: That's right. So we need an
2 alternative to that --

3 MR. GLINERT: Maybe.

4 DR. TEMPLE: So, we'll think about it.

5 MR. ABRAMS: Dr. Gottlieb?

6 MR. GOTTLIEB: Thanks a lot. You talk
7 about doing linguistic testing to see if cognitive
8 dissonance arises while, when people are viewing the
9 ads. What's the extent of that kind of testing, how
10 long does it take, how many people do you need to
11 survey to see a reliable answer from that?

12 MR. GLINERT: In a sense, it really is a
13 question of what kind of social populations we want to
14 examine. It's a fairly simple matter to take a set of
15 students, put them in front of a TV ad and then
16 administer a questionnaire or whatever. But if you're
17 looking to explore how things work in a natural
18 context, then you've got some very difficult work to
19 do. Again, if you're looking to, as we hope, to see
20 how the semi-literate and other vulnerable populations
21 respond to these things, I think we, one could
22 replicate these experiments fairly quickly. But I
23 think the question is how much of a range of
24 experiments we want to do.

25 MR. ABRAMS: Okay, and final question is

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1 from Ms. Davis.

2 MS. DAVIS: When you were studying the
3 format in the provision of risk information and you
4 were moving that to the end, did that also alter such
5 things like the competition from background music and
6 the visuals in your test ad, or where what people were
7 seeing otherwise the same -- it was just the location
8 in the voice-over and there was text?

9 MR. GLINERT: We went to great lengths to
10 keep absolutely everything the same. We had to go out
11 and find the right music to put it back in, and, yes,
12 we did everything was the same.

13 MR. ABRAMS: Doctor Glinert, thank you
14 very much for your presentation and responses.

15 Our next speaker is John Kamp, from
16 Coalition for Health Care Communications.

17 MR. KAMP: Good morning. Thank you very
18 much.

19 On behalf of the Coalition for Health Care
20 Communication we thank you for the opportunity to
21 present our views. I'm going to try to save a lot of
22 time here by summarizing our longer material which
23 we're going to put in the record. So, I'm just going
24 to outline a few points that we think are very
25 important, and then end with a major question.

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1 First, we want to know that the advantages
2 and the perceived disadvantages of DTC, despite all
3 that, we're convinced that DTC is here to stay.
4 There's no scary Halloween scenario around DTC. DTC
5 research demonstrates that DTC helps patients become
6 aware of new drug options. It stimulates
7 conversations with doctors. It leads to better
8 prescribing. And it improves patient compliance with
9 their drug regimen. FDA itself has been on the
10 leading edge of much of this research, and we're
11 pleased that several witnesses today are talking more
12 about new research in this area. New research needs
13 to continue to be done.

14 We note, however, that some of the most
15 important issues around consumer communication --
16 namely, the best way to improve health literacy, to
17 increase patient compliance, and to communicate the
18 safety information -- all of these are still not
19 really well understood. And we must be very careful
20 as we change regulation not to create a problem.

21 Our current scheme of DTC advertising is
22 not broken, so let's be very careful as we tinker with
23 it not to fix it in ways that move us backwards. Some
24 proposed fixes that we're hearing about DTC would do
25 just that. Here's one. Because some drugs are not

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1 completely safe, and some might have hidden safety
2 issues, DTC must go. It's a non sequitur. Cars, like
3 drugs, are sometimes recalled for safety reasons.
4 Cars, like drugs, can kill if not used as directed.
5 And even when used as directed, cars, like drugs, have
6 latent unknown and sometimes deadly safety issues.

7 It makes no more sense to ban advertising
8 in response to drug recalls than it would to ban car
9 advertising in response to brake recalls.

10 And let's not fall into the seemingly
11 sensible cause for a rigid 1-, 2- or 3-year moratorium
12 on drug ads, somewhat like a phase IV clinical trial.

13 Such schemes undermine the very integrity
14 of the drug approval process by the FDA and they need
15 to be rejected outright.

16 At the same time, we applaud the PhRMA
17 principles on DTC. For example, we think it was
18 appropriate for PhRMA to give caregivers much more
19 time to be educated about the drugs before the launch
20 of DTC. These flexible programs enable companies to
21 balance the needs of professionals and consumers, but
22 still speed innovative drugs to patients. But a rigid
23 rule here could inhibit the public health. We all
24 contemplate -- as we all contemplate the possible
25 horrors from an avian flu pandemic, neither the FDA

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1 nor the industry should face a well-meaning moratorium
2 that would prohibit consumer information on a new
3 vaccine that was urgently needed throughout the
4 population.

5 Moving on, the FDA staff are becoming
6 increasingly sophisticated about consumer behavior and
7 consumer understanding the messages. Then-
8 Commissioner McClellan stated it most succinctly last
9 year when announcing the brief summary proposals. He
10 said "we have learned that often, more is less in
11 consumer advertising." Consumers can only really take
12 away one, maybe two, at the most three, ideas from an
13 ad.

14 But while not fundamentally broken, it's
15 time for the FDA to do a systematic review of its
16 consumer advertising policies. DTC is the most
17 regulated form of advertising in America and the
18 replete and the very complicated requirements often
19 serve to confuse more than enlighten. Wayne Pines,
20 well known to all of you, may have said it best in a
21 recent FDLI update: "It's time for the FDA to
22 recognize, and to incorporate into its regulatory
23 approach, the view that DTC advertising is not just a
24 derivative of physician advertising. Simply put, what
25 a physician needs to know in deciding whether to

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1 prescribe a drug and how to advise the patient when
2 it's prescribed is different from what a consumer
3 needs to know in an ad."

4 That's a problem.

5 We also recognize and praise the FDA for
6 the recent strides that it's made on the brief summary
7 and the risk information material that enable us to
8 make those messages more consumer-friendly. But the
9 FDA should eliminate the immense subjectivity of FDA
10 advertising policy. For, as Wayne Pines also said in
11 that article, "there's no way for any company or
12 advertising agency to anticipate all the issues that a
13 collective DDMAC review might identify.

14 It's a problem, especially for the FDA
15 itself in these days when more and more DTC ads are
16 going to be submitted for pre-review. An advertising
17 agency and its clients must fully be able to
18 understand the rules and confidently develop ads that
19 are correct before they're submitted.

20 Ron Pintello, CEO of Euro RSCG Health and
21 head of the AAAA Medical Advertising Committee, may
22 have said it best when he noted that it's really a
23 problem also now of consumer understanding, quote,
24 because it's impossible to predict how the FDA staff
25 will react to certain creative executions, even those

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1 that are only slight variations of previously-approved
2 ads, our advertising, our drug company clients are
3 responding by becoming increasingly more conservative.

4 As a result, it's almost impossible to create a
5 compelling advertising message that a consumer can
6 understand.

7 The FDA also has to rethink its
8 advertising approach for another reason. It's no
9 secret that the FDA's reputation and jurisdiction is
10 under attack. As we've discussed with the General
11 Counsel, one of the drug advertising regulators are
12 seeking to whittle away the FDA's primacy in this area
13 through a multiple Federal and state pieces of
14 legislation and state enforcement actions under all
15 types of consumer protection and false claims actions.

16 Meanwhile, private class-action attorneys
17 are getting into the fray by using marketing theories
18 in their high-profile product liability cases. The
19 FDA must develop clear, effective policies that
20 demonstrate their policy understanding and leadership
21 in this area, and demand legislative and judicial
22 deference.

23 American citizens simply do not need
24 multiple sets of drug marketing regulations. They
25 need one that makes sense, that works and is

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1 vigorously enforced by the FDA and only by the FDA.

2 Especially noteworthy -- oh, one final
3 point, it to express our concern about the so-called
4 voluntary constraints on DTC and other marketing that
5 are increasingly part of the drug-approval process.
6 Especially noteworthy is the FDA's approval this last
7 summer of the drug Symlin, by Amylin. Similar, but
8 less extensive limits, have been imposed on other
9 drugs and more are expected.

10 Our question: how do the Coalition and
11 the public appropriately participate in these very
12 important decisions? We have asked to participate in
13 the December hearings on communicating drug safety
14 issues, but we worry that these vital decisions will
15 continually be made out of the public view.
16 Importantly, we recognize that the marketing
17 conditions on drug approval are only nominally
18 voluntary. Much like I volunteered to go to Vietnam
19 once the draft notice was in the mail.

20 Decisions to ban DTC, to ban professional
21 advertising for two years, and to ban marketing only
22 to a limited number of physicians are not private
23 decisions. They are profound public policy decisions
24 and they are matters subject to judicial review under
25 the Administrative Procedures Act and the first

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1 amendment. These mandates require good evidence,
2 public transparency, critical reasoning, tough and
3 objective standards and good common sense. And the
4 burden of proof on all of these is on the FDA. Limits
5 on Symilin marketing may or may not be appropriate.
6 We don't know. The public was not there.

7 On a personal note, I'm a diabetic, and a
8 possible candidate for Symilin. Perhaps it's the most
9 important breakthrough in the treatment of diabetes
10 since the development of insulin in the last century.

11 I'm startled that FDA accepted as a condition of
12 approval the idea that not only I must not know about
13 this drug, neither must my primary care physician. My
14 doctor disagrees with the FDA.

15 Indeed, without a clear public record on
16 these restrictions, they reflect a kind of paternalism
17 that I think is unsuited in our culture and contrary
18 to the basic idea that educated physicians and
19 educated consumers make better healthcare decisions.

20 So, again, our closing question, how does
21 the coalition and the public participate in these
22 vital decisions about healthcare communications.

23 Thank you for the opportunity. I am
24 delighted at the new research that we're hearing about
25 today at this meeting.

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1 MR. ABRAMS: Doctor Aikin?

2 MS. AIKIN: Thank you. You brought up the
3 Wayne Pines quote that DTC is not a derivative of
4 position advertising. In fact, the requirements are
5 different. Do you view this as an argument for
6 separate DTC regulation?

7 MR. KAMP: Yes, I think so. I think
8 you've cleared up exactly as Wayne said it. It's not
9 a derivative of professional advertising. And what a
10 professional needs to know to make a prescribing
11 decision and what he or she needs to know to tell the
12 patient about the side effects are simply not the same
13 things that a patient usually needs to know.

14 MR. ABRAMS: Doctor Temple?

15 DR. TEMPLE: One of your pleas was for
16 less subjectivity in reviewing ads. The alternative
17 to subjectivity is usually rules, guidance that
18 approaches rules but isn't a rule. Is that really
19 what you'd like to see?

20 MR. KAMP: Yes. You raise a very good
21 question. In fact, if this were an easy thing to do
22 we wouldn't have to be here today, right? I don't
23 think so. I worked both at the FTC and the FDA and I
24 watched the FTC engage in many of these same
25 activities. I fear in some way that the FDA as the

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1 drug-approval process organization takes too much of
2 the drug-approval process into the ad-approval
3 process. And therefore, oftentimes it tells the
4 advertiser exactly how to do it.

5 Instead, the FTC does it a different way.

6 It essentially tells the advertiser that it's their
7 problem to make sure that the ad is fully understood
8 by consumers in the way it should be. So, instead of
9 telling them exactly how to do it, and then
10 advertising agencies are going to be very clever to
11 follow those rules, but still get the message across
12 in their own way.

13 The FTC does it another way, by
14 essentially telling you you must know how consumers
15 perceive this ad and it must not be in a false and
16 misleading way.

17 DR. TEMPLE: So, that would mean,
18 essentially, every ad would have to be comprehension-
19 tested before it was put out. Is that --

20 MR. KAMP: It doesn't have to be,
21 according to the FTC rules. But the advertiser is
22 responsible for how consumers understand the ad, not
23 the agency. So it keeps the agency out of sort of
24 this little, sort of making all these little tiny
25 decisions, telling for example, I mean, some of the

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1 kinds of things and, you know, this in some ways is
2 urban legend, so you know, whether it's true or not.
3 One of the advertising agencies I work for has shown
4 me two copies of an ad that used time clocks for it to
5 demonstrate the passage of time. In one case, they
6 used an analog clock, and the FDA said you can't do it
7 that way, you have to reshoot it, we want a digital
8 clock. And, so the agency said, okay, if that's what
9 you want, that's what you get.

10 Whether or not that really made a
11 difference to consumers we don't know.

12 MR. ABRAMS: Doctor Gottlieb?

13 MR. GOTTLIEB: You raise an interesting
14 point, and I'm just curious how you would contemplate
15 such a regime short of requiring companies to come in
16 with copy testing on the advertising itself. Would
17 you rely on competitive forces; maybe competitors
18 would copy-test their other ads of other firms and
19 bring it to the FDA for violation. How would you
20 contemplate that regime working?

21 MR. KAMP: Well, as we all know, the FTC
22 doesn't require or even encourage -- in fact,
23 absolutely refuses to do prior approval. It doesn't
24 absolutely require that everything be copy tested.
25 But it relies on the fact that sophisticated marketers

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1 and sophisticated advertising agencies know what
2 they're doing and if a question arises later, it puts
3 the responsibility on the advertiser that it did it
4 right.

5 MR. ABRAMS: Doctor Behrman?

6 MS. BEHRMAN: I want to follow up on two
7 thing you've said. One was your dismay, if you will,
8 over some information about a new drug was not being
9 rapidly made available through the DTC avenue, and I'm
10 a little curious about what you think is the primary
11 purpose of DTC advertising and then, if you could link
12 that to what you think our primary role is. I gather
13 it's to ensure that the advertisement not be false and
14 misleading, but do you view DTC primarily as an
15 informational tool, a promotional tool, I mean, how do
16 you link those two?

17 MR. KAMP: Yes. Advertising for the most
18 part is best used as an informational tool in this
19 context to perhaps begin a conversation. To begin a
20 conversation that a caregiver might have with a
21 patient. To begin a conversation that a patient might
22 have with a doctor. If you try to do much more than
23 that, it gets very, very complicated and the messages
24 get mixed.

25 The kinds of discussions that we've had

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1 here this morning demonstrate to us that the more you
2 try to do in the ad, sometimes, the less that can be
3 learned. I think that we all in this society know
4 even more than maybe we knew a year ago, but not drugs
5 are not safe in all circumstances. They have to be
6 done carefully. I think we're getting that message.
7 I also think that the drug companies over the last
8 year, especially the last six months, are doing a much
9 better job than some of the ads that Ruth talked about
10 today, about putting that safety information forward.

11 And as she said, using patients to talk about the
12 safety and side-effect information. I think that the
13 industry now gets it much better than it did before,
14 and I'm very pleased to see the kinds of changes in
15 advertising we're seeing.

16 I'll also tell you from the front, from
17 the advertising agency people that I'm talking to,
18 that the companies are demanding different things from
19 their advertising agency that they sometimes ask,
20 demanded as few as six months ago. They now want ads
21 that don't push the envelope on the benefit side, but
22 are pushing the envelope on the full information side.
23 But, again, to go back to your question. You can't
24 ask for much. You can really only begin a
25 conversation, get an idea in the head of the viewer

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1 and reader and then begin what we hope is a
2 conversation that leads to appropriate healthcare
3 outcomes.

4 MR. ABRAMS: As a follow-up to that side
5 conversation, you can't get too much risk information,
6 so you should not try to put too much benefit
7 information too? And, what's too much? Where would
8 you kind of quantify that?

9 MR. KAMP: Well, it's sort of a one-level,
10 one of the very question is one of the things that I
11 think might be better for the FDA to avoid -- sort of
12 that is to micro manage what has to be in and what's
13 enough? How much is too much? If I knew how much was
14 too much I wouldn't have an extra ten pounds on my
15 body right now. I'd stop eating sooner. Those are
16 very difficult, subjective and many times cases
17 questions that I think you have to deal very carefully
18 and I think sort of getting into some of the minutiae
19 on here has actually caused the agency to get itself
20 into some trouble.

21 MR. ABRAMS: Okay. Thank you Doctor Kamp.
22 Our next speaker is Andrew Kleit from Pennsylvania
23 State University.

24 MR. KLEIT: Good morning. I am Andrew
25 Kleit, Professor of Energy and Environmental Economics

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1 at the Pennsylvania State University. On behalf of my
2 co-authors David Bradford, Paul Mietert and Steven
3 Ornstein at the Medical University of South Carolina,
4 I want to thank you for the opportunity to present
5 some results from several of our recent research
6 studies this morning. I note that we have a
7 continuing research program on the issues of DTC
8 advertising. Before we begin, I would like to take a
9 moment to thank to Agency for Healthcare Research and
10 Quality and the National Heart, Lung and Blood
11 Institute, who supported our research. Of course, the
12 views I'm going to express this morning are our own,
13 and do not reflect those agencies' positions.

14 In August 1997, the FDA changed the rules
15 surrounding broadcast DTC. Today, there's a clear
16 divide among policy circles about the consequences of
17 this change. Many groups assert that DTC advertising
18 puts physicians under pressure to prescribe drugs
19 unnecessarily. Other groups assert that DTC
20 advertising can inform people about conditions they
21 might not know they had, or about treatments they
22 might not be aware existed, which would tend to
23 improve healthcare. Obviously, it is important to
24 evaluate these claims of each group to implement
25 effective public policy.

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1 There's now a growing body of research
2 that's becoming available on DTC. Much of it assesses
3 the opinions of the public or providers. My co-
4 authors and I believe, however, that to more
5 completely understand the effects of DTC advertising,
6 we need to examine detailed patient-level data. The
7 limited research that does exist of this sort is non-
8 conclusive about the effects of advertising on
9 economic efficiency. This research we want, the
10 research we wish to discuss this morning is, we
11 believe, precisely the sort that is required.
12 Evaluations of detailed patient-level information
13 using cases that allow us to say something directly
14 about the effects of DTC ads on patient well-being.

15 There are certainly reasons to expect both
16 positive and negative implications of DTC. Economists
17 have discussed the potential for both. For example,
18 researchers have asserted that DTC might move patients
19 who are currently untreated to go see their physician
20 and so become treated. Early work on this issue also
21 suggests that there might be some positive impacts in
22 terms of getting new drugs to penetrate markets more
23 easily, which would promote innovation and better
24 care.

25 On the negative side, economists have also

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1 pointed out the potential of DTC for having anti-
2 competitive effects by making patients less responsive
3 to price changes or by helping incumbents maintain
4 market share.

5 As mentioned above, we believe that our
6 research can directly address some of the key issues
7 raised and currently unanswered in research debates
8 about the role of DTC. We have examined an important
9 patient population, people with osteoarthritis. This
10 is a widespread and debilitating disease. Drug
11 therapy is one of the main approaches to alleviating
12 pain and suffering.

13 Cox-2 inhibitors, one of the drug classes
14 used for treating arthritis pain, has also been at the
15 center of much of the public debate about DTC
16 advertising lately. The two main Cox-2 inhibitors
17 were Vioxx and Celebrex. And both of them were
18 heavily advertised. As you well know, these drugs
19 were also controversial because of the increased risk
20 for serious cardiovascular side effects that are
21 apparently associated with their use. Vioxx was
22 withdrawn from the market in 2004 for this reason.

23 We believe that these drugs present an
24 ideal opportunity to study the impact of DTC. They
25 were heavily promoted. They were believed to have

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1 potentially serious side-effects. But these side-
2 effects were only widely discussed after the drugs
3 were on the market and advertised. So, if we are able
4 to see any positive welfare effects from DTC ads for
5 this drug class, then that would suggest that
6 policymakers would want to take greater care in
7 broadly restricting this practice, at least without
8 further careful study.

9 To conduct our study, we obtained data on
10 patients from nearly 90 primary-care practices
11 scattered across the United States. This data
12 contains all the information one would normally find
13 in clinical charts, including details of diagnoses,
14 vital statistics and detailed prescription histories.

15 We pulled all the osteoarthritis patients
16 out of this data, and examined how their prescribing
17 patterns were correlated with national and local DTC
18 ads spending over the 2000 to 2002 time period.

19 We also collected information on
20 television advertising spending for Vioxx and Celebrex
21 for each month in 75 media markets. Patients and
22 physicians were linked to the closest media markets
23 that were relevant to their location.

24 Our analysis consists of regression models
25 which we used to explain three different dependent

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1 variables. The first is the number of osteoarthritis
2 patients who come into each physician practice each
3 month. This is designed to tell us whether DTC
4 advertising prompts patients to seek, whether the
5 hypothesis that DTC advertising prompts patients to
6 seek care is correct or not.

7 The second regression model explains the
8 number of prescriptions for Vioxx and Celebrex the
9 physician practices wrote each month. This tells us
10 whether there is any change in prescribing overall
11 once patients come to see their physicians.

12 Finally, the third regression model
13 explains how long patients wait after they've been
14 diagnosed with osteoarthritis before they start using
15 either Vioxx or Celebrex. This last model is the most
16 direct test of whether DTC ads improve or harm social
17 welfare.

18 I will discuss this in detail in a moment.

19 Our first set of models, you had clear
20 answers to questions of if patients responded to DTC
21 ads by going to their doctor's office. We find that
22 advertising promotes Vioxx and Celebrex increases the
23 number of patients with osteoarthritis to get office
24 visits each month. This effect is consistent across
25 many ways of specifying our model, or measuring DTC

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1 advertising level locally.

2 The second set of models indicates some
3 interesting dynamics at the market level and are
4 somewhat less easy to interpret. We find that the
5 number of Vioxx prescriptions rose in communities in
6 months where there was more advertising for Vioxx or
7 Celebrex. In that sense, the ads had what we might
8 call class-level effects. Advertising for any brand
9 tended to increase the use of Vioxx. However, the
10 results for Celebrex prescribing are different.
11 Neither Vioxx nor Celebrex DTC spending seems to have
12 had an effect on Celebrex prescribing. Again, these
13 results are stable across our models.

14 However, there are other ways that DTC can
15 be expected to affect prescribing use other than raw
16 counts of the numbers of prescriptions written by each
17 practices each month.

18 These two practice-based studies indicate
19 that DTC advertising has an effect at the micro level.

20 However, this leaves open the issue of whether these
21 DTC-induced changes are good for patients or not. For
22 that, we need a different level of analysis, and we
23 need to conduct an analysis of patient decisions
24 rather than practice-level change.

25 To explore this question, we collected

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1 micro-patient level data and asked how long patients
2 delayed before they started using Vioxx or Celebrex as
3 daily therapy for their osteoarthritis symptoms. This
4 is an important question because clinical guidelines
5 suggest a number of steps that should be taken before
6 patients start daily Cox-2 inhibitor therapy. For
7 example, patients that try changes to their exercise
8 and diet or should try less powerful, over-the-counter
9 pain medicines. So, some delay in taking these drugs
10 is optimal.

11 However, we also know that some patients
12 were better candidates for using Vioxx or Celebrex.
13 In particular, patients who have gastrointestinal
14 side-effects from some pain medications are more
15 likely to benefit from the special nature of Cox-2
16 inhibitors. If DTC ads provide real information, they
17 would encourage these patients to adopt Vioxx and
18 Celebrex sooner. We can identify which patients fall
19 into this class.

20 In contrast, there are some patients who
21 are clearly poor candidates for Vioxx or Celebrex. In
22 this case, we now know that patients with
23 cardiovascular disease or hypertension were at higher
24 risk for cardiovascular adverse events and should try
25 many other options before resorting to Vioxx or

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1 Celebrex for their symptoms. But this information was
2 really only widely discussed after the publication of
3 a key article in the clinical literature in August of
4 2001. So, our second test of whether DTC ads provide
5 real information will be to see whether or not they
6 encourage patients with cardiovascular risk to adopt
7 Vioxx or Celebrex later. However, as an added
8 wrinkle, if it is a DTC information effect, this delay
9 should occur only after August 2001.

10 So, if DTC spending is moving patients in
11 the right direction, we should see that patients and
12 communities or time periods with more DTC spending and
13 who have gastrointestinal difficulties should adopt
14 Vioxx or Celebrex more rapidly. We should also see
15 patients and communities or time periods with more DTC
16 spending and who have cardiovascular problems adopting
17 Vioxx or Celebrex less rapidly, but only after August
18 of 2001.

19 Note that we have a fairly specific test
20 here. In fact, when we estimated our models, this is
21 exactly the pattern we observed. Greater amounts of
22 any Cox-2 inhibitor advertising encourages gastro
23 patients to adopt sooner for all time periods. On the
24 other hand, greater amounts of any Cox-2 inhibitor DTC
25 advertising before our cutoff date of August 2001

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1 encouraged CVD patients to adopt sooner and after
2 2001, August 2001, encouraged CVD patients to adopt
3 later.

4 It's hard to imagine another mechanism,
5 other than the provision of real information through
6 advertisements, that would account for this pattern.

7 Our patient level analyses are remarkably
8 consistent and clear. DTC advertising for Vioxx and
9 Celebrex did affect prescribing behavior and did so in
10 exactly the direction you might want. Good candidates
11 for the drug got the drug sooner; poor candidates got
12 the drug later. Thus, our results imply that Vioxx
13 and Celebrex television ads actually improved the
14 matching of therapy to patients.

15 In summary, we are able to state the
16 following. DTC advertising for Vioxx and Celebrex had
17 the effect of encouraging patients to see their
18 physicians. At an aggregate level, DTC adds affected
19 the rate of prescribing for at least one of our study
20 drugs, and for the average patient DTC television ads
21 in this time period seemed to act to improve matching
22 patients to treatment.

23 In conclusion, we would like to leave with
24 the following message. DTC advertising has become an
25 important feature of the U.S. healthcare system.

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1 There are a number of reasons to expect that DTC ads
2 can improve the flow of information to patients. We
3 have studies the impact of DTC advertising on a drug
4 class, Cox-2 inhibitors, that has been one of the most
5 controversial over the past two decades. Even for
6 these drugs, we find that the net impact of DTCA is to
7 get patients in front of their physicians and to
8 improve the matching of patients to treatment. Thus,
9 DTC advertising has at least some positive effects on
10 social welfare.

11 We view our results, however, as a little
12 light in a very dark place. Much more research at the
13 patient level is needed to understand the impacts of
14 DTC advertising.

15 Thank you very much for the opportunity to
16 speak today. I'll be happy to try to answer any
17 questions you might have.

18 MR. ABRAMS: Ms. Davis?

19 MS. DAVIS: Did you look at all whether or
20 not the physicians that were prescribing to these
21 patients were being, I guess, detailed or promoted to
22 at a similar rate, or what effect that might have.
23 And I guess that the second question that relates to
24 that, did you see if when, this data came out about
25 cardiovascular effects, you talked about patient

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1 adoption of prescription. But do you have any
2 insights into why physicians were prescribing for
3 these patients who might be called inappropriate for
4 the drugs?

5 MR. KLEIT: With respect to the
6 detailing, our conversation with industry folks
7 indicates that detailing for these two drugs which, as
8 you know, were very popular, was constant over this
9 period, basically that, every representative at every
10 opportunity was trying to promote these drugs in
11 meetings with physicians. Now, with respect to the
12 second question, what we observed, and I know you are
13 going to ask to follow up on that, we observed that a
14 switch in prescribing patterns after the August 2001.

15 We don't have direct data on how physicians got their
16 information, but we infer that, excuse me, how
17 physicians got their information, but we infer that
18 physicians kept up with the clinical literature in
19 this area.

20 MR. ABRAMS: Dr. Aikin?

21 MS. AIKIN: Thank you for a very
22 interesting presentation. I was fascinated to see
23 that advertising for both Vioxx and Celebrex just
24 increased Vioxx prescribing.

25 Did you happen to look at another

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1 indication in tracking these data, perhaps one that
2 wasn't specifically indicated by labeling? To sort of
3 get at the issue of perhaps of inappropriate
4 prescribing.

5 MR. KLEIT: We did not have the, we did
6 not look at other indications although of course we'd
7 be open to suggestion.

8 MR. ABRAMS: Okay, Doctor Kleit, thank you
9 very much for your presentation. We have just about
10 10 minutes until our break, so we are going to open up
11 the discussion for comments from the floor. So I
12 invite anybody to come up to comment. If you do,
13 please identify yourself with your name and your
14 affiliation.

15 Okay, I'd like to thank the panel for very
16 good presentations, great interactives, discussion
17 from our questions. Thank you.

18 (Applause.)

19 We will begin -- I'll turn it over to
20 Rose.

21 MS. CUNNINGHAM: I'd like to let people
22 know there is a sign-up sheet out in the front if you
23 would like to speak, you know, later on, when we have
24 an opportunity such as happened just now. And the
25 next panel, please be sure to be back on time. Tom?

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1 MR. ABRAMS: Okay. And we will break and
2 we'll start promptly at 11:15.

3 (Off the record.)

4 MR. ABRAMS: Good morning. If everyone
5 could take their seats. We have an action-packed
6 agenda, so we really need to keep this moving.

7 Okay. We had an outstanding panel of
8 speakers earlier this morning, and I am very pleased
9 that we are starting the second panel another panel of
10 outstanding speakers. We will begin with our first
11 speaker, Patrick Kelly, from Pfizer.

12 MR. KELLY: Okay. Good morning. I'm Pat
13 Kelly, the president of Pfizer U.S. pharmaceuticals.
14 Thank you for inviting me to participate on this
15 panel. And we will also be submitting written
16 comments to the hearing docket.

17 As a representative of Pfizer and the
18 pharmaceutical industry more broadly, I believe that
19 informed dialogue between patients and healthcare
20 providers is the single most important element of
21 healthcare communications. We also believe that
22 information from any source is central to any
23 definition of dialogue. And, as we've stated before,
24 we believe that under the free speech clause of the
25 first Amendment of the U.S. Constitution, patients

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1 have a right to receive information in DTC advertising
2 and our companies have a right to impart it.

3 That said, today I'll focus on the
4 personal and public health benefits of DTC
5 advertising. Let me start by saying that one of
6 Pfizer's greatest responsibilities to our customers
7 and our business is to communicate information about
8 medical conditions and our products in ways that
9 enable the best health outcomes possible. We believe,
10 and research supports, that direct communication with
11 consumers and, more specifically, DTC advertising, is
12 an important and effective channel for this
13 information.

14 Further, we believe that DTC advertising
15 helps patients work with their healthcare providers to
16 make more informed decisions about their health, which
17 in turn, leads to needed diagnoses, appropriate
18 treatment and ultimately better health outcomes, for
19 Americans and our nation.

20 This last point is especially important
21 because there are tens of millions of Americans who
22 are undiagnosed, untreated or under treated for
23 medical conditions that could be treated if they were
24 aware of these conditions or motivated to seek help.
25 These include such serious conditions as high

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1 cholesterol, diabetes, depression, high blood pressure
2 and asthma. For example, today some 35 million
3 Americans don't know they suffer from high
4 cholesterol. And 19 million do know they have this
5 condition, but aren't being treated for it. Here you
6 can all see the numbers of those untreated for high
7 blood pressure and diabetes.

8 Under any analysis, the costs to the
9 healthcare system of these untreated people are and
10 will be substantial. Research has shown that DTC
11 advertising raises awareness of medical conditions and
12 motivates people to seek information, diagnosis and
13 treatment. It encourages consumers to talk to their
14 healthcare providers about benefits and risks, and
15 helps them stay engaged in caring for their own
16 health. In fact, study after study has shown that DTC
17 advertising delivers important information to
18 patients. As patients themselves report, DTC
19 advertising motivates people to seek additional health
20 information. The information that people receive
21 through DTC advertising motivates them to speak to
22 their physicians, to finally advertising-driven
23 conversations result in new diagnoses of important
24 conditions.

25 According to the 2004 Prevention Magazine

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1 survey, more than 65 million patients have talked with
2 their physicians after seeing a DTC advertisement, and
3 29 million of these patients mentioned a condition to
4 their doctor for the first time.

5 DTC advertising has helped one in four
6 patients who have asked about a DTC-advertised product
7 during a doctor visit, received a diagnosis for a
8 previously unknown medical condition. And more than
9 40 percent of these new diagnoses were for such high-
10 priority conditions as diabetes, high blood pressure
11 and asthma.

12 This impact extends to other medical
13 conditions that can have a major impact on consumer
14 health and consumer quality of life. Often, these are
15 conditions such as overactive bladder and erectile
16 dysfunction, which itself is often a surrogate marker
17 for cardiovascular disease, that consumers have been
18 reluctant to discuss even with a healthcare provider,
19 and aren't necessarily uncovered during a routine
20 physical or check-up.

21 These public health and quality of life
22 benefits notwithstanding, we fully understand that
23 critics have serious concerns about how pharmaceutical
24 companies communicate with consumers. They questions
25 whether promotional messages can accurately provide

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1 product information. They also question the
2 appropriateness of the medication utilization that may
3 result.

4 Before tackling these concerns, though,
5 I'd like to note that through our own research
6 conducted over the nearly eight years we have
7 communicated directly with consumers, we've learned
8 much about their health information needs, on how DTC
9 advertising can have a greater impact on healthy
10 behavior. Specifically, we've learned that one, ads
11 need to provide information that motivates consumers
12 to overcome the significant barriers that continue to
13 prevent millions of Americans from seeking
14 information, or starting that all-important
15 conversation with their doctor to get the medical help
16 they need. These barriers range from a lack of
17 awareness to denial and misinformation to low health
18 literacy, perceived stigma and lack of insurance
19 coverage. As this is true across all disease areas.

20 Second, DTC advertising is and should
21 remain a catalyst that drives consumers to get the
22 full depth of information about prescription
23 medicines, something they pursue through a variety of
24 sources, including their healthcare providers. We
25 know that consumers use a variety of health

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1 information sources, including DTC advertising, at
2 various points to become motivated, engaged and
3 committed to better health. Our research shows that
4 the average patient consults four to five different
5 information sources to understand his or her
6 condition.

7 DTC advertising is not, and should not, be
8 viewed as a comprehensive health information source
9 that leads consumers to think that they don't need any
10 more information. Health information needs to be
11 accessible and understandable. Our experience has
12 shown that patients and potential patients often lack
13 basic knowledge of medical conditions, treatments and
14 medications. While we know that 87 percent of
15 patients are aware that prescription medications come
16 with risks that must be discussed with their
17 physicians, they often lack basic knowledge about a
18 medication's specific indications and specific risks.

19 And our research has shown that consumers
20 cannot easily understand medical information. To
21 address consumers' need for easier to read and easier
22 to understand health information, we have developed
23 and applied to all of our consumer print
24 communications, including our ads, clear health
25 communications principles, that insure that all of

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1 these materials are written and understandable at the
2 6th-grade reading level.

3 Four, DTC ads are communicating important
4 risk information. According to the Prevention survey
5 on DTC advertising, completed in January of 2005, 79
6 percent of those surveyed recalled that risk
7 information was included in prescription drug TV
8 advertisements. At the same time, 75 percent recalled
9 that benefit information was included. Both numbers
10 are up, as you can see, from the prior years' levels.

11 In more controlled settings, TV and print
12 ads have been shown to significantly increase risk
13 perceptions, based on comparisons of people who viewed
14 specific ads versus control groups of people who did
15 not. Testing has repeatedly shown significant
16 increases among those who viewed an ad in the
17 perceptions of the overall seriousness of side-
18 effects, recognition of specific side-effects, and
19 recognition of who should not take the advertised
20 medicine.

21 Five, we must reinforce the importance of
22 a good patient/provider partnership and the role of
23 this partnership plays in appropriate diagnosis,
24 treatment and outcome. Good healthcare decisions,
25 including decisions about prescription medicines, can

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1 only be made when consumers consult a healthcare
2 provider, engage in a productive conversation and
3 mutually determine what the best course of treatment
4 is.

5 Let us also remember that one health care
6 decisions, the decision to prescribe medicine,
7 ultimately rests with only one person, the healthcare
8 professional, the doctor. As to the appropriateness
9 of that decision and the utilization of medicines that
10 result, research shows that when consumers visit a
11 doctor as a result of seeing an ad, they usually have
12 the condition the advertised product treats.
13 According to the FDA's own survey, that was 88 percent
14 of the time.

15 Number six, having said all of that, we
16 can do more to increase the proven health benefits of
17 DTC advertising. Despite the many benefits that it
18 has provided, Pfizer has heard the concerns expressed
19 about DTC advertising. And we recognize that more can
20 be done to encourage valuable dialogue between
21 patients and healthcare providers. To help consumers
22 better understand the risks and benefits of
23 prescription medicines, and to continue to motivate
24 people to overcome potential barriers to better
25 health. It was in this context that PhRMA developed

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1 guidelines.

2 At Pfizer, we've taken those guideline
3 steps even a step further. From our media budget
4 we've diverted the rough equivalent of financial
5 support for one major medicine to address general
6 public health as a stand alone brand, if you will. By
7 doing so, we hope to communicate information that
8 supports prevention, compliance and constructive
9 doctor/patient dialogue, without mentioning any
10 medicine.

11 We're also, as it's been seen, postponing
12 advertising any new medicine until physicians have at
13 least six months to become familiar with them.

14 In addition, our branded TV and print ads
15 and product websites now include language informing
16 patients that their doctor may recommend alternative
17 treatments, such as diet, exercise or other non-Pfizer
18 medications, and that only the doctor knows what is
19 right for you.

20 We are no longer running ads that do not
21 include the indication, benefits and risks associated
22 with the advertising medicine, our so-called reminder
23 ads. We'll begin using a new consumer-friendly and
24 consumer-tested print brief summary with FDA's
25 approval. We're running an ad campaign that is

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1 devoted to our comprehensive prescription assistance
2 programs, Pfizer Helpful Answers. And we'll fund
3 further research to help further improve risk
4 communication in DTC TV advertising. We're seeking
5 input on this research from the FDA and third parties,
6 and we'll adjust Pfizer's communications based on the
7 results.

8 As the FDA considers how to maximize the
9 benefits of DTC advertising, we urge consideration of
10 these important factors:

11 One, the record show that DTC advertising
12 benefits consumers and healthcare more broadly.

13 Two, it's critical to provide information
14 about prescription medicines to consumers in a way
15 that is clear, understandable and accurate.

16 Three, we must do all we can to help
17 consumers work with their healthcare providers toward
18 the best healthcare outcomes possible.

19 Four, the current health information
20 universe is broad and deep. This enables consumers to
21 take advantage both of the information they seek out
22 and the information that is delivered to them through
23 mass communications. Let's continue to expand
24 information options, not limit them.

25 And, finally, we need to understand the

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1 barriers that people face engaging in health behavior
2 and create communications that address those barriers.

3 We must focus on assuring that consumers continue to
4 benefit from accessible, understandable and motivating
5 health information.

6 On behalf of Pfizer, thank you again for
7 the opportunity to participate.

8 MR. ABRAMS: Thank you, Mr. Kelly, for a
9 great presentation.

10 And your research, when your science
11 indicated that there's increased awareness of risk
12 perception in DTC advertising, yet much of the data
13 from the research that we're seeing indicates that
14 patients and physicians are feeling that patients are
15 not getting enough risk information. Whether it's not
16 there, enough it not there or not taking away, can you
17 elaborate on that?

18 MR. KELLY: Well, it's a fair question and
19 it's an important question. I think it is, as is
20 being discussed here, a determination of how is enough
21 to reach whatever the level is we expect. Is it that
22 we will accept that a consumer understands that there
23 is risk inherent in any medication, and that there are
24 risks inherent in this specific medication, or do we
25 need them to be able to recite the specific side-

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1 effects that might occur with that medication. So, I
2 think it comes down to, in this case, a matter of
3 determining what we think is an effective standard, or
4 the approximation of understanding of risk in the
5 consumer population.

6 MR. ABRAMS: And, have you done research
7 as far as drilling that down, what the consumer should
8 have or we believe would be optimal?

9 MR. KELLY: Well, I think that we continue
10 to pursue research that is that specific in
11 determining if there is some point at which the risk
12 information becomes so overwhelming that it actually
13 deters the patient from seeking or seeking health or
14 seeking help in that case. And that's the boundary
15 that we seek to define. We don't know, yet. Again,
16 we have, like other companies, been testing a variety
17 of new approaches that are intended to see where we
18 can provide what is presumed to be adequate provision
19 of risk information and still motivate patients to
20 take action with that information.

21 MR. ABRAMS: Doctor Behrman?

22 MS. BEHRMAN: What have you thought about
23 internally. We can now talk a little about balancing
24 risks and benefits. And to a certain extent while
25 that's hard, at least count them and recommends what

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1 they are, but one issue that came up in the last panel
2 that we struggled with internally, have you thought
3 internally within your company about the entire
4 message of the ad and how do you ensure that one part
5 of it doesn't dilute or obscure the other part. Have
6 you talked about that or thought about that?

7 MR. KELLY: Absolutely. And I think that
8 starts though with an understanding and appreciation
9 of what is accomplishable in sixty seconds or thirty
10 seconds, if you're talking about TV advertisement, or
11 a page or two if you're talking about print
12 advertising.

13 Within that context, then, it is at least
14 our interpretation that the regulations are quite
15 clear, that you need to be able to adequately
16 communicate what the product is for, you're allowed to
17 communicate what the product might provide in the way
18 of benefits, as long as you balance that with some
19 approximation of that description of the benefit with
20 the description of risk. Accomplishing those three
21 things would seem to be the core recognition of what
22 the regulations envision and, in fact, command.

23 Then the question is, can we accomplish
24 that in a way that still accomplishes what the ad is
25 intended to do, which is to motivate action. That

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1 action can be in two forms. Either it is to seek out
2 further information in the area is being discussed, or
3 to consult with their healthcare provider.

4 Accomplishing all of that is a rather
5 complex matter within the context of these short
6 bursts of --

7 MS. BEHRMAN: Yes.

8 MR. KELLY: -- information. So I think we
9 need to kind of step back and establish what it is we
10 think is reasonable to be accomplished within that
11 context, and then ensure that we are accomplishing it
12 as effectively as we can.

13 MR. ABRAMS: Ms. Wolf?

14 MS. WOLF: Do you have any information on
15 the differences between what we call health seeking or
16 disease awareness ads that you talked about at the end
17 of your presentation? How differently those might
18 bring people to their doctors as opposed to health
19 product ads --

20 MR. KELLY: Yes.

21 MS. WOLF: -- bringing people in.

22 MR. KELLY: Yes, we do. And, in fact,
23 that's one of the findings that is not necessarily
24 well understood is that general health awareness and
25 health seeking ads do not drive patients to the doctor

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1 to anywhere near the degree that information about a
2 solution or a potential solution will. Again, one of
3 the things we face in the patient populations that
4 we're talking about is there may be some built-in
5 inertia, either associated with perceived barriers to
6 them seeking health and seeking treatment for their
7 disease or medical condition, as well as just a
8 general inertia about this problem isn't serious
9 enough for me to worry.

10 What we have found is that if you express
11 that just you should be aware that there is a medical
12 condition or a disease that you should worry about, it
13 doesn't generate as much action as if you then say and
14 there might be potential solutions that you should
15 consult with your provider about. So it is the other
16 connection that's important towards a motivating
17 action.

18 MS. WOLF: And is there any difference
19 within that distinction whether patients or consumers
20 do or do not have insurance?

21 MR. KELLY: Again, we don't have a lot of
22 research in that particular last point. But we do
23 know through the research we've done more broadly,
24 that the lack of insurance coverage is a barrier to
25 taking action in many disease states.

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1 MR. ABRAMS: Doctor Temple?

2 DR. TEMPLE: Let me see if I have my mike
3 on, is that on?

4 You answered Ms. Wolf's question about
5 health-seeking ads, but you were referring to an ad
6 that's only a health-seeking ad. But, product ads can
7 have health-seeking components. Some of the early
8 statin ads were quite good that way. Do you have any
9 insight into whether those elements contribute to
10 better understanding and what I'm focusing on
11 particularly is the need for a long-term use of these
12 agents and compliance. I mean it's really a public
13 health disaster that people, with all the things
14 you've shown, that people with elevated blood pressure
15 and abnormal lipids don't treat them long-term. So,
16 that question about the health-seeking component,
17 whether that contributes, then I have another
18 question.

19 MR. KELLY: Sure. So, I think that there
20 is a contribution that is oriented towards seeking
21 health, or even better I think, seeking help as a way
22 to understand what the objective is here. And I would
23 not suppose that because I was answering that question
24 on health seeking only, as opposed to health seeking
25 as a component within product messages.

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1 I think that the other part of your
2 question though, there is a very important component
3 towards these ads, in these ads, relative to trying to
4 continue treatment in those patients that have
5 received that particular treatment. The ads do serve
6 as a reminder to that. Now, the research has been
7 conflicting as to how much of a degree that reminder
8 helps. Again, it was cited in one of the earlier
9 presentations, there's some research that has seen
10 that it is a modest, to almost insignificant, effect
11 on compliance.

12 We've seen other studies and done other
13 studies and shown it is a more significant effect. So
14 I think there is value to health-seeking as well as
15 reminding to continue on your medication or treatment
16 that the doctor has prescribed that should be a
17 component of this kind of advertising.

18 DR. TEMPLE: I was going to ask you about
19 the possibility, I mean, the difficulty with a
20 national ad is that it is hard to know what effect
21 you've had on compliance. I mean, you sort of have to
22 move national compliance and that's a tall order.

23 There might be more localized environments
24 in which, an HMO or something might let you in to try
25 to promote maintenance of lipid therapy, say. I mean,

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1 there are all sort of interested in that in some ways
2 even though it costs money. Are you contemplating any
3 things like that? It would be an enormous step if
4 somebody could show that there are communication
5 devices that could actually do that.

6 MR. KELLY: Absolutely. We're engaged in
7 that. The most successful venue for that that we have
8 found in our experience is the pharmacy. It is not
9 the health plan level but at the pharmacy level where
10 patients are interacting with pharmacists on the
11 prescription or the refilling of the prescription of
12 the medication. And we've been able to show anywhere
13 from 30 to 50 percent increase in compliance rates
14 using pharmacy-based interventions.

15 MR. ABRAMS: And are these good studies
16 with, you know, randomization to pharmacies --

17 MR. KELLY: They are absolutely.

18 MR. ABRAMS: -- and stuff like that?

19 MR. KELLY: They are absolutely.

20 MR. ABRAMS: Okay. Well, I hope you'll let
21 us know about that.

22 Mr. Kelly, thank you very much. Our next
23 speaker is Abby Mehta from Gallup & Robinson
24 Incorporated.

25 MS. MEHTA: Good morning. It's a pleasure

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1 to be here and I'd like to commend the FDA for the
2 opportunity to speak today. I hope you'll find this
3 presentation interesting and helpful in reference to
4 your questions about the use of certain standard
5 advertising practices. I'll be presenting research
6 findings regarding celebrities and advertising. Thank
7 you.

8 I have some experience on celebrity
9 advertising effects across various consumer products,
10 and it was also the topic of my doctoral dissertation.

11 Currently, I'm the Director of Research at Gallup &
12 Robinson, a marketing and advertising research company
13 which has been conducting advertising research for
14 over 50 years.

15 We have undertaken masses of data analysis
16 from our data base to understand better how
17 celebrities work, as well as conducted specific
18 studies on the subject. Last year, Gallup & Robinson
19 was commissioned by Pfizer to design a study to
20 evaluate and understand the impact of celebrities in
21 the DTC area. The results of this study I hope will
22 be of value and in answering FDA's questions about
23 celebrity advertising.

24 So, the important question is, does
25 celebrity advertising perform differently from non-

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1 celebrity advertising? More specifically, is
2 celebrity advertising better able to break through the
3 clutter, gain attention and be memorable as compared
4 to non-celebrity advertising? How is celebrity
5 spokespersons in advertising perceived? How is the ad
6 itself with the celebrity perceived? Does celebrity
7 advertising persuade more than non-celebrity
8 advertising? And what impact does celebrity
9 advertising have on the advertised brand?

10 First, I'm going to briefly present some
11 research about general consumer products and brands
12 and then discuss the DTC advertising study.

13 There is research evidence that celebrity
14 advertising can deliver a premium in terms of breaking
15 through the clutter and obtaining higher awareness
16 levels for the ad and the brand. Based on an analysis
17 from Gallup & Robinson's database of consumer
18 products, on average day-after recall of celebrity
19 magazine ads is about 34 percent higher than that of
20 general ads. There is, however, a wide range of
21 results and celebrities don't guarantee break through.

22 While over half of the celebrity ads showed above
23 average recall levels, roughly one in three were at
24 parity and about one in six celebrity ads was found to
25 be below average.

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1 In terms of celebrity perceptions, ratings
2 for celebrity spokespersons are significantly higher
3 than ratings for non-celebrity and non-celebrity
4 spokespeople or non-celebrity actors in identical or
5 similar advertising for attributes such as
6 likeability, credibility, physical attractiveness,
7 although there are some exception seen for particular
8 celebrities in particular contexts. Additionally,
9 celebrity advertising in general is also more liked
10 than non-celebrity advertising.

11 In terms of persuasion, though, celebrity
12 advertising results are more mixed. Celebrity ads may
13 or may not motivate purchase interest. Buying
14 interest for print ads amongst recallers of the ad on
15 average was only four percent higher than that of non-
16 celebrity or general other ads. And again, in our
17 database of massive data analysis.

18 We see a wide range of results, roughly
19 one in three celebrity print ads shows above-average
20 persuasion levels. Half are at parity and about one
21 in five falls below average.

22 So, those were the general findings. We
23 looked more specifically at the DTC category. Two
24 health conditions were studied: migraines, a
25 symptomatic condition; and high cholesterol, an

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1 asymptomatic condition. An experimental research
2 design was used. Identical celebrity and non-
3 celebrity ads were created, and the performance of
4 these ads were compared.

5 Two celebrities and one non-celebrity was
6 used per condition for a total of four celebrities and
7 two non-celebrities. Celebrities were selected after
8 appropriate research. We used fictitious brands, so
9 the results would be clean and not -- prior knowledge
10 of the brand would not be coming into the ad.

11 The ads were tested by Gallup & Robinson's
12 established magazine ad testing methodology, MIRS,
13 which has been in use for over five decades. It is an
14 in-contest, in-magazine, at-home exposure design which
15 involves and I can explain that. It involves
16 recruiting target respondents for a magazine
17 readership test. Test ads, either celebrity or non-
18 celebrity ad, is tipped into the magazine and this
19 magazine is placed with a qualified respondent. A
20 telephone interview is conducted with the respondents
21 the day after they've read the magazine. And data is
22 collected during this interview.

23 First, recall is taken for the ads based
24 on a brand Q, after which respondents are asked to
25 open their magazine, look at the ad again and

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1 recallers and non-recallers are then force-exposed to
2 the ad and further questioning is taken. A total of
3 about 1,050 sufferers of migraines or high cholesterol
4 from 15 different geographically-dispersed national
5 markets, participated in the study these such
6 findings.

7 On average, recall levels for the
8 celebrity ads was significantly higher than for non-
9 celebrity ads. Perceptions, after cost exposure, were
10 also significantly higher for the celebrity ad for
11 being more attention getting and eye catching.

12 Celebrity spokespersons in ads were
13 consistently rated significantly more favorably than
14 non-celebrity spokespersons for a variety of
15 attributes such as likeability and credibility, among
16 others.

17 Celebrity ads were also more liked and
18 seemed to be more impressive overall than the non-
19 celebrity ads, but they were not perceived as
20 providing more important messages or being more
21 informative or even more believable overall.

22 In terms of persuasion as measured, as
23 interest in the product among those that recall the ad
24 the day after reading the magazine, there were no
25 differences across all celebrity and non-celebrity

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1 ads.

2 After forced exposure, motivation to
3 consult doctors shows celebrities were more effective
4 in one of the two conditions only. In the migraine
5 conditions, celebrities had higher levels of doctor
6 consultation intent than the non -- whereas the high
7 cholesterol condition, there were no differences
8 between celebrities and non-celebrities.

9 In terms of brand reactions, overall a few
10 global image attributes for celebrity ads showed
11 higher results. The brand was seen as more unique and
12 sometimes likely to improve the quality of life. But
13 none of the specific brand efficacy and performance
14 measures shows any consistent differences across
15 celebrity and non-celebrity ads. I've listed a few
16 attributes here to show you the results across the two
17 conditions. There were no differences for the
18 celebrity and non-celebrity ads in migraine or the
19 high cholesterol condition.

20 In conclusion then, results of the study
21 showed that on average celebrity DTC ads can and do
22 show higher break through clutter, gaining attention
23 and memorability on a day after basis. Celebrity
24 spokespersons are rated more favorably than non-
25 celebrities in the DTC ads and the celebrity ad itself

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1 is perceived more positively on an overall liking
2 basis and a few other measures like that. But
3 celebrity ads are not seen to be providing more
4 important messages or being more informative and
5 believable.

6 Celebrity ads may or may not motivate
7 doctor consultation. Various factors, including
8 health conditions seem to influence celebrity
9 effectiveness. And while a celebrity-endorsed brand
10 is seen as unique and sometimes is seen to be
11 improving the quality of life, its efficacy and
12 performance is not expected to be different than that
13 of a non-celebrity ad.

14 Thank you.

15 MR. GOTTLIEB: Thanks a lot.

16 MR. ABRAMS: Dr. Gottlieb.

17 MR. GOTTLIEB: Sorry. Two quick
18 questions. Have you looked at breaking down what the
19 celebrities are being asked to do in the advertising
20 and whether having them talk about the benefit
21 information and having risk information presented in a
22 different format is creating more difficulty
23 interpreting both sets of information? And you talked
24 about health condition influencing the impact of the
25 celebrity. Are you speaking to the fact that have you

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1 gleaned from your data that having celebrities talk
2 about disease conditions in sort of a first person way
3 has a higher impact? Is that what you were referring
4 to there?

5 MS. MEHTA: Yes and no. The first
6 question, did we look at risk benefits differently by
7 celebrity, is that what you --

8 MR. GOTTLIEB: My question is you talked
9 about cognitive dissonance and I'm just asking whether
10 -- what the celebrity is being asked to do in the
11 advertisement, if you've looked at that in terms of
12 what their role is in the ad and whether that's
13 creating more of an inability to recognize the risks
14 relative to the benefits in this advertising?

15 MS. MEHTA: In this study, we created very
16 identical ads, whether it was a celebrity or a non-
17 celebrity and we just compared the results of these
18 two. We did not manipulate how or what the celebrity
19 was doing and in other areas we've seen that the
20 celebrity is well involved with the product, they can
21 be more effective, but in this case we just studied
22 the one format.

23 Your second question was about --

24 MR. GOTTLIEB: I think you answered that
25 as well. It was about you said something to the

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1 effect of health condition --

2 MS. MEHTA: Yes, we studied migraines and
3 high cholesterol and we saw that in the migraine
4 condition the doctor, the motivating doctor
5 consultation was affected by celebrities, but in the
6 high cholesterol it was not.

7 MR. ABRAMS: Dr. Ostrove.

8 MS. OSTROVE: Well, thank you very much.
9 It was very interesting. And as you've -- I'm sure
10 you've heard earlier today, we're very interested in
11 the risks, the communication of risks as well as the
12 benefits. Has there been any attempt to look either
13 in terms of the day after recall or in terms of a
14 forced exposure what consumers, what your research
15 participants got in terms of the risks of the
16 products?

17 MS. MEHTA: We did not ask any questions
18 about the risks in our research. The questions are
19 general. The day after recall of the -- do you
20 remember an advertising for XYZ? Do you remember
21 that? And then respondents are asked four open-ended
22 questions. What did the ad show you and what did it
23 tell you and what did you learn about it. And so we
24 don't -- we didn't ask specifically about the risk
25 messages.

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1 MS. OSTROVE: Do you think that your
2 methodology would allow you to do that?

3 MS. MEHTA: Yes, of course, we could.
4 This is, like I say, standard questions that have been
5 used, but it could be adapted.

6 MS. OSTROVE: And for most consumer
7 commodities, the interest is in the benefits and
8 whether the benefits are coming across, but clearly in
9 our particular situation, it's a little bit different.
10 We're also interested in whether the risks are coming
11 across and it seems as if, especially looking at it in
12 this -- you have the potential here for a much less
13 artificial kind of research environment than some of
14 the others than we've been hearing where it's very
15 clearly a forced exposure. So it seems to me that
16 there's -- there is some real potential.

17 MS. MEHTA: Yes, I'm sure we could
18 construct some appropriate questions to get at that if
19 that was the objective of the study.

20 MS. OSTROVE: Thank you.

21 MR. ABRAMS: Dr. Aikin?

22 MS. AIKIN: Dr. Ostrove covered my
23 question.

24 MR. ABRAMS: Thank you, Dr. Mehta, thank
25 you very much for a very informative presentation.

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1 MS. MEHTA: Thank you.

2 MR. ABRAMS: Our next speaker is Michele
3 Spence from Kaiser Permanente.

4 MS. SPENCE: Thank you and good morning.
5 I'm Michele Spence from Kaiser Permanente and today
6 I'm going to talk to you about a study which looks at
7 direct-to-consumer advertising of Cox-2 inhibitors,
8 the impact of appropriateness of treatment.

9 We conducted this study with the UCLA
10 Department of Public Health and it was funded by the
11 California Health Care Foundation.

12 Our research aim was to determine whether
13 patients who have seen Cox-2 ads and asked their
14 doctor were more or less likely to receive a
15 prescription for a Cox-2, according to clinical
16 guidelines.

17 We decided to study Cox-2 inhibitors
18 because at the time of this study in 2001, Cox-2s were
19 heavily advertised. \$78.3 million was spent on
20 advertising Celebrex and \$160.8 million was spent on
21 advertising Vioxx.

22 These drugs are high cost. They are
23 generally 10 to 15 times the cost of traditional
24 NSAIDs and they are widely used. And we also decided
25 to study the Cox-2s because we had a clear definition

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1 of appropriateness. So we looked at some clinical
2 guidelines that reserved the Cox-2s for patients at
3 increased risk of GI bleeding.

4 We took our data from two sources, from a
5 mail survey of 3,000 Kaiser Permanente patients in
6 Southern California and also from our administrative
7 prescription databases. This was a stratified random
8 sample. Half of the patients received a new
9 prescription for a Cox-2 and half of them received a
10 new prescription for a traditional NSAID. And then
11 these were the patients that we surveyed about DTC
12 ads.

13 The surveys included questions like have
14 you seen ads for Celebrex? And after you saw the ads,
15 did you ask your doctor about Celebrex? And we
16 included a set of questions about Vioxx as well. And
17 to measure appropriateness, we asked questions which
18 gauged the level of GI risk for the patient. And this
19 was based on a score tool. This is a standardized
20 tool that was developed by Gurkirpal Singh at Stanford
21 and it's used to identify patients at highest risk of
22 serious GI events that are treated with traditional
23 NSAIDs.

24 The surveys were mailed in February 2001
25 and they were available both in English and in

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1 Spanish.

2 Okay, we looked at three different
3 clinical guidelines for GI risk and we decided to look
4 at three guidelines because we wanted to allow for
5 variations in what is seen as appropriate and also we
6 didn't want to be criticized for just using the Kaiser
7 guideline. So our Kaiser guideline stipulated that
8 patients who are at highest risk that measure score,
9 score number four on the score tool, they're at
10 highest risk and therefore the most appropriate
11 candidates for a Cox-2 inhibitor.

12 We then looked at the modified Kaiser
13 guideline for patients who scored three or four were
14 the most appropriate candidates for Cox-2. And
15 finally, we used a set of criteria developed by Loren
16 Laine. And this is a much broader definition of GI
17 risk. For example, any patient who is over the age of
18 65 would be considered high risk for a GI bleed and
19 therefore an appropriate candidate for a Cox-2.

20 Our dependent variable had three levels.
21 First, those treated with a Cox-2 when the guideline
22 would recommend a traditional NSAID. Second, those
23 treated with an NSAID when the guideline would
24 recommend a Cox-2 and third, those appropriately
25 treated with either a Cox-2 or an NSAID.

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1 Our independent variable was the patient
2 saw the Cox-2 ads and then asked their physician and
3 then we compared those patients with all other
4 patients, so those are either they didn't see the ads
5 or they said they saw the ads, but they didn't ask
6 their physician about Cox-2s.

7 We controlled for a variety of patient
8 covariates, including demographics as well as their
9 duration and location of enrollment in Kaiser. We
10 also controlled for physician characteristics,
11 including age, gender, specialty, their location and
12 how long they've worked at Kaiser.

13 We received a 47 percent response rate.
14 Twenty percent of the respondents said that they saw
15 the ads and asked their physician about a Cox-2. And
16 80 percent of them reported that they either didn't
17 see the ads or they saw the ads and didn't ask.

18 Okay, in this slide, this tells you, sort
19 of breaks down the levels of appropriateness. So it
20 shows you the number of patients prescribed either a
21 Cox-2 or an NSAID using the three different
22 guidelines. And the shaded boxes indicate appropriate
23 treatment. So if you look at the top two lines, this
24 uses the Kaiser guideline. So patients classified as
25 low risk, who got a Cox-2, they would have been

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1 inappropriately treated. Fifty percent of our
2 respondents fell into that category.

3 Patients who were high risk and got a Cox-
4 2 would have been appropriately treated, 9 percent.
5 Patients who were classified as low risk and got an
6 NSAID were also appropriately treated. That was 39
7 percent of our respondents. And finally, a small
8 number of patients who were high risk and got an
9 NSAID, it was only 1 percent.

10 Then we used these same patients and
11 classified them according to the modified Kaiser
12 guidelines, so this is a more generous definition of
13 risk. You'll see that the boxes of appropriateness go
14 up 31 percent in each group. Those that are treated
15 with a Cox-2 and the recommendation would have been an
16 NSAID, went down to 29 percent and those that were
17 high risk and got an NSAID also that went up to 9
18 percent. And the same kind of patterns happen when we
19 use the Laine criteria. We have more people being
20 treated appropriately, classified as being treated
21 appropriately.

22 Okay, our next slide, this is where we
23 used a multivariate regression analysis and the impact
24 of the ads on appropriate prescribing. So using the
25 Kaiser guideline, patients who saw the ads and asked

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1 were four times more likely to be prescribed a Cox-2
2 when the guideline would have recommended an NSAID.
3 And that was statistically significant.

4 Using the other two guidelines, the odds
5 ratios were about three. Patients who saw the ads and
6 asked were three times more likely to be prescribed a
7 Cox-2, to be over-prescribed a Cox-2.

8 We looked at the -- the impact on NSAID
9 treatment. The Kaiser guideline wasn't significant,
10 but if we look at the modified Kaiser guideline,
11 patients who saw the ads and asked were significantly
12 less likely to be under treated with an NSAID. And we
13 also found the same impact with the Laine criteria.

14 In conclusion, patients who saw Cox-2 ads
15 and asked their doctor were significantly more likely
16 to be prescribed a Cox-2 instead of a traditional
17 NSAID according to guidelines. This finding was very
18 robust. It was consistent across three different
19 guidelines and it suggests that DTC advertising leads
20 to inappropriate prescribing of costly medications.

21 We also found that patients who saw the
22 ads and asked were less likely to be prescribed an
23 NSAID when a guideline recommends a Cox-2. This
24 finding occurred in just two of the guidelines and
25 those were guidelines with very broad definitions of

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1 GI risk and it suggests that some patients for whom
2 the drugs are truly appropriate may benefit from DTC
3 advertising.

4 So on balance, we find a simultaneous
5 small benefit in the large costs associated with DTC
6 advertising of Cox-2s. It may avert some under use,
7 but it's offset by increased prescribing for
8 conditions for which the net therapeutic effect is
9 negligible or in the case of Vioxx, even negative.

10 The limitations of the study, we had low
11 overall Cox-2 use in KP, so it probably underestimates
12 the impact of DTC ads. We didn't include a
13 measurement of physician exposure to drug promotion.
14 We only looked at one class of drugs and there could
15 have been potential recall bias among our survey
16 respondents.

17 Finally, the demise of Vioxx should make
18 us reconsider our attitudes toward DTC advertising.
19 This advertising promotes over use of newer drugs
20 without a track record of safety and effectiveness.
21 Consumers need credible, balanced drug information.
22 And finally, there's a need for increased consumer and
23 physician vigilance toward DTC advertising.

24 Thank you.

25 MR. ABRAMS: Dr. Temple?

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1 DR. TEMPLE: This was all done before
2 Vigor was published, is that correct?

3 MS. SPENCE: Vigor was published in 2001.

4 DR. TEMPLE: Maybe 2000.

5 MS. SPENCE: Yes.

6 DR. TEMPLE: Actually, I'm not sure. The
7 guidelines that you're referring to at Kaiser
8 Permanente, they were cost guidelines principally,
9 would that be correct?

10 MS. SPENCE: Cost effective.

11 DR. TEMPLE: I mean before Vigor, there
12 wouldn't have been any particular reason not to use
13 Vioxx or Celebrex. It's just that they're expensive
14 and wouldn't seem to have an advantage. I guess
15 that's the idea.

16 So the advertising interfered with the
17 attempt of Kaiser to carry out what it considered to
18 be rational cost control.

19 MS. SPENCE: We were concerned about the
20 impact of the ads on the appropriate prescribing of
21 Cox-2.

22 DR. TEMPLE: Okay, probably there's a
23 longer discussion, but the idea of the Cox-2 selective
24 ones and the studies that were done were not done on
25 high risk people. They showed decreased bleeding in

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1 general populations and that was the idea of Cox-2.
2 But it is perfectly reasonable that Kaiser would make
3 the judgment that it's worth it for people at higher
4 risk. So this was really about undermining cost
5 containment policy.

6 MS. SPENCE: Yes.

7 DR. TEMPLE: It seems at least possible
8 that could agree with the cost containment policy,
9 wanted less GI bleeding even for people who weren't at
10 high risk. That could explain some of it.

11 MR. ABRAMS: Dr. Spence, thank you very
12 much for a good presentation. We appreciate that.

13 Our final speaker for this panel is
14 Christine Winnicki from Time, Inc.

15 MS. WINNICKI: Thank you and good morning.
16 I'm here today on behalf of Time, Inc. to present
17 some findings from our latest DTC study. It's a
18 consumer study.

19 Time, Inc. has conducted six waves of
20 research on DTC advertising in the past eight years.
21 Part of our latest wave focuses on recent sufferers
22 and the information sources they use and the actions
23 they take from the time when they think they have a
24 problem to doctor diagnosis.

25 Seven conditions were identified as key

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1 conditions for this year's study. They were selected
2 on the basis of the fact that they're gender neutral
3 and that a lot of advertising weight has been placed
4 against them. They included symptomatic conditions,
5 allergies, arthritis, chronic heartburn and depression
6 and asymptomatic conditions, cholesterol, diabetes and
7 hypertension.

8 Our study was conducted on line with
9 Harris Interactive. We used the Harris poll on line
10 study for the U.S. population, first to find our
11 sufferers and also in order to collect some general
12 attitudes towards DTC advertising among the
13 population.

14 We also needed to over sample to find
15 sufferers of our seven key conditions and we did so
16 using the Harris Interactive Chronic Illness Panel.

17 Our final group sizes are large and we
18 compensated for the fact that we both conducted the
19 study on line and that we over sampled for our seven
20 key conditions by weighting the data.

21 We surveyed a total of 3,570 people and we
22 found 1,417 recent sufferers of our seven key
23 conditions. Our field period was about a year ago.
24 It was the end of September through mid-October of
25 2004. We focused on our recent sufferers, meaning

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1 adults who had been diagnosed by a doctor with one of
2 our seven key conditions in the past two years. We
3 wanted them to have the ability to recall what they
4 did and where they turned to for information before
5 formal diagnosis by a doctor, what happened when they
6 were at the doctor's office, as well as what they were
7 now doing.

8 Early on in the survey when we had
9 established that someone was a recent sufferer, we
10 asked them to think back to the period before there
11 were guidelines and tell us if they had either
12 experienced symptoms or aware that they might have a
13 condition.

14 We then explored what information sources
15 they use, if any, to find out what was wrong with them
16 and which they used in order to treat or to learn
17 about treating their condition.

18 It's primarily patients with symptomatic
19 conditions that we spoke to in our pre-diagnosis
20 stage, but at and after diagnosis we had equal
21 representation of symptomatic and asymptomatic
22 condition sufferers.

23 At diagnosis, we wanted to what the doctor
24 recommended to patients and if and where they look for
25 information about their condition or ways to treat it.

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1 After diagnosis, we wanted to know what patients are
2 currently doing and how they continue to learn about
3 their condition and treatments for it.

4 So overall what we found was whether it's
5 pre or post-diagnosis, we find that the recent
6 sufferer turns to the health care provider first, for
7 information about their condition or ways to treat it.

8 That was 71 percent. And that number is largely
9 populated by doctors. They account for 64 percent.
10 Pharmacists and nurses are also included in that.

11 Four out of 10 patients turn to the
12 internet and friends and relatives. By the internet,
13 we mean health-related websites and internet
14 advertising with that number largely being driven by
15 health-related websites.

16 Between 25 and 30 percent turn to
17 magazines, TV, pamphlets or brochures or TV programs
18 in doctor's offices or pharmacies. The magazine and
19 TV numbers you see are a combination of both the
20 content and the advertising. One out of four turn to
21 medical books and journals and one out of five turn to
22 pharmaceutical company websites for their information.

23 Between 6 and 16 percent turn to
24 newspapers, radio or say that letters or pamphlets in
25 the mail are a source of information for them. The

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1 none means none of the particular line items that we
2 presented to them which were 19.

3 Overall, when we look at our five main
4 media sources which are TV, magazines, internet, radio
5 and newspapers, we find that 58 percent of our recent
6 sufferers turn to the media content sources for
7 information about their condition or ways to treat it.

8 And 27 percent turn to the advertising sources.

9 Ad recall and the use of advertising
10 varies greatly by condition. With allergy sufferers
11 and depression sufferers being much more amenable to
12 advertising as a source of information for their
13 condition.

14 We presented various benefits of
15 prescription drug advertising to our general
16 population, as well as our recent sufferers and asked
17 them to tell us whether they agreed or disagreed that
18 prescription drug advertising provided these benefits
19 to them.

20 Over half of adults said that prescription
21 drug advertising made them more confident in talking
22 to a doctor about their condition, provided
23 information about who should or should not take the
24 medication as well as to help them remember the brand
25 or the company name.

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1 Our recent sufferers in particular were
2 significantly more likely to feel that prescription
3 drug advertising provided information on who should or
4 should not take the medication. Over half also felt
5 that it provided clear information on the drug's
6 benefits and supplemented the information provided by
7 a doctor.

8 Our recent sufferers were also
9 significantly more likely to feel that prescription
10 drug advertising helps people evaluate which drugs are
11 best for them.

12 Among our recent sufferers, the majority
13 of our sample had indicated that they had indeed seen
14 prescription drug advertising for at least one of our
15 seven conditions. We focused in on those who said
16 they had seen that advertising both on television and
17 in magazines. We then asked them to tell us which
18 type of advertising was better at providing certain
19 benefits. Overall, we find that both magazines and TV
20 are effective in encouraging people to take
21 medications or to refill their prescriptions. Both
22 say people are more confident in talking to a doctor
23 about their condition and both also help people to
24 remember a brand or a company name.

25 Magazines, in particular, were seen as

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1 more effective at providing sufficient information
2 about a drug's side effects and risks. Magazines are
3 also seen as being either equal to or better than
4 television and providing clear information on a drug's
5 benefits and effective dosages and duration of
6 treatment and directing people to a website for more
7 information.

8 TV ads were seen as equal or more
9 effective than magazines when it comes to brand or
10 company recall.

11 Now let's look at what patients are doing
12 prior -- or recent sufferers, in particular, prior to
13 diagnosis by a doctor. We found that over 60 percent
14 of recent sufferers that we spoke to said that they
15 either had symptoms or were aware that they might have
16 a condition prior to being diagnosed by a doctor. Two
17 out of three of these sufferers tried to address their
18 condition in some way. Forty-one percent took over-
19 the-counter medications. Thirty percent made
20 lifestyle changes like stopping smoking. Twenty-six
21 percent either changed their diet or exercised more
22 regularly. And 24 percent tried some type of self-
23 treatment with home remedy such as an ice pack, which
24 was one of the examples we gave, or alternative
25 medications like St. John's Wort or echinacea which

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1 were specific examples that we gave. And four percent
2 began some kind of therapy. Remember, we looked at a
3 variety of conditions.

4 Now let's see what happens when they're at
5 the doctor's office. Seventy-three percent of our
6 recent sufferers said that the doctor gave them a
7 prescription medication. Nearly half said that the
8 doctor also recommended diet and lifestyle changes to
9 them. Thirty-eight percent said that the doctor gave
10 them a sample and we found that varied greatly by
11 condition with, for instance, half of chronic
12 heartburn sufferers receiving samples from doctors.

13 Even though 38 percent were given samples,
14 only 26 percent said that the doctor gave them
15 literature about the condition and only 13 percent
16 said that the doctor gave them literature about the
17 medication itself. Nine percent said that the doctor
18 recommended an over-the-counter medication for them.

19 Now what are our patients doing on an on-
20 going basis. Well, we see on an on-going basis that
21 our recent sufferers generally say that they are
22 indeed taking prescription medications, but an almost
23 equal number are saying that they elect to make
24 lifestyle changes also in order to treat their
25 condition. Those at diagnosis, 73 percent said that

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1 their doctor gave them a prescription medication or a
2 prescription for a medication and only 70 percent are
3 taking medications on an on-going basis.

4 We found the greatest resistance to be
5 among arthritis and diabetes sufferers. Twenty-nine
6 percent of the patients use alternative medications to
7 treat their condition on an on-going basis and 17
8 percent are taking over-the-counter medications.

9 So what is the summary of what we found in
10 our research that may be relevant today? Health care
11 providers are playing a key role. Advertising is an
12 important information source. It encourages patient
13 and doctor dialogue. It helps patients understand who
14 should and should not take prescription medications,
15 especially those recently diagnosed sufferers and for
16 them in particular, it supplements the information
17 provided by the doctor.

18 We find that magazines and TV work
19 together. Magazines seem to be better at
20 communicating side effects and risks and TV is better
21 at helping patients remember a brand or a company
22 name. Patients choose to address their conditions in
23 an on-going way two ways. They do take prescription
24 medications, but they also make lifestyle changes.

25 And we found a need for more patient

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1 communication. Doctors are giving out samples but not
2 enough are giving out literature about conditions or
3 medication information.

4 Thank you.

5 MR. ABRAMS: Dr. Gottlieb.

6 MR. GOTTLIEB: Thank you, Christine. As a
7 physician, I was heartened to see I'm a better
8 information tool than the internet.

9 (Laughter.)

10 Two questions. One, do you have any
11 information on why the magazine advertising was more
12 effective risk communication tool than the television
13 and when you looked at people who had turned to the
14 internet for information, do you have any sense of
15 what they did on the internet, whether they went to
16 search engines where they might be more apt to first
17 encounter something that was sponsored versus going to
18 trusted health care sites or what their behavior was
19 on the internet?

20 MS. WINNICKI: We unfortunately didn't
21 delve further into either of those questions, so it
22 would be speculative on my part to say anything
23 further about that.

24 MR. ABRAMS: Any other questions from the
25 FDA Panel?

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1 Okay, Ms. Winnicki, thank you very much
2 for your presentation.

3 I want to thank the second panel for their
4 excellent presentations. Also, I'm going to make a
5 request of the second panel as I did for our first
6 panel and everyone in the audience to submit the data
7 that you present summaries for if you're willing to
8 make it publicly available. This helps the Agency
9 develop its policy.

10 Thank you very much.

11 (Applause.)

12 Now we're going to -- we have 10 minutes.
13 We're going to open the floor for questions. We have
14 a sign up sheet. So I would for ask the first person,
15 Brad Bernard from Life Med Media Company.

16 MR. BERNARD: I will try to speak up.
17 Brad Bernard. We have created a community of diabetic
18 patients. (inaudible- SFUL)

19 For example, on our website and television
20 program along this area and this has just recently
21 occurred in the last several months we've seen this
22 increase.

23 (Inaudible- SFUL) DTC ads (inaudible-
24 SFUL) better dialogue and interaction (inaudible-
25 SFUL).

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1 Thank you very much.

2 MR. ABRAMS: Thank you, Mr. Bernard. We
3 have no other members of the public signed up on the
4 sign up sheets. I invite anybody who wishes to make a
5 public comment, if they wish to at this point, come to
6 a microphone.

7 Okay, I remind folks to, if you wish to
8 submit comments to the docket, you can do that as well
9 and we look at all comments. We appreciate those.

10 We're going to break for lunch now. We'll
11 return here at 1:35 and we'll start our other two
12 panels promptly at 1:35.

13 Thank you.

14 (Whereupon, at 12:27 p.m., the meeting was
15 recessed, to reconvene at 1:35 p.m.)

16 MR. ABRAMS: Good afternoon. We are going
17 to start our afternoon session. Our afternoon session
18 will consist of two panels. We will have a break in
19 between the two panels.

20 Okay. So we'll begin with the first
21 panel. And our first speaker will be James Gardner
22 from One to One Interactive.

23 PANEL 3

24 MR. GARDNER: Hello. Good afternoon. I'm
25 James Gardner with One to One Interactive. For those

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1 of you who don't know us, we're a mid-sized
2 Boston-based interactive marketing services firm. We
3 have a fair amount of experience in interactive
4 marketing, specifically with direct consumer promotion
5 of regulated medical products. So there's a lot of
6 both knowledge and a lot of interest in the topic on
7 our part.

8 What I'm going to be doing in the next 12
9 minutes is sharing some of our perspectives on the
10 role of the interactive channel in direct consumer
11 marketing and perhaps enlightening the panel on some
12 of the best practices we have seen, both with clients
13 and on clients, and some thoughts on how the FDA might
14 move to promote it, too, which is something we would
15 strongly advocate.

16 Before I begin, I wanted to just thank the
17 panel for the privilege of being here today. It is an
18 honor to be part of the process. And we certainly
19 appreciate the opportunity to join you today.

20 Just stepping back and reflecting a little
21 bit on what we heard this morning, one of the things
22 that struck me personally was just the fact someone
23 obviously I guess in hindsight said the interactive
24 channel is somewhat of an oversight or an afterthought
25 in the grand scheme of direct consumer marketing.

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1 It's completely understandable, though it
2 does somewhat pain me as an interactive marketer to
3 hear that. But I understand completely that the
4 traditional channels of television, print, radio are,
5 just by their nature, a lot higher profile, where a
6 lot more money is being spent. And, frankly, it's
7 where a lot more of the controversy is being
8 generated.

9 That being said, in the spirit of sharing
10 some of our experiences in using the interactive
11 channel, what I thought I might do today is share some
12 of our beliefs as an agency -- Obviously these are our
13 beliefs, not the beliefs of our clients, I'll just
14 stress that -- about what we have seen as best
15 practices and some thoughts that the FDA might take
16 away from today.

17 The first and somewhat obvious, although
18 sometimes it forgets forgotten in the discussions, is
19 that for millions and millions of Americans, the
20 interactive channel is an indispensable part of how
21 they manage their health. It certainly doesn't
22 pretend to take the role of the interaction with the
23 physician, but as a first line of defense, it's where
24 by many counts, up to 100 million Americans are
25 turning for health information today, more so than a

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1 lot of the other channels that seem to attract
2 attention.

3 What we would also postulate is that used
4 responsibly -- and I would stress that because the
5 interactive channel is only a tool. It can be
6 misused. It can be used improperly. But when it's
7 used responsibly, it can really play a valuable role
8 as a public health education channel as well as making
9 good sense for the pharmaceutical marketers. That's
10 important. They're not charities, obviously. It
11 needs to work both in the public's interest and in the
12 interest of the pharmaceutical marketers.

13 What I would also point out is that
14 relative to some of the other communication channels
15 that are being used, I would point out that the
16 interactive channel has some pretty unique advantages
17 that might cast this in a somewhat different light
18 than some of the conventional channels that have been
19 used, specifically as a relationship-building vehicle
20 as well as an outreach and education channel.

21 And then, lastly, the FDA in my opinion
22 can certainly play a really instrumental role here in
23 driving its usage and driving its adoption going
24 forward.

25 So let's step back and just share some of

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1 the data about the interactive channel's usage as a
2 health education vehicle. What we know from research
3 that was released about two weeks ago by the Pew
4 Internet Project is that 68 percent of U.S. adults now
5 have online access. So it's no longer just a niche
6 communication vehicle. That's approaching the level
7 of the adoption of cable and some of the other
8 so-called mass channels.

9 What we also know is that in terms of its
10 usage by different demographic segments, there is
11 widespread usage. Specifically, 79 percent of U.S.
12 adults have researched health information in the past
13 year. Eighty-two percent of women have researched
14 health information, which is slightly higher than men.

15 Again, given the propensity of women to manage health
16 information for their families, that is not
17 surprising.

18 What is somewhat in cycle is that usage
19 tends to increase with age, which, again, correlates
20 in our experience to a greater preponderance of health
21 management issues, the onset of different conditions
22 that warrant adults going online and researching
23 different medical conditions.

24 What we also see is that usage tends to
25 increase with experience online, which forebodes well

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1 for the use of the channel going forward as people
2 develop more experience with using the internet. And
3 as broadband adoption increases, we'll certainly see
4 more and more adults going online to manage their
5 health.

6 In terms of what they are doing online,
7 there is a lot of condition information being
8 researched, a lot of drug information being
9 researched. What we would call it here beyond the
10 obvious is that condition information is at the top of
11 this list.

12 There are a lot of sensitive topics or
13 complex topics being researched, again something that
14 doesn't necessarily lend itself to the more
15 traditional channels. And I would call it things like
16 sexual health information or mental health issues,
17 where for many people there is not a comfortable place
18 to find that information, but in the privacy of their
19 home, they can certainly access a Web site and find
20 high-quality information.

21 In terms of the beneficial impact that
22 consumers are playing back when asked, -- this was
23 some research done by the Boston Consulting Group two
24 years ago -- a couple of key things jumped out in
25 terms of the benefits that people were seeing as they

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1 used the online channel to manage their health.

2 Ninety percent of them claimed that it
3 enhanced their understanding of a health problem,
4 which is quite significant. Eighty percent commented
5 it affected how they managed their overall health.

6 Seventy-five percent changed how they
7 communicated with their doctor. They didn't specify
8 if that was for the positive or for the negative, but
9 I've got to assume in almost every case, they were
10 going with more information and having a more informed
11 dialogue that led hopefully to a better diagnosis and
12 more effective treatment.

13 And then, importantly, 65 percent of these
14 respondents commented that it improved their
15 compliance with drug treatments. Again, that's a
16 particular strength of the interactive channel and how
17 it's being used today by pharmaceutical marketers. In
18 many cases, it's a significant compliance tool via the
19 use of e-mail and desktop applications.

20 What I want to do now is just share some
21 of what I would call best practice success stories.
22 These are not work done by our agency. So there's
23 hopefully some objectivity that I would call these
24 best practices.

25 The first is a promotion that is actually

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1 live right now done by GlaxoSmithKline in partnership
2 with the American Lung Association using a number of
3 vehicles, including TV and online promotion. They
4 hope to reach asthmatics who are not adequately
5 controlling their condition, which is a serious,
6 serious health issue. They may be using inappropriate
7 devices or not treating their condition at all.

8 What it asked people to do was take the
9 asthma control test and measure in a pretty
10 quantitative fashion with five questions how well they
11 were controlling their asthma. This was all done
12 online.

13 Then the call to action was after you have
14 taken the test, if you are scoring in the red zone, go
15 talk to your doctor about how you should be
16 controlling your asthma more effectively. So I think
17 that is a pretty effective educational example of how
18 the online channel can really reach out and drive
19 people into their doctor's offices for an informed
20 conversation.

21 Another example by Pfizer is there was a
22 Pfizer for Living Web site addressing the need
23 expressed by a lot of physicians and by a lot of
24 consumers for objective, credible information and
25 engaging tools that they can use to manage their

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1 health and improve their knowledge of conditions.

2 Pfizer developed this Web site unbranded
3 to their drugs, obviously, to provide a lot of tools
4 and a lot of resources beyond just straight content, I
5 would stress. There are encyclopedias. There are
6 quizzes, self-assessment surveys, and a lot of really
7 rich tools that will help people learn about a
8 condition and then ultimately, as the Web site
9 suggests, go speak with their health care professional
10 with an informed point of view.

11 Then the last one is a project done by
12 Roche. Obviously Tamiflu doesn't really need extra
13 promotional support at this point. But they were
14 addressing the unique effects of this drug, which is
15 that it's most effective when taken immediately after
16 exposure to the influenza virus.

17 So you have a somewhat unique compliance
18 problem right there because if the flu virus is
19 sweeping into your geography, traditionally there has
20 been a real challenge in educating people that they
21 need to go to their doctor and discuss whether or not
22 they need to get a flu shot.

23 This desktop application is downloaded
24 onto your computer. So it's not a traditional Web
25 site. You enter your Zip Code. And then on a

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1 periodic basis, it downloads data from a flu-tracking
2 source of data. And it will alert you if the flu
3 virus is within two days of your geography and
4 obviously suggest that you go seek professional help
5 because you are at risk of being exposed.

6 So these are some unique examples of how
7 the channel is being used to drive people into their
8 doctors' offices, to drive compliance, to drive just
9 general education, all things that traditionally
10 offline channels have struggled with.

11 I wanted to, lastly, just call out some of
12 the unique qualities of the online channel. Obviously
13 the most interesting one is the fact that every
14 experience online is a voluntary user-initiated one.

15 Traditionally the complaint, if you will,
16 about some of the mass channels is that they are
17 intrusive, in many cases providing irrelevant
18 information at the wrong time, on the wrong condition,
19 and in a way that you're not comfortable seeing it.
20 This is especially irritating in the case of sensitive
21 drugs or sensitive conditions. When you are online,
22 you are choosing to go to a Web site or you are
23 choosing to use a search engine. So there is a lot
24 more user control.

25 I would also point out the fact that it's

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1 a lot more balanced. Again, that was a concern that
2 was discussed this morning. I think the online
3 channel is somewhat unique in that it gives users the
4 opportunity, both to view the safety information, the
5 fair balance information, potentially to print it but
6 certainly to digest it at their leisure, as well as to
7 use that as the jumping off point for additional
8 research online, perhaps at the FDA Web site, perhaps
9 at the National Institutes of Health, but it's a great
10 jumping off point in a way that a lot of the other
11 channels don't provide.

12 The fact that it is dynamic and engaging
13 is also something unique. We know that consumers
14 learn most effectively when they're given an
15 opportunity to actually engage with content via quiz,
16 via survey, via some type of tool. The online channel
17 is very effective at doing that.

18 And, lastly, there is this idea of a
19 modest investment, which, again, is not necessarily a
20 concern of the FDA but certainly goes to the issue of
21 the amount of money that is being spent on traditional
22 mass advertising. For a much more modest investment,
23 you are able to reach a similar sized audience and
24 publicly provide a lot richer experience in terms of
25 the education that you are disseminating.

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1 So how can the FDA help? This is what I
2 wanted to leave you with as just some final thoughts.

3 For those of you who are not familiar and comfortable
4 with the online channel and using it to manage your
5 health, give it a try.

6 You know, go to WEBMD. Go to Yahoo!
7 Health. Go to some of the other high-quality sites
8 that are out there. See what is being done by some of
9 the pharmaceutical marketers. Do some searches on
10 Google or Yahoo! using condition terms or drug terms
11 and be exposed to some of the best practices that are
12 out there.

13 Compare and contrast that while you're
14 doing it with some of the mass channels. I think
15 you'll see that the interactive channel is very
16 unique. And certainly as you contemplate potential
17 regulation of direct consumer promotion, I would
18 encourage you to think through whether or not the
19 rules that apply to other channels are most suitable
20 here.

21 Lastly, encourage its responsible use,
22 again responsible use. I think, as we have seen with
23 some of these examples today, when it is used in an
24 education and compliance mode, it can be very, very
25 effective. And that is certainly something that I

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1 would personally like to see expanded going forward.

2 And then, lastly, support innovative
3 applications, like the desktop application that we saw
4 from Roche. That is very unconventional. And I
5 applaud them for doing something so innovative and
6 distinctive to solve a compliance problem in a way
7 that I think is going to be quite effective.

8 That is the end of my comments. I again
9 thank everyone for giving us the opportunity to
10 participate in the process and would certainly field
11 any questions.

12 MR. ABRAMS: Thank you.

13 Dr. Gottlieb?

14 DR. GOTTLIEB: Thanks for that. I
15 appreciate the comments, although I might quibble with
16 your comment that it's a voluntary experience here,
17 either that or I want to get a copy of your pop-up
18 blocker.

19 I wanted to just ask you quickly. You
20 know, I think most people, their interaction with the
21 internet is to go to the search engines and type in
22 some search terms. Is there any evidence that the
23 search engines are steering people towards more
24 credible outlets of information or that consumers
25 online are paying attention to things like accrediting

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1 bodies that accredit good information versus stuff
2 that might not be as reliable?

3 MR. GARDNER: Yes. That's a great
4 question. Our experience is that if a consumer
5 actually has a prescription in hand, their usual
6 reaction is to go to a search engine and usually use
7 the drug name to get to the drug site or directly
8 enter it.

9 And we are seeing evidence of people
10 becoming more savvy in their searching, which I think
11 was part of your question as well, using multiple
12 terms to refine their searching. So they're getting
13 more and more relevant results.

14 Certainly Google and some of the other
15 higher-quality search engines are consciously trying
16 to push the great quality content to the top of that,
17 like the National Institutes of Health or the CDC or
18 FDA Web site, which are known to be very, very
19 credible.

20 DR. GOTTLIEB: That is actually built into
21 their algorithms how they rank stuff?

22 MR. GARDNER: Yes. Although their
23 algorithms are proprietary, there is evidence that
24 they tend to have a bias towards .gov sites or .edu
25 sites, which tend to be objective and not commercial.

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1 That's correct.

2 MR. ABRAMS: Thank you, Mr. Gardner.

3 Kristin, do you have a question?

4 MS. DAVIS: Yes. Thank you for your
5 presentation. I just had a quick question.

6 You were talking about some of the
7 benefits of this medium versus some of the others. I
8 was wondering if you have any information that might
9 be relevant to the agency's objectives of making sure
10 that risk and benefit are both presented and how this
11 medium does as far as what people take away from it.
12 Have you researched that at all?

13 MR. GARDNER: We don't have specific
14 researchers in the agency. Certainly in working with
15 pharmaceutical companies we follow the FDA's
16 guidelines on fair balance, disclosure of safety and
17 prescribing information scrupulously.

18 MS. DAVIS: Okay. Thank you.

19 MR. ABRAMS: Okay. Thank you, Mr.
20 Gardner.

21 Our next speaker is Gail Javitt from the
22 Genetics and Public Policy Center from Johns Hopkins
23 University.

24 MS. JAVITT: Good afternoon. My name is
25 Gail Javitt. And I am a policy analyst with the

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1 Genetics and Public Policy Center at Johns Hopkins
2 University.

3 The center was founded in 2002 with the
4 mission to create the environment and tools needed by
5 key decision-makers in both the private and public
6 sectors to carefully consider and respond to the
7 challenges and opportunities that arise from
8 scientific advances in genetics. I appreciate the
9 opportunity to speak to you today and to raise a
10 serious problem related to direct-to-consumer
11 advertising of genetic tests.

12 Genetic testing is becoming an
13 increasingly important part of health care. Genetic
14 tests can help diagnose genetic conditions and guide
15 treatment decisions, help predict risk of future
16 disease, inform reproductive decision-making, and
17 assist in medication choices for a variety of
18 diseases, including several types of cancer.

19 While the number of tests available is
20 exploding, genetic tests are subject to far less
21 scrutiny than other medical products. And FDA
22 oversight, in particular, has been quite limited.

23 In recent months, several news reports
24 have discussed a genetic test called the Baby Gender
25 Mentor. The test, which is advertised and sold over

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1 the internet, claims to diagnose the sex of a fetus as
2 early as five weeks of pregnancy, with more than 99.9
3 percent accuracy.

4 According to news reports, the test has
5 been sold to thousands of women, many of whom have
6 received false reports. In other words, the test
7 predicted a baby of one sex, a baby of the other sex
8 was born.

9 The Baby Gender Mentor is sold to
10 consumers as a kit over the internet. It claims to
11 diagnose fetal sex, which while merely a matter of
12 curiosity for some expectant parents also can
13 correlate with sex-linked genetic disease.

14 The Baby Gender Mentor is, therefore, a
15 diagnostic device. But to date, FDA has taken no
16 action regarding the claims being made for this
17 product or regarding the test itself.

18 This one genetic test is just the tip of
19 the iceberg. The past few years have seen a
20 proliferation of genetic tests advertised and sold
21 directly to consumers. These tests run the gamut from
22 the mainstream to the truly alarming.

23 One Web site advertised and sells a test
24 that it claims can diagnose genetic predisposition to
25 addiction and other behavior disorders, such as ADHD.

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1 The Web site also advertises and sells a
2 variety of so-called nutraceuticals to treat
3 conditions such as alcoholism, cocaine addiction,
4 tobacco addiction, ADHD, and PMS. Again, FDA has
5 taken no action to date, to our knowledge, against
6 these claims or these products.

7 Another Web site advertises genetic
8 testing for the purpose of predicting and avoiding
9 adverse reactions to drugs, to prescription drugs.
10 The company claims such testing can improve the safety
11 and effectiveness of more than one-third of the most
12 commonly prescribed drugs, such as antidepressants,
13 heart medicines, and painkillers.

14 The test claims to predict based on an
15 individual's genetic makeup how he or she will
16 metabolize a particular drug and, thus, whether and in
17 what dose the drug will be harmful or helpful.

18 In other words, the Web site claims the
19 results of these tests can improve the responses of an
20 FDA-approved drug or, conversely, tell that the drug
21 is contraindicated.

22 Yet, to our knowledge, FDA has not
23 reviewed these claims or the tests themselves. While
24 FDA has approved one kit for drug reaction testing,
25 laboratories are not required to use that kit. So

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1 that there is a lack of regulatory parity for this
2 kind of increasingly prevalent genetic testing.

3 These are only a few examples of tests
4 that are currently available DTC, predominantly over
5 the internet. The unregulated advertising of genetic
6 tests for a myriad of conditions, some of which are
7 highly dubious, leaves consumers vulnerable.

8 According to a 2004 survey conducted by
9 the Genetics and Public Policy Center, the public
10 widely believes that the government already regulates
11 genetic tests and, moreover, widely supports such
12 regulation.

13 However, contrary to this widespread
14 belief, little has been done to ensure that the claims
15 made about genetic tests are truthful or that the
16 tests are safe and accurate. Of the more than 800
17 genetic tests currently clinically available, FDA has
18 approved only about a dozen.

19 While there may be independent
20 jurisdictional limits to the agency's activities
21 regarding some genetic tests, FDA can and should do
22 far more. Moreover, FDA can and should collaborate
23 with its sister agencies within independent
24 jurisdictions, such as the FTC and CMS, to create a
25 seamless web of safety to protect consumers from the

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1 harmful consequences of bad information and bad tests.

2 Public health and the public expectations demand such
3 protection from the federal government.

4 In July 2005, the Genetics and Public
5 Policy Center launched a genetic testing quality
6 initiative. The goals of this initiative are to
7 foster a framework of oversight in which the validity
8 of tests is accorded by the science before they are
9 offered to consumers and which uses of outcomes of
10 tests can be evaluated over time, in which
11 laboratories demonstrate their ability to get the
12 right answer reliably, in which health care providers
13 are educated about tests and able to provide them to
14 patients with adequate context and counseling, and in
15 which patients have confidence in the claims made
16 about the tests and about the tests themselves.

17 I realize that much of this hearing is
18 devoted to DTC advertising of drugs. Nevertheless,
19 FDA has a critical role to play here as well to ensure
20 that accurate and sufficient information is available
21 about genetic tests, particularly when these tests
22 inform drug prescribing.

23 Over the coming months, we hope to work
24 with the agency to discuss ways that FDA can ensure
25 that the information directed to consumers regarding

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1 genetic tests is truthful and adequate and that the
2 tests being advertised are accurate and reliable.

3 Thanks very much for your time.

4 MR. ABRAMS: Ms. Wolf?

5 MS. WOLF: I just want to clarify a couple
6 of things. FDA's jurisdiction in terms of these
7 genetic tests is not entirely straightforward or
8 clear. And I think that we are currently working with
9 the department in terms of looking at how we might
10 more or better regulate the kinds of claims that are
11 being made.

12 Unless the reagent is part of the kit,
13 there is a disconnect between FDA's regulation of the
14 reagent and the lab's use of the agent to do testing.

15 And it's important. You know, it would be useful to
16 have input on how we would be able to work with the
17 labs. We work with the centers for Medicare services
18 in terms of their regulation.

19 MR. ABRAMS: We need to just clarify the
20 question for the speaker. This background is useful,
21 but we're limited as far as time. So if you have a
22 clarifying question, that would be great.

23 MS. WOLF: I just sort of would like to
24 know if you have any specific ideas on the kinds of
25 things you would like to see FDA be able to do given

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1 the framework.

2 MS. JAVITT: Sure. We have to some extent
3 more than probably we can discuss right now. But I do
4 want to respond to the jurisdictional point.
5 Obviously the agency has a governing statute. And
6 we're sensitive to that.

7 But at the same time, in various points in
8 history, the agency has taken a position it can
9 regulate all of these tests. And as far as I know,
10 the last public statement about FDA's jurisdiction is
11 that it can. In recent years, there may have been
12 differences of opinion about that, but I think it's
13 not entirely clear.

14 And the fact that the agency has been
15 unclear about what it is willing and what it feels it
16 can do is somewhat frustrating and leaves advocates
17 for the quality of genetic testing at a little bit of
18 a loss into how to proceed. So clear signals from the
19 agency in either direction would at a minimum be
20 helpful.

21 And to the extent that the agency has more
22 jurisdiction than it is currently exercising, which I
23 think is a very defensible position, we believe more
24 could be done around the areas of clinical validity,
25 at a minimum, to prevent the obviously false claims

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1 that are allowed to proliferate.

2 MR. ABRAMS: Does the panel have any more
3 clarifying questions?

4 (No response.)

5 MS. JAVITT: Thank you.

6 MR. ABRAMS: Okay. Ms. Javitt, thank you
7 very much for your presentation.

8 Our next speaker is William Person from 50
9 Plus WEBHealth.

10 MR. PERSON: Thank you very much. Good
11 afternoon. My name is Bill Person. I'm President of
12 the 50 Plus WEBHealth.

13 A little bit of background on my company
14 and myself. We spent three years designing the
15 medical information Web site. I guess we're the third
16 group here talking about the internet. Specifically
17 for adults over 50, we have conducted marketing
18 research on adult health issues, including what
19 information adults are looking for and how to
20 communicate health issues to adults.

21 The site basically provides the best Web
22 site links by disease and health issues. We cover 23
23 diseases and 17 health issues, including prescription
24 drugs, flu vaccines, links to the VA, Social Security,
25 and the warning sites from the FDA.

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1 For those of you who haven't visited the
2 site, just briefly we have health issues on the left
3 and then topics on the right that you can basically go
4 into and get information on.

5 My presentation is going to focus on
6 adults over 50, which comprised 46 percent of the
7 health care market. Health care and its costs play a
8 very intimate role in the lives of this market
9 segment. The presentation will focus on prescription
10 drugs only. The presentation will also focus on the
11 internet as a communication vehicle for adults over
12 50.

13 The first recommendation, any
14 communication agreement that is decided on must have a
15 distinct market segment strategy to consider the
16 message is delivered, received, and understood. From
17 the prospectus that came out on this conference, they
18 discussed age, language, and others. I would like to
19 just highlight under the age area vision, reading,
20 memory retention, are all different for the age
21 groups.

22 So if you put together a policy that
23 you're communicating to the public, it must understand
24 these market differentiate and how people will receive
25 it differently. I know recent announcements indicate

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1 the pharmaceutical industry recognizes this need for
2 market segmentation.

3 Main overall recommendation is the truth.

4 Honesty is essential. One of the topics that has
5 been continually mentioned here today is about
6 information cannot be misleading. Display risks along
7 with benefits.

8 The people I have worked with, consumers I
9 have worked with, I believe can manage the risks.
10 They are well-aware with any health care solution
11 there are risks, and they are aware of it. The people
12 I work with, adults over 50 with Medicaid and
13 significant health care issues, the benefits -- many
14 of the patients are living -- significantly outweigh
15 the risks. So the benefit-risk ratio is extremely
16 high for the people I work with.

17 One thing the group would like to see is
18 just the history of success for particular health care
19 solutions. The FDA and the health care industry must
20 continually build credibility. That has to be an
21 underlying criterion in everything that goes forward.

22 And, lastly, the public needs to be
23 educated in their responsibility to be aware of and
24 understand the benefits of drug risks. You are going
25 to see a little later on how the public is becoming

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1 more and more involved in managing their health care.

2 They need to be more and more aware of the risks.

3 Communication requirements should have
4 effective monitoring system to assure it's effective.

5 We're talking about how we communicate to adults. We
6 need to make sure that we're monitoring it, ensure
7 that it's working, and if it's not working, change it.

8 And I'll give you some recommendations on this at the
9 end.

10 Consumer-directed communication methods
11 are historically magazines, TVs, and almost up until
12 the late '90s the doctor-patient relationship was the
13 key area.

14 I just pulled this out as an example of a
15 back page of a magazine ad where it basically puts in
16 the health risk. This one happens to be on Lamisil,
17 actually, very easy to read for an adult over 50,
18 vision problems. It has the risks on the right side,
19 the side effects on the right side, so very easy for
20 somebody to look at and understand. Many of them,
21 unfortunately, are a little more challenging. The
22 table on the top right does a very job of listing at
23 first the facts but very difficult and challenging for
24 somebody to read.

25 Adults are seeking health information on

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1 their own. And we'll get into some statistics on
2 that. One of the reasons is they're continually
3 reading in a variety of publications that 200,000
4 patients, a little under that, are dying each year in
5 hospitals.

6 There was a quote in Time magazine about
7 two years ago. When you try to explain how you're
8 feeling, chances are your doctor will interrupt you 23
9 seconds in the recital. And that is out of the
10 Journal of the American Medical Association.

11 I continually in my work see topics like
12 the bottom two there, where studies show Americans get
13 only have the recommended medical care. This is why
14 the adults who have the ability to go to the internet
15 are going to the internet and looking for health care
16 information.

17 So as far as the status of adults with
18 communication and health care issues, the public will
19 not accept the policy of health care information only
20 from the public. The public will not accept the
21 policy of limited or rationed information on products,
22 including new products.

23 The key reason now is the public has the
24 option of finding the information elsewhere on the
25 internet. They no longer have to rely on going to the

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1 doctor's office and finding health care information.
2 They can dial up, do a search, go to a Web site, and
3 get information.

4 The first speaker talked a lot about the
5 Pew reports. So I'll go through this very, very
6 briefly. I know we're under some time constraints
7 here.

8 Basically, the Pew report came out and
9 lists half the adults, Americans, are searching online
10 for health information with prescription drugs near
11 the top of the list. Wall Street Journal just early
12 this year talked about internet chapters searching
13 online, exercise fitness, prescription drugs. People
14 are going to the internet and looking for information,
15 and they're finding it.

16 Again, some Pew information, again
17 discussed earlier, 93 Americans using the internet for
18 health topics, media audit report. Internet usage
19 growth is driven by the older age groups. You heard
20 about that, actually, from the first speaker this
21 afternoon.

22 Some conclusions from the Pew report.
23 Disabled or chronically ill users are avid online
24 communicators. So we can talk about some statistics
25 about adults. The people that have health care

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1 problems, who we are really talking about today, are
2 avid users.

3 Fifty-seven percent are looking for
4 others. So it's just not somebody going and looking
5 for their issue. They're doing it for a friend,
6 neighbor, or whatever. Chronically stable and dually
7 diagnosed are more frequent users.

8 I underline this last one because I think
9 it is very key to my whole presentation.
10 Seventy-three percent of health seekers say the
11 internet has improved the health and medical
12 information services they receive. The public is
13 viewing this avenue of information as successful.

14 You heard from Pfizer this morning about
15 the fact that there are a number of people out there
16 that aren't diagnosed. They have health issues. More
17 importantly, there are solutions out there, and they
18 are not being diagnosed.

19 These are just some statistics from Rand
20 in the Wall Street Journal about a year or so ago.
21 Another article in the Wall Street Journal talked
22 about doctor awareness being low.

23 Diagnosis advertising on media, TV,
24 magazines is very prevalent. And hopefully you are
25 all aware of that. I consider it a distinct segment

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1 of direct and consumer advertising, but I think it's
2 very critical.

3 A massive number of health issues go
4 undiagnosed. And this fact raises overall health care
5 to the factor of quality of life. And, frankly, for
6 Pfizer and others, it's an opportunity for solution
7 providers.

8 There are too many people out there today
9 where we have solutions that aren't aware of it. And
10 currently there are a number of professional online
11 diagnostic options. You heard the first speaker talk
12 about some online options, people going in, doing
13 little checklists, and then taking it into their
14 doctor's office.

15 And, by the way, I think doctors,
16 physicians are key to this health care program used on
17 the internet. In everything I'm talking about today,
18 the doctor still plays a very vital role.

19 Just a comment here on the new drug
20 promotion, the consumer policy. And I have read where
21 drug companies and the FDA are discussing limiting the
22 advertising on new products until doctors are familiar
23 with it. I think it's a great policy. The doctor
24 absolutely needs to be a key element.

25 With the availability of health care

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1 information via the internet, it's going to be days or
2 weeks before patients walk in to the doctor and say,
3 "Doctor, what about this? Is this the right thing for
4 me?"

5 The point I'm making right here is that,
6 you know, whether FDA and the drug companies agree to
7 delay things, the consumer is going to find out about
8 it and be asking for it.

9 Second key comment there. If a solution
10 to a health issue has passed all tests by the health
11 care provider, the pharmaceutical company, and the
12 FDA, we have a right to make sure that the people who
13 can benefit from it know about it right away.

14 Some brief statistics on internet use.
15 And I need to move along here. You look at the center
16 column there. You can look at internet use by people
17 50 to 60, 63 percent; 65 and up, 30 percent. Five
18 years, these are going to be in the 90s. So if you
19 look at the growth rate of people using the internet,
20 it's growing significantly.

21 Again, moving quickly, Bell South, SBC,
22 Verizon are putting in internet service around the
23 country. I guess the City of Philadelphia is talking
24 about going across the board. FCC has some statistics
25 in Business Week about homes of broadband.

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1 Internet content options. There's
2 unlimited data access, global access. There are over
3 a billion people now with internet access.

4 Sharing options. You can take a report
5 off the internet and send it to your sister, brother,
6 wherever. Print out options. You can go in and print
7 out something and bring it in to your doctor's office.

8 The number of health care information
9 resources -- and this is why the internet is so
10 valuable and has a lot of information -- Reuters
11 covers more health care conferences, press releases,
12 and journals. AARP for adults over 50, great health
13 care Web sites, numerous government-backed Web sites.

14 The Wall Street Journal has health issues
15 because they're basically financial news. Clinical
16 trials are now online. The New England Journal of
17 Medicine basically paid to get their service, but
18 after six months, everything is free.

19 These are just a couple of articles from
20 the Wall Street Journal. What they do, they've got a
21 couple of great authors here. They take very complex
22 medical issues and put them in a form that the
23 consumer can understand.

24 Internet search options. It's not all
25 things to all people. You go in and do a Google or

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1 Yahoo! search. You're going to get more information
2 than what you can deal with.

3 A comment from Woman's Day a year or so
4 ago, "What makes the internet useful for health care
5 information, you can find everything. It also makes
6 it maddening how to sort through it."

7 Communications from consumers. Presently
8 there are limited requests for feedback until you come
9 back to the doctor. The internet offers a very
10 efficient method to check on a patient's progress.
11 You can identify health reaction problems sooner. I'm
12 sure the patient is following up on recommendations.

13 Also communications from consumers, the
14 FDA's adverse reaction program should even be more
15 effective by broader promotion of its availability and
16 use via the internet. Last year 422,500 responses
17 came into that service. And I would recommend the FDA
18 look at expanding that.

19 Conclusion? The public needs to play an
20 active role in our health care. The public is already
21 demanding and pursuing an active role in our health
22 care. Consumers are aware of the trade-offs with
23 health care solutions. Doctors and others in the
24 medical system need to continue to have a strong role.

25 I believe the 73 percent rating of those

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1 who say they are benefiting from the internet for
2 health reasons will grow as information becomes easier
3 to access. The internet changes the health care
4 communication rules.

5 Recommendation? The safety of the
6 consumer must be maintained. FDA policy should take
7 into account consumer market segmentation, continue to
8 allow advertising while requiring effective
9 notification of risk and historical success rates
10 along with benefits, and share truthfulness and
11 integrity of all communications monitored, key word
12 under there.

13 And I think that the FDA can do that, the
14 effectiveness of cautionary advertising, educate the
15 consumer on their need to manage their risks, and
16 allow direct-to-consumer advertising promptly after
17 new product is approved.

18 Thank you.

19 MR. ABRAMS: Dr. Aikin?

20 DR. AIKIN: You propose a monitoring
21 system for the effectiveness of cautionary
22 advertising. What sort of system do you propose? And
23 what sort of variables would you measure in such a
24 system?

25 MR. PERSON: What you need to do is work

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1 with people who are taking certain drugs, make sure
2 they understand the health risks of the different
3 measures so they know what they're doing, really
4 measure it by the people who are using it to measure
5 whether they got the word or wherever, just what
6 they're trying to do.

7 DR. AIKIN: So you propose to talk to
8 people who are actually taking the drug after they
9 have been exposed to the advertising?

10 MR. PERSON: Yes. People who are taking
11 the drug, were they aware of the risks when they were
12 taking it? Did they go into it with their eyes open?

13 DR. AIKIN: Okay.

14 MR. ABRAMS: Dr. Ostrove?

15 DR. OSTROVE: Just a quick clarification.
16 I'm not sure if I understand your position with
17 regard to limiting advertising on new products until
18 doctors are familiarized because at one point, it
19 seems as if you felt that was a good idea. But you
20 also believe that direct-to-consumer advertising
21 should be allowed promptly after a new product is
22 approved.

23 MR. PERSON: Basically the bottom line is
24 you've got days or weeks before that doctor needs to
25 know. You've got days or weeks to educate the doctor

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1 because people are going to come in and be asking him.

2 Whether or not the pharmaceutical company
3 or other solution provider educates him, he's going to
4 hear about it. A consumer is going to hear about it
5 from Reuters, Wall Street Journal, or whatever, about
6 a health care solution. And they're going to be in
7 asking the doctor about it.

8 The industry does not have months or a
9 year to educate that doctor on a new product that's
10 out on the marketplace. The consumer will begin
11 talking to him right away. He has other sources to
12 find out about that new product.

13 DR. AIKIN: So your sense is that there
14 should not be any kind of a delay in educating the
15 health care professionals right from the get-go.

16 MR. PERSON: You are not going to be able
17 to do that. This group in this room and the health
18 care providers do not have the liberty to go do that.

19 People in the Wall Street Journal will
20 pick up that information on a new product at work with
21 results of a clinical trial. And they will make that
22 available to the public the next day. And literally
23 they do. And the day after that, somebody will be
24 walking into a doctor's office.

25 The reality is that what we're seeing with

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1 the internet is that health care information or people
2 who get that information, there's another vehicle,
3 major vehicle, providing that to the consumer and the
4 consumers looking at it, looking for it.

5 MR. ABRAMS: Dr. Temple?

6 DR. TEMPLE: That wasn't quite the
7 question. We understand that you believe that people
8 will become aware of novel drugs, probably related to
9 how important they are, and that doctors need to be
10 able to deal with that. Nobody disputes that.

11 The industry has said we are going to wait
12 before we do DTC promotion, which is another source of
13 stimulating attention, until we have had a chance to
14 notify doctors. That is what Nancy was asking about.

15 You seemed to say that that seemed like a
16 good idea before you sort of launched the DTC
17 promotion, but then it wasn't clear at the end of your
18 talk whether you actually did think it was a good
19 idea.

20 It isn't about whether you inform doctors
21 because they do need to know.

22 MR. PERSON: But they don't have a lot of
23 time to do it.

24 DR. TEMPLE: Because the dam is going to
25 break and there will be a lot of people. Okay?

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1 MR. ABRAMS: Okay. Mr. Person, thank you
2 very much for your presentation. Our next speaker is
3 Carole Rogin from the Hearing Industries Association.

4 MS. ROGIN: Good afternoon. I am Carole
5 Rogin. And I appreciate the opportunity on behalf of
6 the Hearing Industries Association to talk with you
7 and be part of this very important hearing today.

8 By way of introduction, the Hearing
9 Industries Association is the trade association of the
10 manufacturers of hearing aids, hearing aid components,
11 and hearing aid-related products, such as batteries.
12 And collectively our members manufacture most of the
13 hearing aids that are sold in the United States on an
14 annual basis.

15 We are here today to reinforce how very,
16 very important direct-to-consumer advertising is for
17 hearing health care in America. Our products, hearing
18 aids, have a neat regulatory profile.

19 Hearing aids, unlike many of the drugs --
20 and I guess I am the first person talking about
21 devices today, but many of the devices that FDA
22 regulates have a virtually unblemished safety record.

23 They are just not the type of product that poses a
24 health risk, especially in context of the full array
25 of drugs and devices that the agency regulates.

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1 Further -- and I think this is very
2 important to the advertising component -- hearing aids
3 are dispensed directly to the consumer without the
4 need for a prescription from a physician.

5 Despite the safety record of hearing aids,
6 the FDA for many years has paid special attention to
7 how hearing aids are promoted to the public while our
8 members respectfully disagree with the level of the
9 need for such scrutiny. We have always thought to
10 work cooperatively with the agency and to assure that
11 all of our customers receive accurate and balanced
12 information.

13 The importance of direct-to-consumer
14 advertising to our companies and to our users cannot
15 be overstated. Very, very importantly, consumers
16 self-initiate hearing examinations, either because
17 they have a concern themselves, not often enough, at
18 the recommendation of their primary care physician,
19 but mostly at the urging and begging of friends,
20 family, and significant others.

21 The goal of our advertising has been not
22 only to promote our product but, very importantly, to
23 educate consumers about the symptoms of hearing loss
24 and to help them understand that for the vast majority
25 of hearing losses, hearing aids are not only the

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1 treatment of choice but the sole treatment available
2 for hearing loss.

3 Additionally, hearing aid advertising
4 differentiates today's hearing aids from those less
5 technologically advanced instruments of just a few
6 years ago. Indeed, direct-to-consumer advertising of
7 hearing aids not only reminds consumers that there are
8 effective devices to assist with their hearing
9 problems, but it also enables them to learn about new
10 innovative products and features that can further
11 assist with their hearing problem.

12 Despite our efforts, the percentage of
13 people with hearing loss who use hearing aids remains
14 inexplicably low. Our surveys have been tracking
15 these numbers for decades. And they remain remarkably
16 and depressingly consistent.

17 Of the 32 and a half million Americans
18 with some degree of hearing loss that interferes with
19 their daily lives, only about 23 percent of them
20 currently use hearing aids.

21 This is unfortunate because today's
22 hearing aids are very effective. While there is an
23 array of advances in miniaturization, multiple
24 microphone technology, and other features, it is the
25 incorporation of digital technology that has

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1 revolutionized our products.

2 We all know someone, grandparent, parent,
3 aunt, or uncle, who bought hearing aids years ago and
4 did not use them because they did not provide the
5 assistance in an array of listening environments or
6 provided inconsistent performance. Today many of
7 these problems have been addressed. And, frankly,
8 satisfaction with contemporary hearing aids is at an
9 all-time high.

10 Hearing aid advertising also addresses
11 another key element. And that is stigma. While in
12 the United States we don't view glasses as any kind of
13 a stigmatizing device and we don't worry about having
14 vision loss, there is still stigma associated with
15 hearing loss or wearing a hearing aid, this despite
16 the fact that untreated hearing loss can be much more
17 visible, if you will, than a hearing aid when people
18 don't understand or respond inappropriately.

19 As Dr. William Slattery of the esteemed
20 House Ear Institute in Los Angeles noted in a Newsweek
21 cover story just a few months ago, "People with
22 hearing losses who don't use hearing aids" -- and I
23 quote Dr. Slattery -- "are afraid to look old but
24 don't mind looking dumb."

25 Direct-to-consumer hearing aid advertising

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1 addresses the problem in two important ways: first,
2 by making clear that hearing loss is nothing to be
3 ashamed of. It is often age-related but, in fact,
4 also a result of living in an age when we listen to
5 rock bands and hold hand-held hair dryers at ear level
6 every day of our lives.

7 Secondly, the advertising highlights
8 today's hearing aids, which differs substantially from
9 the memories that many people have. Today's hearing
10 aids are now so small and fit either entirely in the
11 user's ear or behind the ear that they are virtually
12 invisible.

13 The hearing aid industry has truly had a
14 silent revolution in technology. And we use our
15 advertising and promotion to encourage people with
16 hearing losses to seek help.

17 For people with hearing losses, hearing
18 aids can truly reconnect them with their lives. And,
19 very interestingly, in a study that was just completed
20 by the Better Hearing Institute, hearing aids can
21 increase individual income substantially.

22 Better Hearing Institute, BHI, conducted a
23 study which confirmed that there is a difference of
24 between one and 12 thousand dollars annually in the
25 income of individuals with hearing loss who use

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1 hearing aids and those who don't. This obviously
2 translates into billions of dollars of lose income.

3 I want to assure you that the hearing aid
4 industry takes advertising responsibility seriously.
5 More than a decade has passed since the FDA took
6 enforcement action against bad advertising. And to
7 augment the cooperative actions that we undertook with
8 the agency at that time, HIA developed its own
9 voluntary guidelines for hearing aid manufacturers,
10 for substantiation of performance claims, when the
11 agency in 2002 sunsetted its own guidance document.

12 Additionally, in order to assure that our
13 advertising standards are maintained, the following
14 year HIA developed a voluntary review system that is a
15 process that all of our members agree to employ if
16 advertising complaints or disputes arise.

17 In summary, HIA and, indeed, all of the
18 hearing aid industry believe that direct-to-consumer
19 hearing aid advertising serves a critically important
20 public health function by helping people understand
21 that hearing loss is nothing to be ashamed of; by
22 helping them understand that that loss can be
23 corrected with hearing aids; and realizing that, in
24 the words of Dr. James Fuhrman, who is President and
25 CEO of the National Council on the Aging, untreated

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1 hearing loss is not a benign condition.

2 HIA believes that the advertising by our
3 members is being done pretty uniformly in a
4 responsible way and that we have systems that assure
5 that this sense of responsibility is maintained.

6 We appreciate the opportunity to be here
7 today to reinforce how very important
8 direct-to-consumer advertising is for our industry and
9 the people that we serve. And I would be happy to
10 answer any questions.

11 Thank you.

12 MR. ABRAMS: Ms. Davis?

13 MS. DAVIS: Hi. Thank you for your
14 presentation.

15 It sounds like you haven't had a lot of or
16 you haven't had, really, an increase in treating
17 hearing loss, even though there is branded DTC
18 advertising going on. And I was just wondering if
19 there has been any testing within this market of
20 either other types of promotion, maybe unbranded
21 campaigns or of the use of specific mediums of
22 promotion to see if they would have an impact on
23 getting patients treated for this

24 MS. ROGIN: There has not been a great
25 deal of scientific research on the part of the

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1 companies that advertise. We have done a great deal
2 of work with the medical community looking at the
3 impact of messages to primary care physicians about
4 hearing health care. And through one initiative, for
5 instance, we were able to increase the percentage of
6 general physical exams that include any kind of a
7 hearing test, including just the question, "How is
8 your hearing?" from 16 to 21 percent of those physical
9 exams through advertising to physicians. But there
10 has not been a really scientific review of messages to
11 consumers.

12 MR. ABRAMS: Thank you, Ms. Rogin, for
13 your presentation.

14 MS. ROGIN: Thank you very much.

15 MR. ABRAMS: Our next speaker is Marlene
16 Tandy from Advanced Medical Technology Association.

17 MS. TANDY: Hi. Good afternoon. I'm
18 Marlene Tandy. I'm with the Law Department at Johnson
19 and Johnson. I'm here today as the co-chair of
20 AdvaMed's advertising and promotion working group.

21 AdvaMed, as people in the device industry
22 know, is the national trade association for medical
23 device manufacturers. We have been involved with
24 supporting direct-to-consumer advertising for a couple
25 of years now. We support the concept of

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1 direct-to-consumer advertising.

2 I think, as Dr. Woodcock noted this
3 morning, you know, devices, we're thrilled to be here
4 because we don't really have as much of a presence yet
5 in direct-to-consumer advertising of restricted
6 devices on broadcast media, particularly TV. More so
7 in print we have done, but less so on TV. But we're
8 getting there.

9 And so we started to be a player, I guess
10 is our message. And as a player, we see that we are
11 probably going to as an industry have increased use of
12 direct-to-consumer advertising. We watch what goes on
13 in Rx pharm because, you know, that's important to us
14 as a harbinger of future developments for the device
15 area. And we have also been cognizant of the benefits
16 that people have been talking about,
17 direct-to-consumer advertising.

18 I think it's clear, although we haven't
19 done any studies or research ourselves as the trade
20 association or, you know, our companies by and large,
21 we do have to recognize that there are benefits that
22 have been established by the available research.

23 And in the device area, it was thought of
24 for so long that devices, particularly like implanted
25 products, would be way too complicated to try to

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1 explain to consumers. And we're all consumers. But
2 it was thought that it would just be too difficult to
3 explain a hip implant or a stent or a pacemaker. How
4 do you explain that on TV? And so there was that
5 reticence to kind of get into the area compared to I
6 think the Rx pharm industry.

7 But now we have seen with all of the other
8 DTC ads that have gone on that, in reality, we can
9 make ads in print and in broadcast that do explain
10 surgical procedures, particular products, particular
11 implant, other particular products.

12 And we can inform patients, and we can
13 tell patients that there are options available. We
14 can make people aware. We can make the advocacy
15 groups that are here today and others out there aware
16 of devices so that people generally have an increased
17 opportunity to talk with their doctor in the 23
18 seconds that they get to explain to their doctor to
19 explain what is going on with them.

20 I think that that particular message is a
21 very important one that we have heard, and we have all
22 experienced it, that our time with our doctors has
23 been drastically reduced for a number of different
24 reasons.

25 And so if a patient, if we ourselves are

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1 more informed about something that might be available
2 to us that we have seen on TV or the internet or in
3 print and we write it down on a little list or we
4 print it out from the internet and we're ready to go
5 when we talk to our doctors and we just ask, "What
6 about this? What about that? Could this be right for
7 me? Is it time for me to have an implant?" possibly.

8 So to engage in that dialogue, that's where we see
9 the benefit of DTC.

10 Because I'm a lawyer, I have to talk about
11 like legal things. So those of you who are lawyers
12 will maybe wake up now, you know, at this point where
13 we are talking about legal authority.

14 Restricted devices. What is that? If you
15 are a device person, you know that FDA has authority
16 in the Federal Food, Drug, and Cosmetic Act to
17 restrict the sale or the distribution or the use of a
18 device product.

19 And they can do it basically in two ways.
20 FDA can do it by issuing a formal regulation, a final
21 rule, the proposed rule first, then the final rule to
22 restrict the device or FDA can do it as a condition of
23 approval under the pre-market approval regulations.

24 So for drug people, the PMA is like an NDA
25 and a PMA for a class III device, which it's a

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1 risk-based classification system. So the class III
2 device is the higher risk device category. FDA has
3 conditions of approval when you get that PMA approval.

4 And those conditions can be to restrict the sale of
5 the device or its use in a certain way.

6 What is really important for us today
7 about restricted devices is that is the category of
8 devices for which FDA has jurisdiction over their
9 device advertising. So I'm going to probably say
10 "restricted devices" a lot, but I wanted to explain it
11 since, you know, again, I think this is primarily an
12 Rx pharm audience.

13 Now, we have different statutory
14 requirements in one respect for DTC advertising of
15 restricted devices in the statute, in the Federal Food,
16 Drug, and Cosmetic Act.

17 We have the same requirement as everybody
18 else that the device ad has to not be false or
19 misleading. That is what the statute actually says.
20 What it really means is that it has got to be
21 accurate. You can't mislead by omission or by
22 commission. So you have got to provide accurate
23 information about your product.

24 But then we have this special -- the
25 second bullet here is special to restricted devices.

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1 We in devices -- if you're going to advertise a
2 restricted device, you have to include in that
3 advertising this brief statement. And it actually
4 says in the statute what is written here. So if you
5 look at that, that really looks like it's pretty
6 heavily weighted towards the risk side.

7 You know, we were talking about like fair
8 balance and, you know, benefit versus risk. Well,
9 we've got to talk about the relevant warnings,
10 precautions, side effects, and contraindications. We
11 have got to mention the device's intended use. Great.
12 And we can certainly mention the benefits.

13 But that is a whole lot of information on
14 the risk side that has to be presented in order for
15 this to be a compliant ad. And that is different.
16 Again, this is different. This is a device
17 requirement, not a drug requirement.

18 So because we have that requirement that
19 is in the statute and we already are heavily weighted
20 towards the risk side from that, I'm going to go back
21 up from that brief statement that we have to put in.
22 That's why we think that FDA doesn't need to have some
23 sort of separate regulation. There is no separate FDA
24 regulation right now just focused on DTC advertising
25 for restricted devices.

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1 And we would say that that is okay because
2 that brief statement requirement is pretty clear.
3 It's pretty simple, pretty concise, and we think we
4 have been meeting it. We think we have been mindful
5 of it in our limited experience with our broadcast
6 advertising and our print advertising.

7 We would be happy with a guidance document
8 because we could flesh out some more details. I think
9 it was February in '04 the device center issued a
10 draft guidance document on restricted device
11 advertising.

12 AdvaMED commented on it in August. And,
13 actually, one of the things we commented and we said
14 in our comments was that we would really like to have
15 a public hearing at which device people could present
16 what is relevant to us in terms of our DTC advertising
17 because I think this is one of the first times we have
18 been able to do that. So we thank FDA for listening
19 to us in those comments.

20 We are also going to resubmit those
21 comments to this docket because in those comments, we
22 had a lot of very specific detailed comments on what
23 we thought would be appropriate for a guidance
24 document for how to implement the brief statement,
25 various options to communicate the side effects and

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1 the warnings and the precautions. So I'm not going to
2 get into those specifics here right now because we
3 think we have done that in writing and we are going to
4 resubmit it.

5 We did want to go through the questions at
6 least a little bit that FDA specifically asked for
7 today's hearing. And, again, we're going to put in a
8 new submission to this docket that is going to answer
9 these questions in more depth. But we just wanted to
10 cover them briefly here.

11 As I said, we think that by following our
12 existing statutory requirement that is heavily
13 weighted towards the risk side, that we will be able
14 as a device industry to adequately communicate to
15 consumers the relevant risks of the device that is
16 being advertised.

17 We didn't answer question 2, by the way,
18 because that is an Rx pharm question. So we're not
19 involved with that. So I'm skipping to question 3.

20 In question 3, we have a little bit more
21 specific recommendations. We think that when we have
22 a device-specific ad for a restricted device, that, of
23 course, we have that relevant safety information, the
24 brief statement that has to go in there. And, again,
25 we think we have been doing, by and large, pretty good

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1 on getting that into our TV ads and our print ads.

2 Then sometimes we have in the device
3 industry ads that talk about a surgical procedure or a
4 type of surgery. And they don't necessarily mention a
5 device, but they may mention a device. And so we
6 think when we have that kind of ad, that it's
7 appropriate to present more general risk information
8 about the surgical procedure. And in our comments, we
9 actually submitted some ideas for how that statement
10 would look when you have a general surgical kind of
11 procedure ad.

12 We also think that all of these ads,
13 product-specific or surgical procedure ought to
14 recommend that the consumer speak with his or her
15 physician.

16 We do think that that guidance would be
17 useful. We think that FDA has had a number of helpful
18 guidances on how to speak to the lay people. There's
19 right write. There's device guidance for patient
20 labeling. So we think that the guidance should talk
21 about a variety of options and keep encouraging us to
22 develop that consumer-friendly language. I think I
23 just said that. Okay.

24 Last question. We really think that FDA
25 has adequate statutory authority, a whole range of

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1 enforcement options to deal with what the agency might
2 think is a violative ad. So we don't think that the
3 agency needs more authority. We think that on a case
4 by case basis, the agency can choose whatever existing
5 authority to use that they have.

6 Now, this pre-review of device ads, we
7 don't really do a whole lot of this, you know, maybe
8 compared to pharm. And it's an option. We don't
9 think it should be mandatory. Again, people spoke
10 about the First Amendment. But we think it should be
11 an option.

12 But if it's going to be a realistic
13 option, then CDRH is going to have to get some more
14 resources to do this because they just don't have
15 enough. And they don't really have a process for it.

16 Thank you. And I would be open to
17 answering questions.

18 MR. ABRAMS: Dr. Gottlieb?

19 DR. GOTTLIEB: Notwithstanding the fact
20 that there are different statute and different
21 jurisdictional requirements on the device side of the
22 house versus the drug side of the house, you seem to
23 be advocating a consistent approach across all of the
24 advertising, which I guess presupposes that you think
25 there are times in which we have been inconsistent.

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1 You don't need to answer that.

2 My question then becomes, what do you
3 think we should be doing? Is it additional guidances?

4 And are there specific things we should be issuing?
5 Are there operational things we should do internally
6 to take a more consistent approach?

7 MS. TANDY: I wouldn't say that you have
8 been inconsistent. I guess what AdvaMed had said --
9 and, you know, we said it in our comments, so I might
10 as well repeat it here -- is that we have had the
11 feeling over time that the agency just takes the drug
12 rules and slaps them onto devices. So it's not
13 inconsistent. It's that it's not perhaps what should
14 be happening mindful of the statute and mindful of the
15 differences between devices and drugs. So I don't
16 think you have been inconsistent.

17 We do think that the guidance document on
18 restricted device advertising should issue. We
19 recommended a whole lot of revamping towards it, you
20 know. So we thought that we put in a lot of good
21 ideas.

22 And we do think it would be helpful
23 because we don't have a regulation. And so even with
24 just the brief statement requirements, it's still
25 helpful to flesh out a little bit more, you know, how

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1 to do that and various ways in which we could do that.

2 So we would like to see that revised guidance
3 document issued. We think that would be incredibly
4 helpful.

5 You know, we follow this area. We look at
6 any enforcement action that happens. We look at the
7 enforcement actions in Rx pharm. And we try to kind
8 of glean things from there. But, you know, again,
9 that's not as good as having a nice guidance document.

10 I guess I could say if we thought that
11 anything else would really help, we're like the
12 biggest advocate for having more resources in CDRH
13 devoted to the DTC area because we think there's not
14 enough.

15 MR. ABRAMS: Dr. Behrman?

16 DR. BEHRMAN: You had a bullet about
17 technical information.

18 MS. TANDY: That one?

19 DR. BEHRMAN: No.

20 MS. TANDY: No?

21 DR. BEHRMAN: Maybe it's 4? No. Keep
22 going. Maybe 5 or 6.

23 MS. TANDY: This, technical information in
24 consumer-friendly language?

25 DR. BEHRMAN: Yes. Thank you.

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1 So are you saying that should not be a
2 requirement, it should be a recommendation or you feel
3 that impact is already required and we should just
4 emphasize it? What was your point?

5 MS. TANDY: The thinking about there is
6 that, I mean, we would love to hear how you think we
7 should do it.

8 DR. BEHRMAN: Okay.

9 MS. TANDY: We don't want you to tell us
10 that you have to do it this way, this way, this way,
11 but some of the things that FDA has learned through
12 experience that would be really helpful on like when
13 we look at our IFUs, instructions for use, -- that's
14 what we call our labeling in devices -- when you look
15 at the IFU and we're trying to craft our brief
16 statements and so we have all of this technical
17 unbelievable only like a, you know, health care
18 professional person can understand it and then we've
19 got to make it into consumer language for TV, we spend
20 a lot of hours doing that.

21 So we gave some ideas in our comments,
22 but, you know, we would like the guidance to
23 incorporate those ideas and any other ideas.

24 MR. ABRAMS: Dr. Temple?

25 DR. TEMPLE: Okay. Yes. It's probably

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1 because I've just read stories about coded stents in
2 the New England Journal. We have problems with
3 comparative kinds of claims appearing in advertising
4 and what kind of support they should have.

5 It strikes me, although I don't really
6 know device advertising, that the temptation to make
7 claims there must be, if anything, even greater
8 because it's such a big deal.

9 Do you have any particular thoughts on
10 standards and criteria for making comparative claims?

11 MS. TANDY: That's a great question. I
12 guess I would say that what I have seen, where I have
13 seen comparative claims for the device ads is in the
14 professional ads. I haven't really seen it -- I mean,
15 again, we do limit it to DTC broadcast and print, but
16 I haven't really seen it there. And maybe it's
17 because we have limited time, limited space; whereas,
18 like we have a four-page brochure that we could hand a
19 surgeon. And so I have seen it more there.

20 So I think it's more the professional
21 sector, not that we couldn't talk about it, because,
22 again, we try to follow some of the principles that
23 have been laid down in 21 CFR 202 on drug advertising
24 for comparative ads for having the support.

25 Now, in devices, you know it's different

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1 because most of our products are 510(k) products,
2 which means we don't always have to have comparative
3 clinical trials or even any clinical trial data. So
4 we couldn't have that as the standard for making a
5 comparative claim because the product review wouldn't
6 support that and we wouldn't have that data in the
7 product review.

8 DR. TEMPLE: That is sort of why I am
9 asking. In the particular case I am talking about,
10 there were two controlled trials comparing two kinds
11 of coded stents. So you, arguably, have the sort of
12 data you usually have, but in a lot of cases, you have
13 engineering data or something like that.

14 So I just wondered if you had any thoughts
15 about how in that setting without the clinical data
16 you would deal with this or whether it is just too
17 complicated to expect a patient to cope with or what.

18 MS. TANDY: You know, I guess I would say
19 to say on the professional side, when we do it on the
20 professional ads, the way we try to do it, again, is
21 you have got to have valid data to support that
22 comparison.

23 And like if it's a mechanical claim or a
24 performance claim, then we have to have when we do it
25 in the professional brochure a reference. We have to

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1 show maybe the data is on file, you know, that type of
2 level, but we have to have that support.

3 In a consumer-directed ad, I think we
4 would have to have the same thing if we did it. And
5 we would have to figure out a way that we could
6 adequately explain to the consumer what these two
7 devices are, how they were tested, and what the
8 results show.

9 So I think it would be a lot harder. I'm
10 not going to say we couldn't do it because we'd never
11 say we couldn't do it. But I think it's a lot harder
12 in devices because we've got data that we usually
13 don't have.

14 MR. ABRAMS: Ms. Tandy, you mentioned
15 before that the previous thought in industry was it
16 would be too difficult to explain these complex
17 devices to consumers so it's understandable, but then
18 industry apparently took steps to do that.

19 I guess I have a couple of questions.
20 What steps have you taken to do that so we can learn
21 to translate these terms? And then how do you know
22 you're really effective in conveying these complex
23 concepts to the consumer?

24 MS. TANDY: Also great questions. I think
25 we thought as an industry that we would scare people

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1 if we put on TV and we put in print about surgery and
2 implants and stents and have your hip surgery.

3 And we thought, honestly, that it would
4 frighten consumers, you know that nobody really wants
5 to think about these horrible surgeries and awful
6 things that can happen to you that, you know, you need
7 to have surgery. So I think that's why we stayed away
8 from it for a long period of time.

9 Then I think as we saw the Rx pharm, all
10 of a sudden, people seemed to get a lot more
11 comfortable with -- I mean, there are a lot of awful
12 diseases out there. And, all of a sudden, there's a
13 lot of Rx pharm ads for, you know, very distressing
14 diseases. And they're on TV all the time.

15 And then you've got the internet that
16 people are talking. I think that was the hugest
17 explosion that people are actually researching things
18 on the internet and, instead of a mentality like "Oh,
19 no. I want to kind of not hear about these things,"
20 you know, like in the old days, doctors sometimes felt
21 that it wasn't necessary to even tell patients about
22 their own illness because we wanted to try to keep
23 things from them. We were a little more in that vain.

24 But I think that has turned full circle.
25 So we began to realize that if you talked to consumers

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1 about surgeries and implants and if you actually
2 showed an implant, like a consumer wouldn't like react
3 with shock and dismay.

4 So I think that was a turning point. And
5 I think that started us thinking we really could do
6 this, you know. So how do we do it? What are our
7 legal constraints in order to do it?

8 And then I think our biggest challenge so
9 far has been how do we turn that information about
10 what the product is used for and how do we turn that
11 information from our professional-level explanations
12 into the brief statement?

13 And we do. We spend a long time looking
14 at the risks, the side effects, the warnings,
15 contraindications. How do we explain that in a way
16 that a consumer is going to understand in 30 seconds
17 or 60 seconds on TV?

18 And I would be remiss if I didn't mention
19 we also have the help-seeking ads. You know, we run
20 ads where we talk about disease states. And we don't
21 ever mention a device. We may mention that a
22 treatment is available, but, again, it's an education
23 that there are certain diseases out there that people
24 may never have heard of and there is treatment for
25 that, like normal pressure or hydrocephalus.

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1 We ran an ad by Codman, one of the Johnson
2 and Johnson companies, to educate consumers about what
3 are the signs of normal pressure, hydrocephalus, and
4 they should see their doctors if they have those
5 signs.

6 I hope that answered your question.

7 MR. ABRAMS: Yes, it did. So one
8 technique, just to distill this down a little bit,
9 would be to show the consumer the procedure and things
10 like that. Other techniques that you have tried have
11 been successful/have not been successful?

12 MS. TANDY: You know, I probably wouldn't
13 want to talk about the unsuccessful ones, but I will
14 think about that. But the successful ones certainly
15 we actually do have, not on TV but on our Web site --
16 you know, most of the device companies have Web sites
17 that go to the consumer. And we do have a procedure
18 you can watch on some of these Web site, a procedure
19 from start to finish.

20 So if you're going to have your implants,
21 you could go on there. And you could do that. The
22 idea is maybe you could see it on your computer or you
23 see it on like a CD-ROM or a DVD. Maybe it's less
24 scary when you actually get there, you know? So a lot
25 of that seems to have worked well.

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1 I know that the people in our company do
2 measure the responses. And it's very interesting
3 because when most of our ads on TV say, you know, have
4 a Web site that patients can also log into for further
5 information, what I have heard from our people who
6 measure this is that within a short period of time
7 after that ad airs, that there's like this big spike
8 in people coming, hits they call it, hits onto that
9 Web site. And that amazes me because I'm not so
10 computer-friendly yet. And I can't believe that that
11 happens.

12 But it seems to be that the internet
13 combined with the TV message seems to be very
14 effective. Those have been our most effective
15 methods.

16 MR. ABRAMS: I have a request. Any
17 research that you have done for industry that
18 companies are willing to share -- I understand there
19 are obviously concerns about particular products but
20 things that would make this useful complex information
21 more useful for consumers, anything that you could
22 share with us we would really appreciate having
23 submitted to the agency.

24 MS. TANDY: We will look. You know, to be
25 honest, I mean, the research presented today already

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1 was so interesting to me because I know we haven't
2 done any of that as a device industry association, but
3 we will see what we have got.

4 Thank you.

5 MR. ABRAMS: Ms. Tandy, thank you very
6 much for your presentation.

7 Nobody has signed up for providing public
8 comments from the floor. So I invite anybody who
9 wishes to. There are open mikes. We have about ten
10 minutes at this point. If you could identify
11 yourself, name and affiliation, that would be useful.

12 DR. DAY: Ruth Day, Duke University.

13 I appreciate the information about the
14 internet. I am a strong and enthusiastic supporter of
15 health information on the internet. However, there
16 are some things to be concerned about.

17 I believe Mr. Gardner said that the online
18 channel is more balanced because there is more place
19 to show the benefits and the risks. We have done
20 studies and others have as well looking at drug
21 product Web sites. And we have found that the number
22 of points and clicks that it takes to find the side
23 effects is greater than to find the benefits.

24 So this is very much in line with my
25 comments this morning about the cognitive

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1 accessibility of the information. Certainly the
2 internet has more space for more stuff. But what is
3 the ease with which people can find it? That's point
4 number one.

5 Point number two is about these wonderful
6 take-the-test Web sites. They are fun. They are
7 interactive and so on. However, there are some
8 interesting issues. What happens when a person enters
9 his or her information? You have to hit the "SUBMIT"
10 button. Where does that go to?

11 So we have done some studies where we have
12 Jane Does and John Does take the tests. And then we
13 wait for three months to see what happens. And
14 sometimes there has been advertising and promotional
15 material that has been sent to that individual.

16 So where does the information go when
17 someone takes a test? And how is privacy preserved?
18 Of course, you can have some initials or funny name
19 for your e-mail address and so on, but there are IP
20 addresses. And so I think there are some privacy
21 issues.

22 The final point on that is that sometimes
23 a test taker has concerns about privacy and so clicks
24 on the privacy statement. And the privacy statement
25 they think is there to make sure that their data are

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1 private. Privacy statements are mostly about
2 protecting the company. And so people don't
3 understand the privacy statements.

4 So I think there is a range of issues that
5 are in common with DTC in other arenas and ones that
6 are specific to the internet.

7 MR. ABRAMS: Dr. Day, we appreciate your
8 comments. And I hate to be redundant, but just take
9 this because data is important to the agency. It's
10 how much we value data. Dr. Day, if you have data
11 that you would be willing to submit to the agency, we
12 would appreciate it. Thank you.

13 Yes?

14 MR. CAVALLINI: My name is Mario
15 Cavallini. I am with Simstar. It's an interactive
16 marketing agency for the pharmaceutical industry. My
17 position with Simstar is that of manager of
18 competitive intelligence, a little spooky title, but I
19 mention it because my job is consuming and dispersing
20 information. And I am speaking as a consumer of one
21 particular source, which is Manhattan Research.

22 Dr. Gottlieb, earlier you asked the
23 question about people using search engines and whether
24 they are able to find reliable information. What came
25 to mind for me is data that Manhattan Research has.

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1 Manhattan Research has been doing surveys
2 of both patients and health care providers over the
3 past five or six years. In their most recent round of
4 physician survey, what they have been finding is an
5 increasing use of Google and other general search
6 engines by physicians for clinical information.
7 Almost exactly half of the responding physicians in
8 the current round said that they use Google and
9 similar search engines daily for clinical information.

10 One of the things that is interesting in
11 that fact is that they are finding enough there there
12 to keep coming back and using it again. Now, they
13 also have certain advantages in being able to sniff
14 out reliable information. If you take a look at the
15 professional literature in PLOS Medicine, BMJ, and
16 other journals, you will see more articles providing
17 advice on how to use search engines, how to use Google
18 Scholar and Google Image, for instance. So that is an
19 indicator that there should be more emphasis on
20 raising health literacy among consumers on how they
21 can better use search engines.

22 If you look at credibility of research, a
23 lot of it is done by Fogg out at Stanford. His
24 initial studies tended to deal with how professionals
25 use search engines and how they evaluate Web sites.

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1 And a lot of it dealt with credibility markers. But
2 then when he started talking with consumers, their
3 response was "Well, it looks professional."

4 Now, that could be interpreted as judging
5 a book by its cover, but I'm going to make the
6 intuitive leap and say that people are getting more
7 experienced with finding information on the Web and
8 looking up health information in various sources. And
9 so while they may not be fluent in just identifying
10 what those markers are, they're getting more of a
11 sense of what is responsible and reasonable.

12 The other items that comes to mind -- and
13 I thank the previous speaker for her comment because
14 it does dovetail on this -- if you talk with any
15 webmaster of a product dot-com, they will tell you
16 that the most frequently accessed pages tend to be the
17 pages on side effects. People go to Web sites, and
18 they look for side effect info.

19 There is a myth that is connected with
20 that, though. There is a fear that people get spooked
21 by the side effects and then go screaming off into the
22 night.

23 At Simstar, we submitted a query to
24 Manhattan Research, which does collect a lot of
25 information on how people use medical information

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1 sites, how they use product sites, what they do
2 afterwards, what they do at the sites.

3 We asked them to run a cross-correlation
4 on people who identify as looking at the side effect
5 information at a product site and people who use
6 product information sites but don't look up side
7 effect information.

8 What we found across the board is that the
9 people who look up side effect information also are
10 more likely to look up other information. They are
11 much more likely to use the tests and quizzes on the
12 sites. They are much more likely to use the talk to
13 your doctor tools, much more likely to use Telefriend
14 and other functionality.

15 Afterwards, the people that look up side
16 effect information are much more likely to talk to
17 their friends. They're much more likely to go to the
18 doctor. They're much more likely to be confined with
19 their drugs. It's really amazing to see the
20 connection.

21 MR. ABRAMS: Thank you for your comments.

22 That concludes this panel. I thank the
23 panel for their excellent presentations.

24 (Applause.)

25 MR. ABRAMS: We will take a 15-minute

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1 break and start promptly at 3:15. Thank you.

2 (Whereupon, the foregoing matter went off
3 the record at 3:00 p.m. and went back on the record at
4 3:19 p.m.)

5 MR. ABRAMS: Welcome back. We are having
6 our final panel of the day. And we will begin with
7 Rebecca Burkholder with the National Consumers League.

8 MS. BURKHOLDER: Thank you.

9 PANEL 4

10 MS. BURKHOLDER: The National Consumers
11 League, the nation's oldest consumer organization, is
12 pleased to be here today to comment on
13 direct-to-consumer promotion of prescription
14 medication.

15 Founded in 1899, NCL is a private,
16 nonprofit advocacy group representing consumers and
17 workers on marketplace and workplace issues. Our
18 mission is to protect and promote economic justice for
19 consumers and workers in the United States and abroad.

20 NCL has long been interested in ensuring
21 that consumers receive accurate and helpful
22 information about their health care, including
23 information about prescription medication.

24 Direct-to-consumer advertising
25 prescription drugs, DTC, is part of a long-term

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1 systematic shift towards patient-centered care. With
2 this shift, it is critical that consumers are able to
3 assess risks and benefits of health care treatments,
4 including prescription medication.

5 Today I would like to focus my remarks on
6 the following. First, I will talk about the
7 presentation of risks and benefits in current DTC
8 promotion; second, some suggested improvements for
9 DTC; third, other communications regarding
10 prescription medication, including in pharmacy
11 communications; and, fourth, a bit about FDA
12 oversight.

13 First, I would like to talk a little bit
14 about the risks and benefits information in current
15 DTC ads. DTC can be a useful tool for initiating and
16 complementing patient health care professional
17 communication.

18 Armed with balanced clear information,
19 consumers can initiate dialogue with their physicians
20 about the risks and benefits of and alternatives to
21 prescription drugs as well as talk about medical
22 issues they may not otherwise.

23 A 2002 NCL survey of over 1,000 adults
24 showed that more than half of those who saw a DTC ad
25 were motivated to take action. Thirty-one percent

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1 decided to talk with their doctor about the medication
2 of their next appointment and 26 percent, over a
3 quarter, sought more information about the drug from
4 various sources.

5 Those who sought more information from
6 pharmacists, medical or drug reference books, or a
7 health Web site wanted to know if the drug was right
8 for them or a family member.

9 In addition, the survey showed that
10 consumers are wary of DTC advertising and cynical
11 about the motives of pharmaceutical companies. More
12 than half agreed that the ads just help pharmaceutical
13 companies sell their drugs and nearly half think the
14 ads are largely responsible for the increased cost of
15 prescription drugs and that they encourage people to
16 ask for drugs they don't need or cannot take.

17 As we know, DTC needs to do a better job
18 of presenting balanced risks and benefit information
19 and not create unreasonable expectation or promote
20 inappropriate use.

21 We know that consumers are failing to take
22 away important health information after seeing,
23 hearing, or reading a DTC ad. While risk information
24 is present in these ads, it may be hard to comprehend
25 due to the technical vocabulary and formats used, such

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1 as small type.

2 In broadcast ads, risks may be missed by
3 consumers when they are listed very quickly in one
4 continuous segment and while contradictory visual
5 images are shown.

6 Confusion of risk information can affect
7 consumers' perception of risk. We encourage you in a
8 continuing study of the most effective way to present
9 risk and benefit information to consumers.

10 Given what we know about current DTC ads,
11 we would like to suggest some improvements. FDA's
12 current requirements and policies for prescription
13 drug advertising and promotional labeling are really
14 ill suited to communicating information to consumers.

15 FDA should revise its regulations and
16 policies to allow for more consumer-friendly
17 information about the safe and effective use of
18 prescription drugs that is clear and understandable to
19 the average consumer.

20 NCL supports FDA's 2004 draft guidance
21 recommending alternatives to the current brief summary
22 common in most print ads. Because the brief summary
23 is an accompanying advertisement and a consumer must
24 still obtain a prescription before receiving the
25 medication, which when dispensed will be accompanied

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1 by more information on safe use and risks and
2 benefits, NCL believes certain information can be
3 deleted from the brief summary, including exhaustive
4 risk information, dosage, and administration. In this
5 context, less is really more. The emphasis in DTC ads
6 should be on the most serious and common side effects.

7 NCL further believes that a standardized
8 information panel, such as an Rx facts box, much like
9 the successful format that is now being used for
10 nutrition facts, supplemental facts, and OTC drug
11 facts, would be a better way to communicate risks and
12 benefits to consumers. Coupled with user-friendly
13 language and adequate provision for the consumer to
14 obtain additional information from other sources, this
15 approach would be helpful to consumers.

16 We are encouraged that FDA seems to
17 consider this type of standardized information panel
18 as one option in the 2004 guidance. NCL is also
19 pleased to see that some pharmaceutical companies are
20 seeking consumer input to reformat the risk and
21 benefit information in creative formats, such as
22 question and answer and fast facts formats.

23 For DTC ads to truly educate or benefit
24 consumers, they should not only contain understandable
25 risk information but also information on the drug's

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1 benefits. Many ads use vague qualitative terms to
2 describe the benefits; for example, lower your number
3 for cholesterol drugs. The ads' actual benefit data
4 may lead consumers to believe that a drug works better
5 than it actually did.

6 A benefit box with published data on the
7 chance of various outcomes with or without the drug
8 should be considered for inclusion in DTC ads.
9 Consumer perception of drug effectiveness could be
10 improved with this type of information.

11 NCL would also welcome more educational
12 content about disease and conditions in DTC ads. If
13 consumers understand the role of drug therapy in
14 treating their disease or condition, they will have
15 reasonable expectations of the drug's benefits. In
16 addition, we would encourage more disease awareness
17 communication without the promotion of a specific
18 drug.

19 If we really want to improve public
20 health, we should spend some of the billions of
21 dollars spent on DTC on messages about disease
22 awareness, health conditions, diet, exercise, and drug
23 compliance that is not product-specific.

24 For certain under-diagnosed diseases and
25 untreated conditions, such messages are conversation

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1 starters between patients and health care
2 professionals. These communications should include
3 evidence-based information and direct consumers to
4 other sources for more information.

5 Third, I would like to talk about other
6 communications consumers receive about prescription
7 medications. We know that consumers obtain
8 information about prescription drugs that they take
9 from many sources: from physicians, pharmacists, drug
10 package inserts, health plans, internet, magazines,
11 newspapers, family, and friends. Given this, FDA
12 should consider how its policies can foster, rather
13 than hinder, the flow of communication from these
14 alternative channels.

15 Restrictions and disclosures that are
16 necessary for sponsored DTC ads may not be appropriate
17 for communications from health care professionals and
18 pharmacists and may even consider with consumers.
19 Amount and type of information required to accompany
20 prescription drug communications should depend upon
21 the particular type of message.

22 A one size fits all requirement is not
23 appropriate. For example, sponsored messages that
24 encourage patients to continue to take the drug
25 therapy that has already been prescribed and dispensed

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1 are different from ads in the mass media and should
2 not be treated the same way. These compliance
3 messages should not be considered promotional in this
4 context.

5 In addition, customized messages delivered
6 by a pharmacy with a drug should also not be treated
7 in the same way. These messages are part of the
8 practice of pharmacy. And the pharmacist is readily
9 available to talk about the drug dispensed and
10 adjunctive or alternative treatments with the patient.

11 FDA we believe should follow the
12 Department of Health and Human Services' final privacy
13 rule, which deems refill reminders and
14 pharmacy-initiated communications be part of a health
15 care professional's treatment of a patient, not
16 marketing. NCL would welcome further guidance from
17 the FDA on in pharmacy communications.

18 Finally, a few comments on FDA overnight.
19 NCL believes FDA should be able to review all DTC ads
20 before deployment. This would enable agency staff to
21 revise material if needed so misleading information
22 does not reach consumers.

23 In order to effectively and efficiently
24 review ads in a timely manner, FDA will, of course,
25 need the resources to provide sufficient review staff.

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1 If FDA is not able to review these ads before they
2 are deployed and ads are later found to be misleading,
3 the sponsors should be required to engage in
4 corrective action to remedy the misrepresentation.

5 We would also like to see consideration by
6 the FDA of prolonging the period between drug approval
7 and initiation of product promotion; in other words, a
8 moratorium on advertising for certain drugs when there
9 is the need to gather more safety information, educate
10 physicians and health care professionals.

11 It has been suggested that FDA should even
12 consider adding a provisional status for some drugs.
13 Such a status would allow time for limited exposure of
14 the product to appropriate patients while there is
15 additional post-approval safety data collection.

16 In conclusion, I would like to thank the
17 FDA for allowing us to comment on this important
18 issue. Thank you.

19 MR. ABRAMS: Thank you for your
20 presentation.

21 Your presentation included many
22 interesting concepts, a whole lot of concepts, and
23 suggestions of what FDA should do. What would your
24 advice be to the agency as far as if we were going to
25 incorporate these? Should we do it by guidance

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1 development, changing regulations, some other
2 mechanism?

3 MS. BURKHOLDER: We would see that there
4 needs to be a change in regulation, that those
5 regulations were not written incorporating the lay
6 comprehension evaluative criteria, but that's an
7 important starting point to redo the regulations so
8 that the idea that understandable consumer information
9 needs to be part of the DTC promotion in advertising.

10 MR. ABRAMS: Thank you.

11 Dr. Temple?

12 DR. TEMPLE: I was particularly intrigued
13 by your thought that there should be more detailed
14 effectiveness information. We think about that, too,
15 but how to do that is considered challenging.

16 I mean, you have heard all of this, I am
17 sure, but you give the percent reduction in heart
18 attacks. And that sort of overstates it. You should
19 actually give the actual percent difference between
20 the populations.

21 Do you think it is realistic to think
22 that, at least on more complicated things, that can be
23 done well without sort of making more trouble?

24 MS. BURKHOLDER: Is it realistic? We
25 would like to see more study on this issue. And I

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1 think what we have seen is that it is possible for
2 certain drugs to do that.

3 I agree with you that it is a tricky
4 issue. I think we really need to look more carefully
5 about how we can do that. We know consumers generally
6 think the drug is more effective. And when they are
7 presented with this benefit information, they
8 generally have a lower view of effectiveness but have
9 found it to be very helpful.

10 DR. TEMPLE: When we first approved
11 over-the-counter H-2 blockers, there was a package
12 insert that showed that the difference between
13 treatment for one and treatment with placebo is about
14 50 percent.

15 But we wanted it in there so people knew
16 how modest the effect was. But we were never
17 satisfied that we had actually succeeded in
18 communicating anything to people.

19 MS. BURKHOLDER: Right. And I think part
20 of it is that consumers need to be continually
21 presented with some of this information. I think when
22 they are presented with it, they will become more
23 savvy and perhaps become more detailed.

24 Thank you.

25 MR. ABRAMS: Dr. Ostrove?

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1 DR. OSTROVE: Interested in just hearing a
2 little bit more about your belief concerning wanting
3 to see more in the way of disease-oriented promoted.

4 This morning Pat Kelly kind of talked
5 about that and talked about how it doesn't seem to be,
6 I guess the way it has been done doesn't seem to be as
7 effective, in getting patients in to see the doctor.

8 Well, you know the question I guess in my
9 mind is, is that the right dependent measure? You
10 know, is that the right thing that we should be
11 looking at? Is there something else that you all
12 would have in mind, for instance, as an assessment of
13 the value of the disease-specific promotion,
14 disease-oriented promotion, as opposed to
15 product-oriented?

16 MS. BURKHOLDER: That's a very interesting
17 question. I would think that it would be very hard to
18 assess the impact of those. But, in addition to just
19 talking to your physician or going to see your
20 physician, some of it, as we know, consumers are
21 turning to the internet, to other sources to gather
22 more information. So after seeing ads such as that,
23 they may be seeking out other sources of information
24 that still may be helpful to them.

25 I would also say that perhaps we can do

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1 better with those disease awareness ads. We do know
2 that DTC is prompting people to talk to their doctor
3 about a drug. It seems like if we could do those ads
4 right, we could prompt more people to talk to their
5 doctor about a condition or disease.

6 DR. OSTROVE: Thank you.

7 MR. ABRAMS: Ms. Burkholder, thank you.
8 And we thank you for your patience with the technical
9 difficulties distraction.

10 Our next speaker is Lee Hammond with the
11 AARP.

12 MR. HAMMOND: Good afternoon, ladies and
13 gentlemen. My name is Lee Hammond. I am a member of
14 AARP's Board of Directors.

15 On behalf of our over 35 million members,
16 we would like to thank you for convening this public
17 hearing and for including AARP in your discussions
18 about direct-to-consumer advertising of prescription
19 drugs.

20 In two weeks, millions of older and
21 disabled Americans will have the opportunity to choose
22 prescription drug coverage as a part of their 2006
23 Medicare benefit options.

24 The new Medicare benefit prescription drug
25 program will help millions of beneficiaries afford

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1 needed medications. We now need to take the next step
2 to make prescription drugs affordable for Americans of
3 all ages.

4 One of the places to start is by changing
5 some of the direct-to-consumer advertising practices
6 that lead to unnecessary increases in drug spending.
7 Direct-to-consumer advertising of prescription drugs
8 can be helpful to consumers. If done well, ads can
9 provide general information about a specific disease
10 or condition, particularly one that is historically
11 under-diagnosed and/or treated. These ads also cause
12 increased and often unnecessary health care spending.

13 In recent years, the amount of money spent
14 on prescription drug direct-to-consumer advertising
15 has skyrocketed. Between 1997, when the FDA relaxed
16 its guidelines for broadcast advertising, and 2004,
17 spending on direct-to-consumer advertising increased
18 by \$3 billion. In 1999, just 25 top-selling medicines
19 promoted directly to consumers accounted for about 41
20 percent of the nearly 18 billion increase in retail
21 drug spending from the previous year.

22 The link between increased
23 direct-to-consumer advertising and the overall
24 increase in health care costs is real. For instance,
25 patients are prescribed often unnecessarily, new

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1 heavily advertised pharmaceuticals as the first-line
2 therapy, rather than the older, equally effective but
3 often less expensive, medications.

4 Providers often feel pressure to prescribe
5 the advertised prescription drug, perhaps forfeiting a
6 meaningful dialogue with the patient about other
7 appropriate courses of treatment, including non-drug
8 treatment alternatives.

9 A recent study in the Journal of the
10 American Medical Association found that doctors were
11 five times more likely to write a prescription about a
12 specific drug requested by their patients compared to
13 those who did not mention a specific drug.

14 AARP believes that the FDA should be given
15 the resources and the authority to require review of
16 advertisements, both print and TV, before the ads are
17 disseminated to the public.

18 Some broadcast DTC ads now include more
19 direct communication of risk information. We do not
20 know if or how this will translate into more cautious
21 prescribing for new drugs.

22 Unfortunately, the risk information
23 printed in DTC ads is neither useful nor informative
24 for consumers. In most cases, it's nothing more than
25 a microtype reprint of a so-called brief prescribing

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1 summary.

2 The search suggests a direct relationship
3 between risk statement completeness and consumers'
4 perception of drug safety and appeal. We support the
5 FDA's current research plan to develop more
6 consumer-friendly risk communication strategies for
7 print advertisements.

8 Earlier this year the Pharmaceutical
9 Research and Manufacturers of America's Board of
10 Directors approved voluntary guidelines on
11 direct-to-consumer advertising of prescription drugs.

12 These guidelines are welcome, but, rather than
13 relying on the industry to police itself, we believe
14 that the Food and Drug Administration must play a
15 bigger role, starting with the revising of its 1997
16 guidance for industry, consumer-directed broadcast
17 advertisements.

18 We urge the FDA to work in consultation
19 with other interest groups, including consumers and
20 providers, to ensure that direct-to-consumer
21 advertisements inform the consumer and provide clear
22 accurate information and that the ads encourage the
23 consumer to have a productive dialogue with their
24 provider about treatment options, including
25 prescription and non-prescription medicines, lifestyle

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1 changes, if applicable.

2 Finally, we believe that the U.S. health
3 care system can also benefit from a more serious
4 investment in the research of comparative clinical
5 effectiveness of prescription drugs.

6 Unlike other countries, the U.S. does not
7 require that drugs coming onto the market demonstrate
8 enhanced effectiveness and safety profiles in
9 head-to-head trials with drugs already available in
10 the marketplace.

11 Congress as a part of the Medicare
12 Modernization Act of 2003 authorized \$50 million in
13 funding in F.Y. 2004 and "such other sums as may be
14 necessary" in subsequent years for comparative
15 effectiveness research.

16 To date, Congress has only appropriated 15
17 million for this valuable research. This amount is \$2
18 million less than Merck spent advertising Vioxx in
19 1999, its first year on the market.

20 With Medicare footing the bill for many
21 prescription drugs starting in 2006, this is a perfect
22 opportunity for Congress to boost funding for
23 comparative clinical effectiveness studies that will
24 provide scientifically based information on the
25 relative clinical effectiveness of different

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1 prescription drugs within the therapeutic class.

2 In some cases, the newer drug may be the
3 best treatment option. In other cases, the best
4 treatment option may be an existing brand name or
5 generic drug. Broad dissemination of the results to
6 both the public and health care professionals may help
7 to reduce the influence of direct-to-consumer
8 advertising.

9 Direct-to-consumer advertising is just one
10 way to inform consumers about newly approved
11 medicines. While AARP will continue to examine how
12 DTC can best educate and inform consumers, we will
13 also pursue other ways to promote appropriate and
14 cost-effective prescribing to help consumers make wise
15 choices about their medicines.

16 Thank you.

17 MR. ABRAMS: Dr. Temple?

18 DR. TEMPLE: I just want to say one thing.
19 To my best knowledge, at least none of the European
20 countries require the drug be better than what is
21 available. They do ask for comparative data.

22 MR. HAMMOND: They do ask for comparative
23 data.

24 DR. TEMPLE: That's true. And it can
25 affect their price, but it's not a requirement. One

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1 of the points you made earlier -- and it's certainly
2 true -- is that the things that are promoted in DTC
3 advertising are the new branded ones. That's
4 certainly true.

5 Do you have a thought about what the
6 remedy is? I mean, I don't think anybody is going to
7 promote generics or older drugs that have generic
8 competition very much. And, in fact, they don't.
9 What are your thoughts on what one could do about
10 that?

11 MR. HAMMOND: I think there are two things
12 that could be done. And one goes back to the
13 cost-effectiveness studies with the drugs that are
14 already on the market.

15 The second is the encouragement of the
16 consumer to actually create a dialogue with their
17 health care professional concerning these things. The
18 health care professional generally knows what is
19 available, both in the pharmaceutical name brand
20 market and in the generic market. I found in my case,
21 for example, in many instances my health care provider
22 has said there is a generic drug which will do just
23 the same thing.

24 So I think encouraging that dialogue is
25 certainly one of the major ways that we can actually

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1 reduce the cost I think of some of our prescription
2 drugs for people.

3 DR. TEMPLE: So the doctor would have to
4 say that there is a generic drug that is different. I
5 mean, in fact, advertising of drug stops once there is
6 a generic pretty much. But they may continue to
7 promote a different molecule that is more or less the
8 same.

9 So the doctor would have to say you don't
10 have to use this ace inhibitor. You can use that ace
11 inhibitor because there is a generic available for
12 that.

13 MR. HAMMOND: That is a possibility, yes.

14 MR. ABRAMS: Dr. Ostrove?

15 DR. OSTROVE: It's really just a request.
16 You mentioned that patients are often prescribed
17 products that are inappropriate, prescribers feel
18 pressured. And I'm assuming that as part of your
19 testimony that you will be submitting to the docket
20 that -- I mean, it would be very helpful for us to
21 have those references.

22 MR. HAMMOND: I think staff could make
23 sure that that is involved in the written testimony.

24 DR. OSTROVE: Fantastic. Thank you.

25 MR. HAMMOND: Thank you.

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1 MR. ABRAMS: Mr. Hammond, thank you very
2 much for your presentation.

3 Our next speaker is Gary Stein from the
4 American Society of Health-System Pharmacists.

5 DR. STEIN: Thank you.

6 ASHP is a 30,000-member national
7 professional association that represents pharmacists
8 who practice in hospitals and other components of
9 health care systems. For more than 60 years, ASHP has
10 helped pharmacists improve medication use and enhance
11 patient safety.

12 Luckily, we had our policy-making
13 council's meeting in Bethesda in mid September, just
14 after the notice of this meeting came out. And we
15 were able to poll some of our members regarding the
16 questions the FDA asked in that announcement.

17 We will be submitting more extensive
18 comments in a written submission by the February
19 deadline, but I would like to present our initial
20 views on the questions and our members' initial views
21 on the questions that FDA asked in its announcement of
22 the meeting.

23 Our members believe that certain ads, such
24 as for drugs for erectile dysfunction, are shown all
25 day long. And children are exposed to these ads. One

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1 of our members said the parents, of course, to discuss
2 the issue, which is certainly not the intention of the
3 direct-to-consumer advertising but may confuse the
4 parents of smaller children.

5 In terms of the presentation of risk
6 information, our members feel that the language should
7 be at a low-grade level. Print ads are written in
8 order to ensure that lay people understand the
9 advertisements.

10 The discussion of risk should not be
11 presented with positive backdrop images. Coupons and
12 money-back guarantees, which will hold the specific
13 questions that FDA asks, should not be allowed because
14 they convey the idea that the medication always works
15 and that there are no risks.

16 The expression of benefits in percentages,
17 such as works in 70 percent of patients, we feel that
18 this tends to induce consumers to overlook or to
19 minimize risks.

20 It's uncommon for drug companies to do
21 comparative studies. They often take two separate
22 studies and compare efficacy, even though both drugs
23 were not included in the respective studies. This is
24 very misleading. And the FDA should prohibit such
25 comparisons.

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1 In terms of whether changes in certain
2 required prescription drug disclosures might improve
3 the usefulness of the information for consumers, the
4 language in the package insert is difficult to
5 navigate for consumers, of course, and it's written
6 for a health care professional to interpret and not
7 for a lay person.

8 We recommend that it be presented at a
9 lower grade level, as we often do, our members often
10 do, for their patients when using print materials.
11 Also, the fact that the package insert is printed in
12 is not conducive to reading. Often seniors are
13 looking for this information and cannot read those
14 documents as printed. And the font size should be
15 sufficiently large to be readable.

16 As far as the question of whether changes
17 in the requirements for disclosure of certain
18 information in broadcast advertising could improve the
19 usefulness of the information for consumers, the
20 disclosure is usually at the end of the advertisement
21 and it's said very quickly, not allowing consumers to
22 comprehend it.

23 We recommend that it be spoken and at the
24 same time appear on the screen so that the consumer
25 can follow along. And also the visual background and

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1 the context should reinforce the information that's
2 presented.

3 In terms of new communication
4 technologies, our members believe that the FDA needs
5 to regulate Web-based promotions. Direct mailings to
6 consumers, such as CDs that are sent to consumers,
7 also need to be regulated.

8 The Federal Register notice of the meeting
9 also asks what action FDA should take when companies
10 disseminate violative promotional materials to
11 consumers.

12 And one of our members said that there
13 should be a graduated fine structure culminating in a
14 six-month moratorium for a company's entire product
15 line for direct-to-consumer ads after a third offense.

16 This would give companies pause before trying to push
17 beyond the regulations.

18 In terms of whether current DTC ads
19 present benefits and risks in an accurate and
20 non-misleading balanced and understandable way,
21 currently the FDA requires a fair balance between
22 benefits and risks, but there is no definition of
23 fair. Is this 50/50? Some of our members believe so?

24 The risks are usually discussed toward the
25 end of the advertisement and discussed in a rapid-fire

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1 manner. The terms are often in what one member called
2 medical speak and not in layman's terms.

3 We have been discussing the idea of
4 direct-to-consumer advertisements. We had a policy
5 developed in 1997, when these ads first became
6 prominent. And when our policy-making council met in
7 September, we addressed direct-to-consumer
8 advertising. And this is not a fully ratified policy
9 yet, but this is the direction I think that we're
10 going is to support direct-to-consumer advertising
11 that is educational in nature about prescription drug
12 therapies for certain medical conditions that
13 appropriately include pharmacists as a source of
14 information and, further, to support
15 direct-to-consumer advertising specific prescription
16 drug products with the following requirements. Such
17 advertising should be delayed until post-marketing
18 surveillance data are collected and assessed. The
19 risks and benefits of therapy are presented in a
20 comprehensible format that allows informed decisions
21 on both the part of the consumer and the health care
22 provider and that there is a clear relationship
23 between the medication and the disease state.

24 Like I said, since 1997, ASHP policy has
25 opposed consumer advertising of specific prescription

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1 medications. In September, our council acknowledged
2 the current state of direct-to-consumer advertising
3 and the possibility that some consumers may be induced
4 to seek treatment as a result of such marketing.

5 And we strongly believe that specific
6 product advertising should be delayed for newly
7 approved products until post-marketing data can be
8 annualized to determine the ongoing safety of a
9 product. The increasing demand for such products
10 before such an analysis would present a possible
11 premature risk to the public health.

12 We also believe that such advertising
13 needs to be more forthright and comprehensible about
14 the disease state to be treated and the risks and
15 benefits of treatment.

16 And I will be happy to answer any
17 questions that you might have.

18 MR. ABRAMS: Ms. Davis?

19 MS. DAVIS: I thank you for your
20 presentation.

21 I have a clarifying question. You talked
22 about the emerging technologies and that FDA should
23 regulate these. Do you have any specific
24 recommendations for regulations that might address
25 these technologies or were you just speaking as a

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1 general matter?

2 DR. STEIN: We think this is as a general
3 matter. I think that when we submit our written
4 comments, we'll try to come up with something more
5 specific.

6 MS. DAVIS: Thank you.

7 MR. ABRAMS: Dr. Temple?

8 DR. TEMPLE: I assume the thought that
9 there should be a delay in this kind of advertising
10 until surveillance has had a chance to go forward is
11 based on recent issues, like antidepressants and
12 COx-2.

13 DR. STEIN: Absolutely.

14 DR. TEMPLE: Surveillance did not reveal
15 either of those results. They were revealed through
16 randomized trials in children, which were then pulled
17 together to get the data, and by several very large
18 comparative trials and subsequently some
19 placebo-controlled trials with the various COx-2
20 inhibitors. That makes it a little unclear what you
21 mean about surveillance.

22 If those are the models, I guess I would
23 like to hear more about what you are looking for in
24 terms of actual surveillance. Some adverse reactions
25 are seen that way.

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1 DR. STEIN: Right. That is what we were
2 considering: adverse reaction reports and public
3 prevention.

4 MR. ABRAMS: Dr. Gottlieb?

5 DR. GOTTLIEB: You mentioned that you
6 think the advertising should be written at a fourth
7 grade level. Is that based on observation from ASHP
8 or other kinds of benchmark to other types of consumer
9 --

10 DR. STEIN: That's based on observations
11 of our members who are dealing with patients.

12 MR. ABRAMS: Mr. Byrd?

13 MR. BYRD: You mentioned something about,
14 if I remember correctly, comparative claims. Could
15 you clarify a little bit about comparative claims
16 regarding other products?

17 DR. STEIN: Clinical effectiveness trials
18 is what we were talking about.

19 MR. BYRD: Not head-to-head trials but --

20 DR. STEIN: Right.

21 MR. BYRD: -- separate trials --

22 DR. STEIN: Right.

23 MR. BYRD: -- being used together?

24 DR. STEIN: Yes.

25 MR. ABRAMS: Dr. Stein, we thank you for

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1 your presentation.

2 Our next speaker is Lisa Van Syckel with
3 Drugawareness.org.

4 (Whereupon, a tape was played.)

5 MS. VAN SYCKEL: My name is Lisa Van
6 Syckel. I am also Michelle's and Christopher's
7 mother. When Michelle was given Paxil, it turned out
8 she actually had Lyme disease. She has been treated
9 for Lyme disease. She is now in her third year of
10 college majoring in criminal justice and doing just
11 fine.

12 My concern is with the drug advertising.
13 These drugs are being prescribed off label. And we
14 were promised the black box warnings. I don't see
15 black box warnings on television. I don't see them in
16 the print. I don't see them in magazines. And, you
17 know, when you look at the article, it says "may have
18 increased thoughts of suicide."

19 Ladies and gentlemen, you heard a 911 tape
20 of a child attempting suicide. When you look at the
21 black box warning in the ad, which is on the second
22 page behind, where parents don't see it. Does that
23 really put out the full effect of a suicide in a child
24 due to a drug?

25 I want you to look over here on the side.

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1 This is from GlaxoSmithKline from 1997, their sales
2 representatives. Look at it. It says,
3 "Discontinuation." Why this is an issue, one billion
4 dollars.

5 My daughter attempted suicide on day two
6 of Paxil withdrawal. Had I seen that, had doctors
7 been given that, would my daughter have gotten Paxil?
8 Probably not. Would he have told me about
9 withdrawal? Absolutely.

10 Why didn't GlaxoSmithKline warn us in
11 their advertising? Withdrawal doesn't happen, they
12 say. But they knew about it. They were more
13 concerned about their billion dollars than they were
14 about the life of a child.

15 Now we have in the schools promoting
16 materials for medications off label. And I'll read it
17 to you. It says, "Mental illness has never been more
18 treatable, but there is a deafening silence about it
19 in all classrooms. So begins the brochure on break
20 the silence through education.

21 This program is a new curriculum that will
22 be introduced in the classroom for this school year.
23 It is specifically designed to reduce the stigma of
24 mental illness and provide information on all aspects
25 of this illness, signs of mental illness, coping

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1 skills, needed support from family, and the
2 availability of therapies and medications.

3 Materials are designed for specific age
4 groups: preschool, school age, teenagers. The
5 materials are packaged with instructions, worksheets,
6 and lesson plans that will encourage student
7 participation. Poster games, follow-up activities,
8 definitions, a book, and recommended sources give the
9 teacher the broad range of approaches appropriate to
10 the class level and abilities.

11 Comparing mental illness to physical
12 illness helps the child understand that mental illness
13 is like high blood pressure. Both are helped by
14 treatment and drugs.

15 These drugs are not effective in children.
16 They don't work. That's been proven. That's why
17 they have been banned in the United Kingdom. And the
18 other thing that I would have liked to have known,
19 which the FDA was aware of, is that a Dr. Palazzo, who
20 was a clinical investigator for Paxil in the OCD
21 trials of Paxil for OCD -- they knew that she was
22 changing records. She has been charged 15 counts of
23 fraud.

24 Why did the FDA keep that silent during
25 the hearings? Why didn't they say one of their

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1 doctors, one of the clinical investigators, was
2 charged 15 times with fraud? Isn't that something the
3 public should know about? Shouldn't the public know
4 that if our child becomes violent on a medication,
5 that Pfizer has got a prosecutor's manual on how to
6 prosecute our kids? Lovely, isn't it?

7 We're trying to take care of our children.
8 As parents, if a child is going to suffer a side
9 effect, we need to know about it. We need to know how
10 to prevent it, take care of it. But, my God, if we
11 can't control it and that child commits a violent act,
12 we have got Pfizer going into the courtroom with our
13 prosecutor.

14 Pfizer should be wanting to help our
15 children, not prosecute them. It makes no sense. And
16 then, you know, the FDA says that there was no
17 homicide, suicide in the clinical trials. That's
18 wrong.

19 It was detected on July 19th or July 17th,
20 1983, but Pfizer submitted a document to the FDA and
21 said the reason why the 43-year-old man was
22 discontinued from the trial was because of nausea and
23 agitation. Agitation in the context of a clinical
24 trial is homicide. And it's right there. I've got
25 the document if you would like to see it.

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1 I would like to know why Pfizer filed a
2 document with the FDA and didn't tell them the truth.

3 So we want them to put direct-to-consumer marketing
4 ads out there that are false?

5 I would like to see a complete ban until
6 you at the FDA can take control of these people and
7 make sure that our children are safe because, ladies
8 and gentlemen, when you go home tonight and you place
9 your head on your pillow, think about the children in
10 the stories. Think about the 911 tape that you heard
11 of my children. My daughter was misdiagnosed. Think
12 about that.

13 If they're willing to place our children
14 in harm's way, if they're willing to kill our children
15 for the sake of the almighty dollar, can you imagine
16 what they would do for the whole public? They can't
17 be trusted.

18 You know, I would like to know from the
19 FDA. I mean, you have meetings of drug safety. You
20 have meeting after meeting after meeting. And nobody
21 has done anything. Aren't you adults? Don't you have
22 courage to do something about this, stand up and say,
23 "We're going to protect our kids, And we're going to
24 make sure that they don't promote off-label
25 prescribing to children"?

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1 Thank you. Emotion got away with me. I
2 apologize.

3 MR. ABRAMS: This is a part 15 hearing.
4 So FDA doesn't comment on questions posed to it. I
5 just want to clarify that.

6 Do we have any questions from the FDA
7 panel?

8 (No response.)

9 MR. ABRAMS: Ms. Van Syckel, thank you for
10 sharing your thoughts and your presentation with us.

11 Okay. Our final speaker is Diana
12 Zuckerman from the National Research Center for Women
13 and Families. We thank you for hanging in there to be
14 our final presenter today.

15 DR. ZUCKERMAN: Thanks very much.

16 Well, I'm last, and I will show some
17 pictures. I hope that will help in being last.

18 I'm Dr. Diana Zuckerman. I'm President of
19 the National Research Center for Women and Families.
20 Ours is a nonprofit organization dedicated to
21 improving the health and safety of women, children,
22 and families.

23 There are a lot of different ways to do
24 that, but it ends up that direct-to-consumer
25 advertising has a lot more impact on the health and

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1 safety of women, children, and families than I think
2 any of us imagined would be possible.

3 So what I would like to talk about today,
4 having heard some wonderful examples of why it is
5 important to regulated direct-to-consumer advertising
6 and wonderful examples of ideas of what could be done
7 to make advertising much more informative and helpful
8 to consumer, but today I'm going to really focus on
9 what is, not what could be. I think you have heard
10 some wonderful things about what could be, but I am
11 going to focus a little bit more on what is and what
12 the problems are that we have currently.

13 Next, please, or do I do it? Oh, I'm
14 sorry. There we go. Okay. I'm going to just show
15 some ads from magazines. And obviously this one for
16 Vioxx is a few years old.

17 What I really want to talk about is the
18 power of this ad. We can talk about the specifics of
19 the language and exactly what wording is here, but the
20 power of the ad is the image.

21 This is a beautiful image. And I
22 congratulate Merck for this wonderful photograph. It
23 really reminds me of a Norman Rockwell painting of
24 what we wish our lives were like.

25 When I first looked at this, I thought it

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1 was a mom. And then I realized, of course, no, she's
2 a grandmother. Look at her. She looks fabulous. And
3 she's bending on her knees. And she has no pain. And
4 that is the power of the image that they are selling
5 an idea that if you buy this product, your life can be
6 like this. And that is, in fact, what advertising is
7 all about.

8 My training is in psychology and
9 epidemiology. The epidemiology comes in handy when I
10 am looking at the risk data, but the psychology really
11 comes in handy when I think about how you sell
12 products and how you change people's attitudes and
13 behavior.

14 If you want to change people's attitudes
15 and if you want to change people's behavior, you don't
16 just talk to them about facts. You give them an
17 image. And this is a very powerful one.

18 The wording is great, too, "What if how
19 your body feels wasn't always the first thing on your
20 mind?" But it is the image that is so powerful.

21 And here is another one from Vioxx. These
22 were both in women's magazines a few years ago. The
23 wording actually on the right side is the same for
24 both of the ads, but, again, that's just a beautiful
25 image. This time it's a little bit more obvious that

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1 the woman is not 30 years old but, again, this great
2 image of how great your life could be without pain.
3 And that is what Vioxx is all about in these ads.
4 It's not about the specifics of the wording.

5 Both of these ads did have information on
6 the back side of the ad that did talk a little bit
7 about what the risks are, but, really, the power is in
8 the image.

9 This ad is for hormone replacement
10 therapy, again a couple of years old. So there are no
11 warnings about everything that we now know should be
12 warned about for hormone therapy, but this is, again,
13 just a great image, all of these happy mid-life women
14 looking fabulous, being inspirational.

15 And on the one side of the ad, you can't
16 probably read it, but the language is all about "If
17 you are one of the over 11 million women who take
18 Premerin or Prempro, we want to hear from you." And
19 it's all about telling your story.

20 The other side is very important because
21 that is where all of the risk information is. That
22 was on the back side of the ad, of course. And
23 assuming that you can't read it from the PowerPoint,
24 let me just tell you the very top part, which has
25 risks, just in a few sentences.

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1 We can talk about should this be at the
2 fourth grade level or should this be at the sixth
3 grade level or should this be at the eighth grade
4 level. And when our center did a booklet for breast
5 cancer patients, for example, we decided on, NCI
6 actually decided on, the sixth grade level as being
7 really important so that most patients would be able
8 to understand it.

9 This is the wording of just a few
10 sentences at the very beginning, words like "close
11 clinical surveillance," "endometrial sampling," and
12 "undiagnosed persistent or recurring abnormal vaginal
13 bleeding." I mean, that is all just a few words in
14 the first couple of sentences of risks if anybody were
15 to actually ever read it. And that font size is
16 really, really small. So that would make it
17 difficult.

18 The next ad is Zoloft. And this was I
19 think in Glamour magazine, yes, Glamour magazine, a
20 couple of years ago, again a fabulous image, "This is
21 what your life could be like." On the right side,
22 which is actually the back side of the ad, they don't
23 even have paragraphs on this stuff.

24 So these are the warnings that patients
25 are getting. And instead of having even paragraphs,

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1 let alone any white space, they have just done wording
2 right across the page. It's actually quite impossible
3 to read, even if you're young enough to read Glamour
4 magazine.

5 This next one is from Newsweek, very
6 recently, an ad for Aderal. This is a product that
7 has been reported to be associated with sudden deaths
8 in pediatric patients. But there is nothing like that
9 in this ad, again just a great image of a very happy
10 mom, very happy child, and how happy they're going to
11 be if he's taking this particular medication.

12 I did look on the Aderal Web site to see
13 what kind of warnings they have for their product
14 because, of course, they are supposed to have warnings
15 on their Web site. The main part of their Web site,
16 where it talks about it, basically says thing like
17 "This product was evaluated for safety in over 20
18 studies." I'm sure that's true, but it doesn't say
19 what the findings were. It only says it was studied
20 in over 20 studies.

21 This is my personal favorite. This is
22 Newsweek last week. This is supposed to be an
23 informative ad. All it is is you can get a free
24 sample of Ambien, which, as I'm sure you all know, is
25 for sleeping. That's all it is. That's the

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1 information it has. Bring this in. Get your free
2 sample, nothing about risk, not even about what it's
3 for, just you can get some freebies. Again, this was
4 Newsweek just last week.

5 Here is another ad, also from Newsweek,
6 two weeks ago. There have been some complaints about
7 this ad because it is kind of creepy. You know, it's
8 funny. Most of these images are beautiful and
9 compelling. This is compelling in a different way.

10 It sort of makes you a little bit sick.
11 And the idea is if your toenails are brittle, you have
12 these little disgusting creatures causing that
13 problem.

14 Again, it's a little hard to talk about
15 this as an informative ad that's helping patients make
16 important health decisions. This is a product that is
17 effective, but it has some very, very substantial side
18 effects. And you wouldn't know it from this ad.

19 You know, I don't know how effective it is
20 to get people to want to buy the product, but it sure
21 is effective to make you not want to have this
22 particular problem, I'm sure.

23 So, just in summary, I just wanted to say
24 that when we're talking about what we need to do about
25 direct-to-consumer advertising, there are enough

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1 studies that tell us how powerful these ads are, but
2 looking at them I think helps us to think about where
3 we are right now. Where we are right now is that
4 medical products are being sold just like any other
5 product, just like the toys that my children want or
6 the other products that people want to buy.

7 And, instead of really giving us
8 information about risks and benefits, really, all the
9 goal is to make us want to get them. And they're
10 effective, but they're not educating us. And it is
11 the reason why prescription drugs have been going up
12 about 28 percent per year during this time where there
13 is so much advertising and we're just surrounded by
14 it.

15 Thank you.

16 MR. ABRAMS: Dr. Zuckerman, thank you for
17 your presentation.

18 You showed a couple of advertisements and
19 you made a point of the image that you're selling what
20 you can be, promotion. How would you advise the
21 agency to regulate something like that? Where do we
22 draw the line? And what factors should we consider?

23 DR. ZUCKERMAN: Well, I think, at the
24 minimum, you would want risk information to be put in
25 a font that's as large as the benefit information. It

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1 shouldn't be on the back. I mean, I'll talk about
2 magazine ads because those were my examples right now.

3 Obviously TV is a different issue.

4 If you look at magazine ads and all of it
5 is imaging in large lettering about the benefits and
6 most of the risk information is in tiny fonts on the
7 back that many people never even look at, even if they
8 do, it's actually impossible to read.

9 I think of all of the people who are -- I
10 mean, most drugs are being sold to aging people, whose
11 eyesight is not so great. And, yet, these fonts are
12 like a size eight or nine font that most of us really
13 can't read, even when there is white space.

14 There are some ads that are better now. I
15 mean, I have seen risk information that's better.
16 There are some that actually you can read. It looks
17 more like a 10-point font or maybe even 11. And
18 there's some white space around it so you can read it.

19 But I think the absolute minimum is that
20 the risk information be understandable and really
21 obvious. And we have never had that. That has just
22 not happened yet. So there might be some little bit
23 of risk information on the front side of an ad, for
24 example, but most of the real risk information is on
25 the back, where people don't know it.

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1 And I can tell you that I asked my
2 daughter, my teenage daughter, who gets a lot of
3 magazines. And, of course, they sell a lot of
4 prescription acne medication and other things on the
5 magazines. I said, "Have you ever looked on the back
6 side of an ad?"

7 And she said, "What are you talking
8 about?" She actually had no idea what I was talking
9 about. It had never occurred to her to flip over an
10 ad and that there was information on the other side.
11 Just for the many magazines she reads and has read for
12 years, she never knew what that stuff was and just
13 never even looked at it.

14 MR. ABRAMS: So how can we get people to
15 look at that information? Suggestions? Put it on a
16 different page? Incorporate it? As you said, there
17 is more white space in some of these ads. Some
18 suggestions as far as those?

19 DR. ZUCKERMAN: Well, it shouldn't be on
20 the back. It should be next to it, and it should be
21 incorporated in the ad. I mean, I'm not a lawyer.
22 And I'm not going to try to get into the legal issues.

23 I think that advertising for medical products should
24 be very different than advertising for cars or toys.
25 And I think that there should be different rules for

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1 that.

2 And there are some rules about providing
3 risk information, and I think we should take it
4 seriously so that we can actually understand it and
5 that it's part, I mean, incorporated as part of the
6 ad.

7 If I went back to this image, at the very
8 least, it should be on that. Oh, I'm sorry. It's
9 online, but I guess it's not on there. It should, at
10 the very least, be next to that beautiful image of the
11 happy woman in her garden. The information about risk
12 should be right there, not on the back.

13 MR. ABRAMS: Dr. Behrman?

14 DR. BEHRMAN: Following up on Mr. Abrams'
15 question, can we go to the Aderal ad?

16 DR. ZUCKERMAN: Sure.

17 DR. BEHRMAN: So there you have, as you
18 pointed out, a mother and a son and her life has been
19 made complete. So one problem that you're bringing up
20 in the presentation is the risk information, but could
21 you give us some insight on how would you advise us
22 that the message that just the image is sending? What
23 are your thoughts about that in terms of what this is
24 promising to this --

25 DR. ZUCKERMAN: Well, I personally think

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1 that the image is so powerful that it should be
2 regulated. As I said, I'm not a lawyer. So I don't
3 know what the limitations are on that.

4 But when you have an image that is
5 powerful, I mean, who are we kidding when we say this
6 is an educational ad? You know, I do think that it's
7 possible that people don't know about depression or
8 ADHD and that it can be educational to let people know
9 that there are other kids like theirs and other
10 parents with problems like theirs and other people who
11 feel depressed the way they do. You know, that can be
12 educational, but that just isn't what is going on in
13 these ads.

14 So I guess my question is, you know, at
15 the very least, you want the information incorporated
16 into the ads. But I think there should be limits on
17 how powerful these images can be. I don't pretend to
18 know how one goes about doing that, but all I know is
19 that the law was interpreted differently than it used
20 to be.

21 DR. BEHRMAN: Can I ask a follow-up? So
22 what you are saying is that there is a message in the
23 image --

24 DR. ZUCKERMAN: Yes.

25 DR. BEHRMAN: -- apart from what is in the

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1 words. Do you believe -- I guess you said you
2 basically have a psychology background, epidemiology
3 background -- that you could inform or correctly
4 expand on that message with additional words or do you
5 think that is impossible?

6 DR. ZUCKERMAN: Well, I mean, anything is
7 better than what we have got now. I mean, I can tell
8 you there is a whole research, for example, on smoking
9 which shows that kids know that smoking is unhealthy,
10 but when they see advertising images showing people
11 smoking, looking sexy, and living exciting lives,
12 those images are more powerful. And they have done
13 research that shows that the kids will say it's more
14 important to them to look a certain way than to know
15 what the truth is.

16 So you could do, you know, FDA could,
17 study an impact of an ad to see what is the message
18 that is going. And if the requirement is that the
19 message be educational about the risks and benefits of
20 the ad, it could be studied. It has been studied on
21 other things.

22 MR. ABRAMS: Dr. Temple?

23 DR. TEMPLE: I think you might be saying
24 that the images are so powerful they defeat the
25 possibility of fair balance in the ad, but I had a

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1 more specific question.

2 You actually I think are suggesting that
3 there ought to be at least some of the most important
4 adverse reaction information in the body of the ad,
5 which many ads do not. I couldn't actually read any
6 of the ones you had there, but those didn't.

7 But there is also more information, maybe
8 not as much as is incorporated in this brief summary,
9 but would you think that anything more than what is in
10 the main body of the ad is simply irrelevant and that
11 you have to concentrate on getting the most important
12 stuff in there or could it be that if you got the most
13 important stuff, you still might want to have an
14 improved version of a brief summary that gave more
15 information than you could reasonably get into the ad?

16 DR. ZUCKERMAN: Okay. I should say before
17 I answer your question that, as other people have
18 stated, anything that restricts advertising for the
19 first year or two, I think, or more is a wonderful
20 thing. So let me start out by saying that, that I
21 think because the images are so powerful, to the
22 extent that they can be limited until we know more
23 about how this product actually works in the real
24 world, that would be very important.

25 To get back to your question, I do think

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1 that the most important part of the ad is the image
2 with the words, you know, not on a plain white
3 background with a tiny, tiny font.

4 I do think it would be fine to have
5 additional information, in addition to what is
6 incorporated into the main part of the ad.

7 It should not be on the back for the
8 obvious reason that most people never read it. It
9 should not be in tiny fonts for the reason that most
10 people can't even read it or wouldn't bother to read
11 it.

12 And I will tell you honestly I have looked
13 at some of these backs of ads, where, even when I was
14 highly motivated, I couldn't read it. I mean, it was
15 just, you know, I was there with my magnifying glass
16 and I still couldn't. It's just experts in this will
17 tell you it's formatted in a way that makes it
18 completely undesirable to read. People don't read
19 them.

20 So I think it would solve the problem in
21 that people who were motivated to find out could read
22 it. And that's true now, where we do have some ads
23 where on the back of the ad, you actually can read it.

24 It's large enough and it asks a question in a bold
25 handwriting, bold font, and then it answers it and

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1 it's readable.

2 But the question is, how are you going to
3 make people read it? But at least it's there. On
4 some of these ads that I'm showing, it's not even
5 there. So it's better to have it there than not
6 there. But the truth is look, they're designed this
7 way for a reason. They're designed this way to sell
8 the product. That's why they look like this.

9 You know, I guess what I would like to see
10 from the FDA is an acknowledgement that this is what
11 has been going on and a real effort to change it.

12 Now, this is I think the second time I
13 have been in this room giving this talk, although not
14 with pictures. I thought that might help, but, you
15 know, I haven't seen change in the last few years.
16 And I would really like to see some change.

17 I think I have a lot of faith that FDA can
18 do this and I see other HHS agencies, for example,
19 really requiring things at a fourth grade or a sixth
20 grade or an eighth grade reading level that is
21 important for consumers to understand. And I would
22 like to see that in the ads.

23 DR. TEMPLE: The particular thing that you
24 think would help most, though, just so we're clear on
25 what your message is, is, in addition to improving the

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1 second page, if that's going to be done at all, is
2 more balance in the body of the ad.

3 DR. ZUCKERMAN: Right. I mean, for
4 example --

5 DR. TEMPLE: More of the safety
6 information?

7 DR. ZUCKERMAN: Absolutely. It's what I
8 saw in some of these ads -- and, you know, I didn't
9 read it to you, but it will say things like certain
10 people should not take drug X, women who are pregnant
11 or nursing. You know, that's who it talks about.

12 So it will have some big risk information
13 like that that is useful, but it won't talk about
14 risks to heart attack or stroke or anything like that.

15 I mean, certainly the Vioxx ad has never said
16 anything about that, although I think they did say
17 high blood pressure.

18 Certainly the hormone replacement therapy
19 ads didn't have any kind of warning information except
20 I think -- oh, I know. They actually had endometrial
21 carcinoma. I mean, give me a break. You know, they
22 can't even say the word "cancer." God forbid somebody
23 might actually understand what they mean.

24 So even when they have risk information,
25 they really try very hard to make it not

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1 understandable. And it should be FDA's job to make
2 sure it is understandable.

3 MR. ABRAMS: Dr. Behrman?

4 DR. BEHRMAN: I'd like to press you a
5 little further. And talked and Dr. Temple followed up
6 on the notion of fair balance. And I think you have
7 been focusing a lot on the safety information.

8 I thought in the beginning you were
9 alluding to the fact that this drug in this ad and the
10 Vioxx ad promised that they work. In other words, the
11 image is that, in fact, your life has, the person's
12 life has, been revolutionized. And in our minds, we
13 would call that 100 percent effective. Have you
14 thought at all about the, if you will, implied claim
15 of the image in those?

16 DR. ZUCKERMAN: Well, yes. I mean, we
17 have talked and other people on the panel have talked
18 about, for example, giving specific information about
19 how much it works. You know, it works in ten percent
20 of the patients or patients feel slightly better, you
21 know, whatever it is.

22 Certainly the image tells you something
23 different. The image says, you know, this is what
24 your day will be like. I don't know how you parse
25 that as a federal regulatory agency, but I know that

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1 if you don't, if there are, first of all, no
2 restrictions on ads and, secondly, no easy place to
3 get the information about how this -- you know, even
4 if Vioxx didn't have risks that are serious and,
5 therefore, not on the market anymore, shouldn't there
6 have been information about how effective it was
7 compared to over-the-counter medication that costs
8 one-tenth of the price or something?

9 And so it is not just the risk
10 information. It's the benefit information that is way
11 out of proportion. So I think that is what you are
12 asking. And I agree with you completely that those
13 images tell you something about effectiveness that
14 that nowhere is explained any differently in the
15 wording.

16 MR. ABRAMS: Dr. Aikin?

17 DR. AIKIN: This is all very, very
18 interesting. Thank you for your presentation.

19 One of our previous panelists talked about
20 the perceived subjective nature of FDA review of
21 direct consumer ads. Clearly the images in
22 advertising are very powerful and they are designed to
23 sell products because it is advertising for a product.

24 Do you have any suggestions for us on how
25 we might go about quantifying evaluation of emotional

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1 pictures?

2 DR. ZUCKERMAN: Well, I would be happy to
3 get back to you on that. I am sure there are people
4 who know how to do that. I am not one of them. I
5 mean, you can study it like anything else. It is
6 really not that difficult. You show these ads to
7 people.

8 I'm not talking about focus groups. I'm
9 not a believer in that as an appropriate objective
10 measure. I mean, you do a study to say, "What is your
11 impression of the product before you see the ad or
12 what is your impression of the product after you see
13 the ad?" or you show one ad to one group and another
14 ad to another randomly selected group and you compare.

15 You know, do they want to get this ad? Will they ask
16 their doctor for this ad the next time they see their
17 doctor?

18 I mean, this is all measurable. I don't
19 think it's magic. You know, I think the hard part is
20 figuring out what FDA is going to do about it, but I
21 don't think it's hard to figure out what is the power
22 and effectiveness of these images. You know, give
23 them the wording with or without the images and see
24 what the difference is.

25 DR. AIKIN: I would agree that it would be

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1 a very useful test with or without the image. My
2 question is, how would we test gradations? Perhaps
3 the person is smiling so much. This is where we get
4 into the issue of subjective review.

5 DR. ZUCKERMAN: Okay. Well, I have to say
6 I haven't thought about this so much. But I suppose
7 in the same way that manufacturers are required to
8 provide data on the effectiveness and safety of their
9 products, they could be required to provide some kind
10 of data in some FDA-determined measurements of the
11 impact of their ads.

12 I mean, I, of course, would rather have
13 FDA do it but need the money from somewhere, maybe
14 user fees, you know, whatever it is. I mean,
15 obviously I would rather have FDA doing the testing so
16 that I would have more confidence that it was
17 accurate, but this is all measurable.

18 I think we run into problems if we say
19 people can't smile in the ads because here -- let me
20 see if I can go back. If you can see -- here we go.
21 I mean, this woman isn't really smiling, but this is
22 still a powerful, wonderful image of -- I mean, I feel
23 like I would be in Monet's gardens here. I mean, this
24 is a powerful image.

25 MR. ABRAMS: Dr. Zuckerman, thank you very

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1 much for your presentation. I want to thank the
2 fourth panel for their presentation and responses to
3 the questions.

4 (No response.)

5 MR. ABRAMS: Okay. We do have some time.

6 If anybody wishes to make public comments from the
7 floor, you're welcome to do so at this point. Please
8 identify yourself by your name and affiliation. Yes?

9 DR. LABEL: I am insufficiently tall, but
10 my name is Rima Label. I'm a physician. And I'm the
11 medical director at the Natural Solutions Foundation.

12 First of all, I want to appreciate the
13 comments of all of the panelists in the last panel. I
14 have some specific questions, first of all, as to
15 whether there has ever been a finding of fact or why
16 there has not been a finding of fact if there has not
17 been concerning the safety of direct-to-the-consumer
18 advertising given that medications, both properly used
19 and improperly used, are among the leading causes of
20 death according to studies, for instance, in JAMA.

21 At least 200,000 people per year die of
22 prescription medication complications and side
23 effects, often from polypharmacy, which results when
24 people have side effects that are treated with
25 additional medications.

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1 So if direct-to-consumer advertising
2 increases the number of prescriptions written, I would
3 like to know whether there has been a focused finding
4 of fact on the dangerousness, the increase in
5 morbidity and mortality, associated with that
6 direct-to-consumer advertising.

7 MR. ABRAMS: If I may interject, part 15
8 hearings allow us to listen for input from the public.

9 It doesn't allow us to answer questions or respond.
10 So if you wish to make comments, we would really
11 appreciate those and consider those.

12 DR. LABEL: Knowing that I will not, then,
13 receive an answer, I as a physician and citizen would
14 like to know that information and would appreciate
15 some guidance as to where that information can be
16 found.

17 Given the fact that lobbying money from
18 pharmaceutical concerns is available aplenty, --
19 according to USA Today last year, 758 million was
20 spent on congressional lobbying by pharmaceutical
21 firms -- it seems to me that now they have gone into
22 the political realm. And it seems to me that equal
23 time might be an interesting contribution for
24 non-pharmaceutical, scientifically validated
25 approaches to those same conditions that

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1 pharmaceuticals are so appealingly and so expertly
2 sold for.

3 Two more comments. I would like to know
4 whether there is any requirement or could be any
5 requirement or suggest that there might be a
6 requirement for a differentiation in
7 direct-to-consumer advertising between long-term and
8 short-term administration for physiological and
9 morbidity and mortality effects of medication in those
10 two conditions, being quite different, especially off
11 label, and also want to comment that given the new
12 freedom initiative for the intensification of the
13 administration of dangerous psycho-pharmacological
14 agents to children and adolescents, I would suggest
15 that equal time for alternatives becomes particularly
16 important for our pediatric and adolescent population.

17 And perhaps the very companies that
18 benefit from direct-to-the-consumer marketing might be
19 compelled to support some additional information so
20 that more appropriate people would receive their
21 pharmaceuticals, rather than the general spectrum of
22 the population.

23 Thank you.

24 MR. ABRAMS: We thank you for your
25 comments.

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1 I want to also state that this is being
2 transcribed. We will look carefully at the
3 transcripts of this meeting. We also encourage folks
4 who have additional comments to submit them to the
5 docket. We will review all of the information that we
6 receive.

7 Yes?

8 DR. GLINERT: Lewis Glinert, Dartmouth
9 College.

10 A brief response to the question that was
11 put to Dr. Zuckerman from the Chair concerning what
12 possibly one could do to regulate images, just
13 speaking having served for a couple of years in the
14 mid '90s on a European Union-funded project on the
15 labeling of infant milk formula.

16 At that time at least, I know that the
17 European Union had some very strict and far-reaching
18 regulations concerning images on infant milk formula.

19 To the best of my recollection, one wasn't allowed to
20 show any kind of maternal image. And that extended
21 even to a ban on teddy bears.

22 MR. ABRAMS: Thank you for your very
23 interesting comments.

24 (Laughter.)

25 MR. ABRAMS: Any other persons here wish

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1 to make a public comment? Yes?

2 DR. ZUCKERMAN: I'm sorry because I feel I
3 missed my opportunity. Of course, it would be great
4 to say no photographic images, I mean, to say no
5 images, words only. I mean, I didn't mention that
6 when asked, but if that were possible, that would be a
7 terrific solution, words only, words that give
8 benefits, words that give risks.

9 MR. ABRAMS: Thank you for that additional
10 comment.

11 Any additional comments from the floor?

12 (No response.)

13 MR. ABRAMS: Well, we had a full day. We
14 want to thank the speakers for their presentations and
15 their responses to the many questions from the FDA
16 panel. We want to thank you for your participation,
17 for coming here and attending the whole session today.

18 I also want to thank the folks who put
19 this together. Rose Cunningham is somebody who works
20 behind the scene and gets everything done. So thank
21 you.

22 (Applause.)

23 MR. ABRAMS: Okay. We will start
24 tomorrow. We have four additional panels. We will
25 begin at 9:00 o'clock. So this concludes this section

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1 of the meeting. We will reconvene tomorrow morning at
2 9:00 a.m. right here. Thank you.

3 (Whereupon, the foregoing matter was
4 recessed at 4:40 p.m., to be reconvened on Wednesday,
5 November 2, 2005, at 9:00 a.m.)

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