

UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

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PUBLIC HEARING

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WEDNESDAY,
NOVEMBER 2, 2005

The Public Hearing was held in the Lower Level Boardroom of the 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
MARTINE HARTOGENSIS
MELISSA MONCAVAGE
NANCY OSTROVE
ROBERT TEMPLE
DEBORAH WOLF
SCOTT GALSON

ALSO PRESENT:

ROSE CUNNINGHAM
JUDITH CAHILL
JOHN CALFEE
JAMES DAVIDSON
ELLEN LIVERSIDGE
PETER LURIE
GARY RUSKIN
RICHARD SAMP
ALEX SUGARMAN-BROZAN
WALLACE SNYDER
KIM WITCZAK
EMILY ALFANO

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MEG COLUMBIA-WALSH

ALSO PRESENT: (CONT.)

JOSEPH CRANSTON

RIMA LAIBOW

KATHY KASTNER

MARK TOSH

SCOTT LASSMAN

PETER PITTS

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ADJOURNMENT

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

(9:05 a.m.)

MS. CUNNINGHAM: Good morning, everyone.

We are about ready to begin, so if you will please take your seats. We have a couple of panel members that may be stuck in traffic, but in the interests of time, we're going to go ahead and start.

MR. ABRAMS: Good morning, and welcome to the second day of FDA's public meeting on Consumer-Directed Promotion of Regulated Medical Products, also known as DTC or direct to consumer promotion.

I'm Tom Abrams, director of DDMAC, the division of drug marketing, advertising, communications in CDER. I will serve again today as the presiding officer at the hearing.

As I mentioned yesterday, the agency, industry, and other members of the public have gained much experience with consumer-directed promotion, so we believe it's a good time to take a step back and to evaluate what regulatory issues should be addressed in FDA's activities.

This hearing is intended to provide a forum and an opportunity for broad public comments concerning consumer-directed promotion of medical

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1 products, including human and animal prescription
2 drugs, vaccines, electronics and medical devices.

3 We had a very productive meeting
4 yesterday, and we had 19 speakers who gave great
5 presentations, and a lot of informative responses
6 from the speakers in reply to questions from the FDA
7 panel. We also had public comments from several
8 members of the audience that were taken from the
9 floor.

10 There was much discussion about DTC at
11 the hearing yesterday, including presentation of risk
12 information, DTC's pass-one pact on the diagnosis and
13 treatment of undertreated medical conditions, DTC's
14 possible impact on other factors in the health care
15 system, data from research in regards to DTC
16 promotion, the use of celebrities in DTC, various
17 ways of presenting the benefit information, and the
18 use of consumer-friendly language in DTC.

19 These discussions were both interesting
20 and informative for the FDA panel. We appreciate the
21 input from interested parties, as these comments and
22 data from research will help guide our policy on DTC.

23

24 We encourage folks who have done research

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1 in DTC to submit it to the docket so it will be
2 publicly available.

3 FDA is a data-driven agency, so we
4 appreciate the sharing of data as it helps us develop
5 our policy.

6 The rules of Part 15 meetings do not
7 allow FDA to respond to questions from presenters or
8 other members of the public who may be making public
9 comments from the floor.

10 The purpose of the meeting is to get
11 input from the presenters and from the public. We
12 also encourage you, when you submit information to
13 the docket, to provide references to support your
14 position. This helps us evaluate and give thorough
15 consideration to the various positions that are posed
16 to us.

17 I would like to now introduce the FDA
18 panel members. Starting from my left is Kathryn
19 Aikin, social science analyst in DDMAC; Robert
20 Temple, director of office of medical policy in CDER;
21 Steven Galson, the director of CDER, which is the
22 Center for Drug Evaluation and Research, naturally.
23 Starting below is Deborah Wolf; Deborah is regulatory
24 council in the office of compliance in CDRH; Nancy

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1 Ostrove, the senior adviser for risk information in
2 the office of planning and office of the
3 commissioner; Melissa Moncavage, the leader of the
4 DTC review group in DDMAC; Martine Hartogensis,
5 promotion and advertising liaison in CBN; Glenn Byrd,
6 the chief of the promotional - the advertising and
7 promotional labeling group in CBER; and Kristin
8 Davis, the acting deputy director in DDMAC.

9 We have 19 speakers for today's part of
10 the hearing, so let me provide the ground rules so we
11 have a most productive meeting.

12 This meeting is informal. The rules of
13 evidence do not apply. No participant may interrupt
14 the presentation of another participant. Only FDA
15 panel members will be allowed to question any person
16 during the presentation, or at the end of the
17 presentation.

18 FDA is here to listen, and will ask
19 clarifying questions, but cannot comment or respond
20 to questions.

21 If time permits, after FDA panel has
22 completed the questioning of each panel, we will open
23 up the floor for public comments.

24 Public hearings under Part 15 are subject

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1 to FDA policy and procedures for electronic media
2 coverage of FDA public administrative proceeding.
3 Representatives of the electronic media may be
4 permitted, subject to certain limitation, to
5 videotape the film or otherwise record FDA's public
6 administrative proceeding, including the
7 presentations by the participants.

8 This meeting will be transcribed, and
9 copies of transcripts may be ordered through the
10 dockets or accessed on the Internet.

11 Each speaker will be provided 12 minutes
12 for their presentation, and then FDA panel members
13 will have up to eight minutes to ask questions. We
14 request that speakers keep to the 12-minute limit, as
15 we have a full agenda today.

16 So I thank you for your participation in
17 today's meeting. We look forward to hearing all your
18 comments on this important topic.

19 Now it is my pleasure to turn to Dr.
20 Galson, the director of the Center for Drug
21 Evaluation and Research, to open the meeting.

22 Dr. Galson.

23 DR. GALSON: Thank you very much, Tom,
24 and welcome to all of you for being here today. I

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1 know this is a very, very important issue for all of
2 you, and for the health of people of the United
3 States, and so I'm very glad that we are able to
4 convene like this.

5 I understand that yesterday was a very
6 full day, and we heard from a variety of different
7 people different perspectives on research,
8 regulation, technology and safety issues.

9 Dr. Woodcock gave you a brief history of
10 how direct to consumer advertising began, and I want
11 to expand a little bit more on that this morning.

12 As you know, FDA has responsibility for
13 regulating, labeling and advertising of prescription
14 drugs and medical devices. If an activity or
15 material is considered to be either advertising or
16 labeling, it must meet certain requirements.

17 We do this to ensure that promotion is
18 accurate and balanced, and helps fulfill our mission
19 of protecting and promoting public health.

20 FDA's regulations give examples of
21 labeling materials, including brochures, mailing
22 pieces, detailing, calendars, price lists, motion
23 picture films, sound recording, et cetera.

24 As Dr. Woodcock told you, FDA requested a

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1 voluntary moratorium on DTC promotion back in 1983,
2 and then withdrew it in 1985,

3 A lot has happened since 1985, including
4 the dramatic growth of DTC and the agency's policy to
5 address this growth. It would take a long historical
6 day to really address everything that has happened,
7 so I want to just go through a few of the highlights
8 so we can really get to what the purpose is and to
9 try to get input from you all, which is the main
10 thrust of how we want to spend our time.

11 We held a Part 15 hearing like this in
12 1995, issued a Notice in 1996 to clarify the
13 preclearance of consumer-directed prescription
14 product promotion, was never required, and asked for
15 additional information to help in the development of
16 overall policy.

17 In 1997, we issued a draft guidance
18 describing ways in which companies could fulfill the
19 existing requirements of adequate provision for
20 access to the approved product labeling in connection
21 with DTC broadcast advertising.

22 This guidance was finalized in 1999. FDA
23 conducted research to try to determine how DTC
24 promotion affects the doctor-patient relationship,

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1 and there is research that has been done outside of
2 that that we've done, as well. We've heard about
3 some of that. And we held a public meeting two years
4 ago to present our results, and listen to the results
5 of other researchers.

6 This was a very insightful meeting, and
7 information was very helpful to us preparing the
8 draft guidances that were then issued in February of
9 last year pertaining to consumer-directed promotion.
10 Comments on these draft guidances are currently under
11 consideration.

12 Since, in the last year, as well, I think
13 you all know that the Pharmaceutical Manufacturers
14 Association has issued a new policy on promotion, and
15 their attempts to try to pay, in particular, some
16 more attention to many of their critics who have said
17 they don't police themselves enough, and that is
18 probably going to fundamentally change the way that
19 we get information from the industry, and perhaps the
20 review that takes place before it comes to us. These
21 are all changes that we are going to have to consider
22 in making final policy decisions in the next year or
23 so.

24 Again, today we've got a very full

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1 agenda. I don't want to take too much time away from
2 it on history. We look forward to what all of you
3 have to say to us. We're very interested. We want to
4 emphasize that everything is being recorded so that
5 even if we don't react or ask questions about it
6 right now, we've got it there, and we can review it
7 along with what was said yesterday, and additional
8 items that are submitted in writing. So there are
9 lots of ways to provide this input.

10 So thanks again for taking time away
11 from your busy schedules to help us in this very,
12 very challenging policy and decision-making arena
13 for the FDA.

14 Thanks.

15 MR. ABRAMS: Thank you, Dr. Galson.

16 And before we begin, I'd like to just
17 review the agenda.

18 We will have two panels this morning.
19 In between the two panels we'll have a break. After
20 these two panels we'll break for lunch, and
21 reconvene, and have an additional two panels in the
22 afternoon.

23 So let's begin our first panel of the
24 second day with Judith Cahill from the Academy of

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1 Managed Care Pharmacy.

2 MS. CAHILL: Good morning.

3 I am Judy Cahill. I am executive
4 director of the Academy of Managed Care Pharmacy,
5 and I'm pleased to have the opportunity to present
6 the Academy's view on a topic that we consider to be
7 of prime importance for those who are involved with
8 the delivery of an adequate pharmacy benefit.

9 The Academy of Managed Care Pharmacy is
10 an organization that is a professional society for
11 pharmacists who have chosen to practice their
12 profession by the application of managed care
13 principles.

14 What that translates into is an
15 organization comprised of senior directors from
16 health plans, from health maintenance organizations,
17 from insurers, from pharmacy benefit management
18 companies, and from manufacturers who have an
19 interest in how the managed care pharmacy benefit is
20 designed, and how it is implemented.

21 That gets the Academy members involved
22 with formulary decision making, examining from
23 intensive manuscripts the attributes and the
24 weaknesses of drugs that are competing for room on

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1 their formularies.

2 It also gets the Academy members
3 involved with drug utilization review, so that they
4 can assess the appropriateness of the drug regimens
5 that their patients are encountering. It also gets
6 them involved with safety and medication error
7 monitoring.

8 One of the important aspects of what the
9 Academy members are involved with is monitoring
10 their patients' use of drugs in order to have
11 effective outcomes in the most productive way for
12 the populations they serve.

13 They are interested in both the clinical
14 aspects of pharmacy benefit delivery, and in the
15 business aspects.

16 We all know that the cost of drugs keeps
17 escalating. We all know that we have a finite pot
18 of resources to address those health care costs that
19 are part and parcel of how we do business in this
20 country today. And because of that, the managed care
21 pharmacist brings both the clinical and the business
22 acumen to bear to try to deliver appropriate drug
23 benefits.

24 There has been heightened interest, of

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1 course, courtesy of the Medicare Modernization Act
2 and the impending introduction of Part D. We all
3 feel as though we're going to be on trial come
4 January 1, 2006, and we're all awaiting, with some
5 breathlessness, what is going to come about. AMCP
6 supports direct to consumer advertising insofar as
7 it can be used to educate the public about disease
8 and the symptoms of disease. We encourage it for
9 the discussion of alternative treatment options.

10 We are fully aware that medications can
11 be an integral part of the delivery of health care
12 for patients, particularly with chronic conditions,
13 but we also realize that the proper decision in many
14 instances for patients is no medication therapy, and
15 that there are other ways that patients can address
16 the disease states that they are afflicted with, be
17 it diet, be it exercise, be it other behavioral
18 lifestyle changes.

19 We do discourage advertising that
20 promotes specific prescription drugs. We believe
21 that, insofar as DTC can improve awareness about
22 disease and disease symptoms, that it plays a
23 crucial role. Indeed, the FDA's own surveys of

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1 physicians have shown over the years that the
2 dialogue that can be encouraged by direct to
3 consumer advertising between patients, physicians
4 and pharmacists, is something that does encourage
5 healthier lifestyles.

6 We do believe that patients need to be
7 informed about what their treatment options are, and
8 what alternatives they have before them, as they are
9 facing choices about how to treat their symptoms.

10 We are concerned that product-specific
11 DTC advertising does a disservice to the public if
12 its aim is only to engender name recognition and to
13 garner market share.

14 We believe it does a disservice if it
15 creates an unwarranted patient demand, and we have
16 seen the studies that have been produced of surveys
17 of physicians who report about the increased
18 dialogue with patients, and the demand on the part
19 of patients for prescription items that they have
20 seen advertised.

21 I'll take just a moment to tell you
22 about an anecdotal study. One of the Academy

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1 members who is pharmacy director for a Portland,
2 Oregon-based health plan, was talking about a
3 routine encounter that he does periodically with
4 physicians. And what he has in front of him is their
5 prescribing profile, and he talks to them about what
6 they are encountering with patients. In one such
7 encounter of this sort, a physician offered that
8 Mrs. Jones came in, sat down, had an ad in hand, and
9 said, doctor, I must have this drug. And he said,
10 well, Mrs. Jones, you are already on that drug. And
11 she said, "Why don't I look 25 years old?"

12 It's just anecdotal in nature. But I
13 think it does exemplify how direct-to-consumer
14 advertising can engender unwarranted need --
15 unwarranted demand on the part of patients for
16 drugs.

17 If the DTC advertising is misleading, if
18 it's not fair, if it's not balanced, if risks are
19 not fully explained, and if it is silent about
20 alternative treatment options, we believe it does a
21 disservice.

22 Dr. Galson pointed out the draft
23 guidance that was passed in August of 1997, and

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1 we've seen these figures before, so I won't dwell on
2 them. But look at the growth of spending on DTC
3 post-August, 1997. A quantum leap, to be sure.

4 The 1997 draft guidance gave
5 manufacturers the ability to identify products by
6 name. It also ushered in a quantum leap from
7 informational advertising to marketing and
8 promotional advertising, and we believe that that is
9 something that is not in the best interests of the
10 public.

11 The FDA remedies, the FDA can issue
12 letters, and those letters that would require
13 revision or withdrawal of an ad are effective. We
14 know of no instances where a manufacturer has not
15 been responsive to the letters that come from the
16 FDA asking for revision.

17 However, because the FDA does not have
18 preapproval, a 30-second ad on Super Bowl Sunday can
19 have an impact that no amount of revision in later
20 days can address.

21 I'd like to take a moment to look at the
22 General Accountability Office findings from a 2002

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1 report when it looked at direct-to-consumer
2 advertising. They concluded that advertising
3 appears to increase drug spending and utilization;
4 that advertising that is concentrated among a small
5 number of drugs for chronic conditions, and many of
6 the same are also promoted to physicians in the type
7 of detailing that is done of physicians. They
8 concluded that some manufacturers have repeatedly
9 disseminated misleading ads for the same drugs, and
10 that manufacturers have failed to submit, or to
11 submit in a timely manner, all newly disseminated
12 ads to FDA for review.

13 Now, there is not a direct causal link
14 between DTC and medication risks. However, because
15 it does - DTC can engender patients to demand drugs
16 that they otherwise would not need, it presents a
17 vulnerability within our system for not only
18 spending money on drugs that are not warranted, but
19 for incurring patient risks.

20 I draw your attention to a Sloan study
21 that was published in the Annals of Internal
22 Medicine just this year. That Sloan study said that
23 in the latter half of 2003, 81 percent of adults who

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1 were on Cox-2 inhibitors did not have
2 gastrointestinal bleeding that would have warranted
3 the use of what has turned out to be a very
4 dangerous medication. And it's this aspect of
5 direct-to-consumer advertising that is of utmost
6 concern to the Academy.

7 Our suggestions are to give FDA
8 legislatively more authority over DTC advertising.
9 We have petitioned Congress, and we will continue to
10 do so, to grant mandatory prior approval for all
11 medication advertising.

12 We also are petitioning Congress, and
13 have done so already, and will continue to do so, to
14 adequately fund the agency so that when this
15 authority is given to them by legislation, they will
16 have the resources to be able to act on it.

17 We also encourage the oversight of the
18 content of direct-to-consumer advertising, and ask
19 that it be focused on raising awareness of disease,
20 that it explore treatment options, that it stimulate
21 patient and provider dialogue, and that it encourage
22 healthier lifestyles. But we do not encourage
23 product-specific advertising.

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1 I'd be pleased to take any questions
2 that there may be.

3 MR. ABRAMS: Thank you, Ms. Cahill, for
4 your presentation.

5 The first question I have, you mention
6 that you have concerns about DTC generating
7 unwarranted demand for prescription drugs, and you
8 also stated that FDA's remedies are effective in
9 stopping misleading promotion. And you made some
10 recommendations which are beyond FDA as far as other
11 groups.

12 If you were to advise FDA more that we
13 could do within our own control, what steps do you
14 think we should take?

15 MS. CAHILL: I would suggest that, with
16 the current authority that we understand that the
17 agency has, that you pay close attention to content,
18 and that insofar as the content is geared to
19 stimulate constructive dialogue between the patient
20 and the physician, or even to not only encourage
21 that, but to start it, to get the patient thinking
22 about why it is that I have this pain in my back,

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1 maybe I ought to go see somebody about this, that
2 that type of encouragement of patients taking steps
3 to receive the care that could lead to intervention
4 in a disease before it becomes problematic, before
5 it advances into a problematic state, is something
6 that we think is very important, and that direct-to-
7 consumer advertising can contribute to. But insofar
8 as it goes to speak to specific drug products, we
9 have a problem with that.

10 MR. ABRAMS: Dr. Temple.

11 DR. TEMPLE: I am not going to remember
12 who said this yesterday, and we haven't seen all the
13 data yet. But at least somebody put forth the idea
14 that, if a general health awareness ad doesn't name
15 a specific product, nobody actually goes to the
16 doctor. I don't know whether that is true or not,
17 and it probably deserves more research before one
18 would believe it. But if that were true, that would
19 argue that, even if you do have a health awareness
20 component to your ad, if you don't - they may need
21 to name a product, anyway.

22 Do you have any thoughts about that?

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1 MS. CAHILL: Well, I would suggest that
2 we look at what happened prior to August of 1997.
3 There was over \$700 million being spent on direct to
4 consumer advertising in that era, and it did focus
5 on raising public awareness of disease, disease
6 symptoms, and to some extent alternative therapies.

7 And in that era, obviously there was a
8 decision on the part of those who were spending
9 those advertising dollars that something was
10 happening.

11 I do believe that, with the increase in
12 direct-to-consumer advertising, we've seen more of a
13 stimulus for encouraging doctor-patient discussions,
14 but it is the unwarranted demand that is our chief
15 concern about what we are seeing today.

16 DR. TEMPLE: And just to follow up, when
17 you say unwarranted demand, do you literally mean
18 that they are getting treatment when they don't need
19 it, or that they are using, say, a more expensive
20 product than they really need to, or something like
21 that?

22 MS. CAHILL: That they are getting

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1 treatment that they don't need.

2 DR. TEMPLE: Any particular things you
3 can identify?

4 MS. CAHILL: Well, the Sloan study is
5 the one that I mentioned before, where 81 percent of
6 the adults on Cox-2 inhibitors did not have
7 gastrointestinal bleeding prior to being put on the
8 Cox-2 inhibitors.

9 I think that the -- probably the
10 bellwether incident that we look at.

11 MR. ABRAMS: Dr. Aikin.

12 DR. AIKIN: You mentioned that you felt
13 that the DTC advertising does a disservice if it is
14 silent about alternative treatments, or alternative
15 options. There are, Dr. Temple can correct me if
16 I'm wrong, regulations that cover the use of
17 comparative claims in advertising. Do you have any
18 suggestions on how advertising could mention
19 alternative therapies without making implied
20 comparative claims to other products?

21 MS. CAHILL: I think we see that to some

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1 extent today, where there is not actual product-to-
2 product citation, but there are some ads that we
3 consider to be more responsible than others that do
4 say, talk to your doctor about what your
5 alternatives are, that this is one alternative,
6 surgery may be another.

7 DR. AIKIN: So just general statements
8 about alternatives?

9 MS. CAHILL: Right.

10 DR. AIKIN: Thank you.

11 MR. ABRAMS: Thank you, Ms. Cahill.

12 Our next speaker is John Calfee from the
13 American Enterprise Institute.

14 MR. CALFEE: Well, thank you. It's an
15 honor to be here talking to the FDA and to everyone
16 else who is here.

17 I'm just going to focus on a fairly
18 narrow topic, but one that I think is worth paying
19 attention to, which is to look at the evidence that
20 has come out of New Zealand, as well as of the
21 United States, and to make some comparisons.

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1 As a lot of people know, New Zealand is
2 the only other advanced country that permits DTC
3 advertising. In both countries it happened more or
4 less by accident. The manufacturers, the industry
5 discovered at some point that advertising to
6 consumers was not prohibited. And so we got DTC
7 advertising here in the U.S., and we got DTC
8 advertising in New Zealand.

9 The two countries are very different.
10 Their health care systems are very different. Their
11 regulations are very different. So a natural
12 question is, what are we learning from these
13 different experiences? And we're fortunate in having
14 a few very good survey researchers in New Zealand
15 who are doing work in this area, some of whom have
16 actually worked to some extent with the FDA to
17 coordinate on some of their efforts. And so we've
18 gotten some information that I think is really quite
19 valuable and does not receive as much attention as
20 it should.

21 As I mentioned, New Zealand has a very
22 small economy, small population; roughly the size or
23 even smaller than the D.C. metropolitan area.

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1 Health care is funded almost entirely by
2 the government. Pharmaceuticals are paid for almost
3 entirely by the government. Drug prices are tightly
4 regulated by the government. The regulatory system
5 for DTC is very different. The requirements in New
6 Zealand are what we would think of as being somewhat
7 broad and general and maybe even a little bit vague,
8 and must comply with the general rules, advertising
9 rules in New Zealand. A code of ethics has been put
10 together by the pharmaceutical industry, meet high
11 standards of responsibility, et cetera.

12 It must make certain sweeping statements
13 in connection with all such advertising such as, use
14 strictly as directed, consult your doctor, et
15 cetera.

16 It must pay attention, the ads must pay
17 attention to whether or not there is an extra fee
18 for the particular drug, bearing in mind that most
19 of these drugs are covered by the government or paid
20 for by the government.

21 Do not mislead, et cetera, et cetera.

22 All of this is done in New Zealand, not

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1 by the same authority that approves new drugs and
2 regulates health care generally, but by self
3 regulation, through the Advertising Standards
4 Authority, which regulates all advertising, not just
5 DTC advertising.

6 I should mention that the system has
7 been changing, and is now changing, and will
8 continue to change, but the data that we're looking
9 at reflect the system that I've been describing.

10 It is a self-regulation scheme run by a
11 very small staff, but with more or less a board of
12 outside medical authorities that give them a lot of
13 input and a great deal of advice which is often
14 regarded as more or less binding.

15 DTC ads are prescreened in New Zealand.
16 The response to complaints from consumers,
17 physicians, competitors, et cetera, the responses
18 are very rapid. It's a very quick and very
19 efficient system. And the entire system is enforced
20 by the government as a last resort, but that almost
21 never happens. It's actually enforced by the media.

22 That is to say, if the Advertising Standards
23 Authority has looked at a particular ad, has decided

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1 there is a problem with that ad, and thinks that ad
2 should be withdrawn or changed, if the manufacturer
3 does not do that, then the media will refuse to run
4 the ads, and that is a very efficient and effective
5 enforcement mechanism.

6 There is no need to go through how DTC
7 advertising is regulated in the United States. I
8 would mention, again, that there are two basic
9 differences between the systems that we are
10 comparing, one being the regulatory environments,
11 and the other being the financing and the price
12 controls of the pharmaceuticals that consumers are
13 interested in.

14 So, what kind of results do we have?
15 This all draws from an article that was published a
16 year or two ago, which I will submit for the record.

17 It does not review all the surveys; it picks out
18 just maybe three or four or five different surveys
19 that happen to be strikingly relevant, and also
20 happen to involve some numbers that facilitate
21 direct comparisons.

22 If you look at overall exposure to DTC
23 advertising, the patterns are extremely similar;

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1 very high awareness of television advertising,
2 strong awareness of magazine advertising, et cetera,
3 and overall the numbers are quite similar in the two
4 countries.

5 Looking at the information that is
6 recalled from advertising, in some cases extremely
7 similar, such as on the benefits of medicine. In
8 other cases, there are striking differences.
9 Details of who should take a particular medicine,
10 there is less awareness of that in the New Zealand
11 ads than in the U.S.

12 Information on who should not take a
13 medicine, far less awareness from the DTC ads in New
14 Zealand compared to the U.S.; the same applies to
15 risk information. This reflects the differences in
16 the regulations. The DTC regs, at least so far, do
17 not have the explicit requirement of a balance
18 between risk and benefit information in advertising,
19 and there is generally less risk information, in
20 some cases far less risk information, in New Zealand
21 ads, although that is moderated according to the
22 actual circumstances, so that a particular drug that
23 involves very substantial risk, you will see more

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1 risk information, or else you won't see the drug
2 advertised at all. The general philosophy has been
3 in New Zealand that most risk information will come
4 from the physician if and when the patient talks to
5 a physician about an advertised drug.

6 Some more information: In some cases,
7 again, the patterns are very similar, such as making
8 people aware of new medicines in New Zealand as in
9 the U.S. It's quite apparent that DTC advertising
10 is quite effective as a force.

11 Helping people make better decisions -
12 again, a small majority agree that the ads do help
13 them make better decisions.

14 There was a question in a couple of
15 surveys, including at least one in New Zealand, at
16 least one in the U.S., about whether ads confuse
17 patients and consumers.

18 And one of the interesting things is
19 that in New Zealand, the confusion level appears to
20 be less, at least the perceived confusion level is
21 less in New Zealand than it is in the U.S., which is
22 roughly consistent with the idea that cleaner and

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1 simpler ads are less confusing, and the ads in New
2 Zealand do tend to be cleaner and simpler.

3 Another interesting question, which is
4 whether or not people assume that only the safest
5 drugs are advertised through DTC, which as a general
6 rule, as you know, is not true, although there are
7 certain drugs that are quite risky, that either tend
8 not to be or flat out are not advertised in the U.S.
9 or in New Zealand.

10 But in New Zealand, a substantially
11 smaller proportion of respondents assumed that only
12 the safest drugs are advertised. And again, I think
13 this is kind of a less is more situation. There
14 isn't a lot of risk information in the ads, in most
15 DTC ads. But patients and consumers tend to assume
16 that it is the nature of pharmaceuticals that they
17 are dangerous, and they assume that even drugs that
18 are advertised with relatively little risk
19 information are, in fact, risky.

20 On the balance of information, this is
21 where you do see some striking differences. Most
22 people in New Zealand think that ads should contain
23 more risk information. Actually, in surveys in the

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1 U.S. also tend to show that most people think the
2 ads should show more risk information, but the
3 majorities are larger in New Zealand than they are
4 in the U.S. My suspicion is that it doesn't matter
5 how much risk information you put in the ads, you
6 always get at least a small majority of people
7 thinking that even more risk information should be
8 in there.

9 Information about the benefits - I'm
10 always surprised at how many people think that drug
11 ads ought to have more information about the
12 benefits of drugs. The proportion actually tends to
13 be higher in New Zealand than it has in the U.S.,
14 although this doesn't put together all of the
15 surveys.

16 There is an item at the bottom here. I
17 trust the information in prescription drug
18 advertisements. Only 29 percent of New Zealand say
19 that they trust ads. I'm not aware of any
20 comparable questions in U.S. ads. But I think it's
21 worth pointing out that one of the things I and some
22 co-authors have done over the years is to go back
23 and look at survey data on advertising generally,

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1 50, 60, 70 years. And what those data show
2 consistently, year after year, regardless of how the
3 FTC or anyone else regulates advertising, is that
4 roughly two-thirds to 70 percent of consumers don't
5 trust advertising if you ask them whether they can
6 trust the information in advertising. The numbers we
7 have here are very consistent with that. It doesn't
8 mean they don't trust any individual ads; it just
9 means they go into advertising with a presumption
10 that advertising is not to be trusted. They think,
11 surprisingly, that it is self-interested.

12 Then we have some information about
13 whether ads give information that is useful in
14 talking to the doctors. Large majorities in both
15 countries say that they do. They think they help
16 with their discussions in talking to doctors.

17 Some conclusions, which I think can be
18 pulled out of this data - and again, I'm just
19 bringing this to everyone's attention because I
20 think there is something to be learned when you look
21 at countries that are very different, especially
22 with very different regulatory regimes, to see
23 whether there are certain kinds of things that tend

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1 to be more or less robust in these very different
2 systems. And I think we do see quite a bit that is
3 useful in looking at these two different bodies of
4 data.

5 The ads in New Zealand are very
6 different from those in the U.S. - not entirely, but
7 in many ways they are. The regulatory systems are
8 very different. The financing of drugs is very
9 different.

10 When we do see substantial differences
11 in the survey results, those differences usually
12 reflect differences in how the ads are regulated.
13 Where you require much less risk information, you
14 do in fact get less risk information.

15 But on the whole, I think that what you
16 are going to learn from both datasets, both national
17 experiences, is that consumers perceive substantial,
18 and on the whole similar benefits from DTC
19 advertising in both the U.S. and in New Zealand.
20 And again, in both cases, there is little, very
21 little evidence, of any significant harm coming from
22 DTC advertising. And again, I think this reflects -
23 - the common experiences of these two countries

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1 reflects the regulatory differences, and suggests,
2 at least to me, that there is a substantial element
3 of what you might think of as robustness in the way
4 DTC advertising, as is true for all advertising,
5 works in these two countries.

6 And that concludes my remarks, and I'd
7 be glad to answer any questions, if I can.

8 MR. ABRAMS: Ms. Davis.

9 MS. DAVIS: Hi, thank you for your
10 presentation.

11 I have a question about the evidence
12 that you have from New Zealand surveys. In the
13 United States some of the survey evidence that we
14 have seen indicates that some of the positive
15 effects of DTC advertising might be getting people
16 to their doctors to treat undiagnosed or under-
17 treated health conditions. Are you aware of any
18 evidence in New Zealand about the effects that
19 advertising there might have on those parameters?

20 MR. CALFEE: That's a good question. And
21 obviously I'll check between now and the end of the
22 comment period. But my recollection is that there

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1 isn't very much. As you know, it turns out to be a
2 difficult topic to research, but I suspect that when
3 I and Gendell Hoek, the New Zealand researcher, when
4 we were putting together this article, that if we
5 had had some really good evidence at hand, we would
6 have put some focus on that. My recollection is that
7 there isn't very much that addresses that directly.
8 But again, I'll check.

9 MS. DAVIS: Okay, thank you.

10 MR. ABRAMS: Dr. Temple.

11 DR. TEMPLE: The last conclusion you
12 showed was that the surveys reveal little evidence
13 of harm. Of course these are surveys of people's
14 opinion about stuff. So, if there were overuse of
15 some drug, an inappropriate use, it wouldn't pick
16 that up, I guess.

17 I wonder if you knew of any examinations
18 in New Zealand that went to the question of
19 inappropriate use, or something like that for some
20 or many classes of drug?

21 MR. CALFEE: Your point is well taken.
22 There are lots of harms and benefits that would not

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1 be discovered. I mean, you could have drastic
2 overuse, and you wouldn't know that. If the drugs
3 are more or less free, I think it's safe to assume
4 that a lot of them are overused. That doesn't
5 necessarily mean that there is any kind of physical
6 harm coming from it, maybe unnecessary expense.

7 I'm not aware of any research on that.
8 I know that there has been some, what I think of as
9 informal research on it, such as surveys of doctors,
10 in which they provide, again, their opinions, their
11 opinions being that some people ask for drugs they
12 don't need, et cetera, et cetera.

13 That evidence, my sense of that evidence
14 is that it is pretty soft. But that doesn't - like
15 I say, that doesn't rule out a lot of problems.
16 And, as you might expect for a country this size,
17 there is just not a lot of government research
18 that's done on this. It's just too small a market
19 to research, and it's a difficult topic to assess.

20 So the short answer is, I don't know.

21 MR. ABRAMS: Ms. Wolf.

22 MS. WOLF: You said something about the

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1 advertising in New Zealand being more clean or more
2 clear. What did you mean by that?

3 MR. CALFEE: What I mean is that the few
4 New Zealand ads that I've seen, TV ads, and we
5 actually had the gentleman who, at least until
6 recently, ran the self regulatory group, speak at
7 one of our conferences, the ads include - as a
8 general rule they do not include the - for some of
9 us, rather elaborate voiceovers that you get in the
10 U.S. TV ads. And so you see something that may focus
11 on a drug, something it could do for you and so on,
12 but it's a much simpler message in the sense that
13 you don't have this back and forth that you have in
14 U.S. ads, it can do this, but it could do that, it
15 could do this, but it could do that, sometimes
16 voiceover, sometimes not, carefully, as you know,
17 carefully arranged to produce something that the
18 manufacturer hopes comes out on balance favorable
19 rather than unfavorable to his drug. So in that
20 sense, they are simpler. The print ads are also
21 simpler. As you know, some of our print ads could
22 hardly be more complicated, and you don't have the
23 extraordinary complexity in the print ads in New
24 Zealand that you do in the U.S. That's what I meant

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1 when they're cleaner and simpler.

2 MR. ABRAMS: Thank you, Dr. Calfee.

3 Our next speaker is James Davidson from
4 Davidson & Co.

5 MR. DAVIDSON: Good morning, ladies and
6 gentlemen. I am Jim Davidson. I serve as executive
7 director of the Advertising Coalition. The
8 Coalition is a group of trade associations and
9 companies that include advertisers, advertising
10 agencies, advertising professionals, broadcast,
11 cable, newspaper and magazine media.

12 The professionals that lead these
13 organizations and their members view themselves as
14 having a tremendous responsibility to their readers,
15 viewers, consumers, clients and companies to provide
16 valuable information to their readers.

17 In a moment, I will share with you some
18 of the feedback from one of those audiences. We're
19 grateful to FDA for its positive leadership in
20 finding ways to better communicate information about
21 health care and prescription medicines to consumers.

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1 You consistently have offered
2 constructive forums for examining DTC advertising,
3 and you have, out of these forums, put forward
4 positive guidance for improving this form of
5 communication.

6 FDA regulations and guidance recognize
7 that advertising in its various formats provide a
8 primary means of getting the attention of consumers,
9 and providing them with the information they need to
10 participate in important decisions about their
11 health care.

12 FDA requires print advertisements for
13 prescription drugs to include lengthier, more
14 complicated brief summary of the product's side
15 effects and counter-indications. Broadcast
16 advertising, on the other hand, must contain a
17 statement of the product's major side effects and
18 counter-indications, and must either make adequate
19 provision for dissemination of the product's package
20 labeling, or present a brief summary of the side
21 effects and counter-indications in the
22 advertisement.

23 The adequate provision requirement can

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1 foster a complementary relationships for broadcast
2 ads to use print publications to disseminate more
3 detailed information for consumers who may not use
4 the Internet or other sources to seek information
5 about what's being advertised.

6 I want to address today four aspects of
7 DTC advertising that I think illustrates the
8 important role that it plays.

9 First, DTC advertising is protected
10 commercial speech.

11 DTC advertising has motivated millions
12 of Americans to seek advice from their doctors, and
13 a significant portion of those seeking help suffer
14 from high priority conditions.

15 DTC advertising raises awareness about
16 under-diagnosed conditions, and helps address public
17 disparities.

18 And finally, I believe that industry
19 self regulation promises to further enhance the
20 quality of DTC advertising.

21 DTC advertising is an important form of

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1 communicating health information, and will continue
2 doing that into the future. It serves neither the
3 public interest nor the public health to seek a ban
4 on speech that is imposed by the government either
5 permanently or for arbitrary periods.

6 It is noteworthy that one of the
7 earliest cases before the Supreme Court on
8 commercial speech, and one of the most recent,
9 involved prescription drugs. Justice Blackmun,
10 writing for the majority in the 1976 Virginia
11 Pharmacy Board case, explained why. As to the
12 particular consumers interest in the free flow of
13 information, that interest may be as keen, if not
14 keener by far, than his interest in the day's most
15 urgent political debate.

16 Twenty-six years later, Justice O'Connor
17 wrote, "If it is appropriate for the statute to rely
18 on doctors to refrain from prescribing compounded
19 drugs to patients who do not need them, it is not
20 clear why it would not also be appropriate to rely
21 on doctors to refrain from prescribing compounded
22 drugs to patients who do not need them in a world
23 where advertising is permitted." The decision struck

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1 down a prohibition on advertising compounded drugs.

2 Successful advertising informs and
3 motivates its readers and viewers. To achieve this,
4 good advertisers must respect their audiences and
5 offer them information that they can understand and
6 use, and upon which they can rely. Anything less,
7 and they risk breaking an intangible bond of trust
8 that exists with their audience.

9 Advertising that does not inform, or
10 that misleads its audience, likely will not get a
11 second chance. Moreover, FDA has extensive powers
12 to regulate ads it determines to be misleading and
13 untruthful.

14 FDA has demonstrated that it is prepared
15 to use that authority to sanction DTC advertising.
16 According to Prevention magazine, an estimated 62
17 million Americans say they have spoken to their
18 doctors about an advertised medicine.

19 Various surveys, including those
20 conducted by FDA, suggest that between 25 and 30
21 million Americans have been prompted by an ad to
22 talk to their physician for the first time about a

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1 medical condition.

2 Nevertheless, if you ask the surgeon
3 general of the United States, the director of the
4 Centers for Disease Control, or the HHS assistant
5 secretary for health, I doubt any of them would say
6 that too many Americans are making appointments with
7 their doctors to seek health care.

8 One of our greatest challenges is to
9 find ways to increase health literacy and awareness
10 of our population, and to motivate Americans to seek
11 health care assistance when it is needed.

12 The message doesn't have to be presented
13 in pristine, white-jacketed format, but in any
14 medium that will prompt the question for further
15 research by the consumer. Advertising should inform
16 and motivate; it doesn't need to be encyclopediac.

17 Former FDA Commissioner Mark McClellan has said,
18 less is more.

19 DTC advertising has demonstrated its
20 ability to play an important and effective role in
21 raising public awareness of health care conditions
22 and treatments. It's helped to lower patient

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1 anxiety or embarrassment by removing the stigma from
2 certain diseases and discussing them with family
3 members and medical professionals.

4 I would note that Harvard University,
5 Mass. General Hospital, and Harris Interactive, in
6 a well known study, determined that 35 percent out
7 of 3,000 people surveyed said that they sought
8 medical advice after seeing an advertisement. It
9 was consistent with earlier FDA and Prevention
10 magazine surveys, but it offered an important new
11 insight. Twenty-five percent of those who went to
12 their doctor received a new diagnosis. Of those, 43
13 percent were for high priority conditions, including
14 hypertension, diabetes, high cholesterol levels, and
15 depression.

16 Instead of looking for ways to limit
17 this speech, DTC advertising expands awareness of
18 health conditions and care for the under-diagnosed
19 and underserved populations in our society. It helps
20 reduce disparities between different population
21 groups, and their access to health care.

22 According to the Centers for Disease
23 Control, nearly one out of three adults has high

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1 blood pressure, or 65 million Americans. Thirty
2 percent, or 19-1/2 million, don't know they have
3 this silent killer, and 25 percent are receiving
4 inadequate therapy.

5 Diabetes, the sixth leading cause of death in the
6 United States - 21 million Americans are affected;
7 that's seven percent of the U.S. population. Six
8 million do not know that they have this disease.
9 Moreover, more than 20 percent of men who went to a
10 doctor seeking treatment for erectile dysfunction
11 were diagnosed with high blood pressure, diabetes,
12 or heart disease.

13 Nearly 40 million Americans suffer from
14 depressive disorder, and yet only four to eight
15 million Americans are receiving active treatment for
16 depression.

17 Between 1987 and 1997, the percentage of
18 Americans being treated for depression more than
19 tripled nationwide from seven-tenths of a percent to
20 2.3 percent. Dr. Mark Olafson, associate professor
21 of clinical psychiatry at Columbia University,
22 attributed the expanded treatment in part to the
23 number of multimillion dollar marketing campaigns.

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1 Other factors included a decrease in the stigma
2 associated with depression, and the arrival of new
3 and more powerful drugs to treat depression.

4 Dr. Richard Kravitz at the University of
5 California at Davis, often cited by critics of DTC
6 advertising, said that the private sector's
7 financial resources and ability to reach huge
8 markets can be brought to bear on the public issue
9 of bone health. DTC apparently works to get people
10 to read and act upon the information they contain.

11 DTC advertising often offers another
12 important means for raising public awareness. It
13 can address public health disparities in underserved
14 populations.

15 Dr. Jane DelGado, who is president and
16 CEO of the National Alliance for Hispanic Health,
17 told a House Energy and Commerce Subcommittee that
18 access to information is a critical piece in the
19 access picture for Hispanic and other under-served
20 communities.

21 New research is showing that health care
22 disparities among black, Hispanic and white

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1 Americans cannot be explained wholly by disparities
2 in income and health insurance coverage among these
3 groups. Other factors, such as lack of information,
4 play a critical role, Dr. DelGado said.

5 Now, I want you to look at a survey that
6 Women's Day conducted. Women's Day is a magazine
7 that reaches 20 million Americans, or one in five
8 American women. The publisher of Women's Day is a
9 member of the Magazine Publishers of America, which
10 is part of the advertising coalition.

11 Through its research to 100,000 people
12 in its reader panel, Women's Day received hundreds
13 of examples of how prescription drug advertising
14 positively affects lives and encourages a dialog
15 between its readers, family members, and doctors.
16 Here are some of their stories.

17 "Advertisements for a product prompted
18 me to visit my physician to seek relief from my
19 migraine headaches. I now take that product and
20 feel that I've been given my life back. I can live
21 again instead of worrying about getting a migraine."
22 That's Debby from Paynesdale, Michigan.

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1 Samantha from Bedford, Texas, said: "I
2 suffered from severe depression and anxiety. I was
3 trying to find something to even out my moods. I
4 discussed many medications with my doctor, and found
5 an ad for this product and spoke to him about it."

6 "It turned out to do miracles for me and
7 my children's well-being. It continues to improve
8 my quality of life."

9 Cindy from Muncie, Pennsylvania: "My
10 mother was very depressed, and after months of being
11 on a prescription, she was not feeling any better. I
12 read about this product and talked to her about
13 getting her prescription changed. She talked to her
14 doctor, got the product, and we saw a change
15 immediately."

16 And finally, Cindy from Geneva, New
17 York, said: "I was waiting for the results of my
18 second bone density test, and remembered seeing an
19 ad for this product which allowed me to review the
20 medication. On meeting with my doctor, it was his
21 suggested medicine, as well, and the ad enabled me
22 to ask questions at the time of my appointment."

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1 I want to devote just a moment to an
2 important new change, and an important component for
3 improving the quality of DTC advertising.

4 The Pharmaceutical Manufacturers of
5 America have launched a major new initiative to
6 address public concerns about DTC advertising, and
7 to establish new industry standards for print and
8 broadcast advertising.

9 Three months ago, PhRMA announced a
10 program of self regulation for prescription drug
11 advertising. Beyond just meeting the legal
12 requirements for FDA regulations, it would require
13 advertising to be accurate and not misleading, and
14 to reflect a balance between risks and benefits.

15 The principles adopted by PhRMA show
16 that member companies are committed to delivering
17 messages that educate patients.

18 While offering constructive criticism
19 over the years, FDA has been a positive force for
20 encouraging the use of DTC advertising to inform all
21 Americans, and particularly to reach undiagnosed and
22 under-treated Americans. The support and guidance of

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1 this agency has provided vital leadership to expand
2 and improve advertising of prescription drugs.

3 Looking forward, we need to focus on the
4 important power that information, in the form of DTC
5 advertising, brings to improving the public health
6 of our nation. When you consider that more than 62
7 million patients have talked with their physicians
8 after seeing a DTC advertisement, and that
9 advertising 29 million patients to mention a medical
10 condition to their physician for the first time,
11 it's a powerful force for improving good health.

12 How many of that 25 percent of new
13 diagnoses identified in the Harvard-Haro study would
14 never have occurred without the prompting of an ad?

15 I hope we don't have to weigh that risk.

16 Thank you very much.

17 MR. ABRAMS: Thank you, Mr. Davidson.

18 You mentioned hyperlipidemia, diabetes,
19 hypertension as being serious conditions, and you
20 mentioned the prevalence of these in the U.S.

21 Have you done research, or have access

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1 to research that shows the impact of product
2 specific advertising on getting patients in to be
3 treated? There is much discussion about this during
4 this meeting. And do you have a comparison to just
5 plain disease awareness communication without drugs
6 being mentioned?

7 MR. DAVIDSON: We have not done the
8 research, but that is actually the focus of Joel
9 Richardson's research in the Harvard-Harris study.
10 That is why they looked at AHRQ, list of diseases,
11 and matched them up with a population of 3,000
12 people that they surveyed to see how they reacted to
13 the advertising, and what the reaction was by the
14 physicians after they were examined. So out of that
15 survey, 35 percent of the 3,000 went to see a
16 doctor, were prompted to see the doctor. And then,
17 let's see, I've got -- about 47 percent went to see
18 the doctor. Thirty-five percent of those were
19 diagnosed as having a serious condition in the list
20 of AHRQ priority conditions.

21 MR. ABRAMS: And have you looked at
22 research as far as disease awareness communications,
23 how effective that would be?

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1 MR. DAVIDSON: They didn't make that
2 distinction between just disease awareness and
3 general advertising. They had to work with the
4 advertising that's available to the public.

5 MR. ABRAMS: Dr. Temple.

6 DR. TEMPLE: One speaker yesterday
7 suggested that it would be useful, more balanced, if
8 direct to consumer ads gave some reasonably
9 quantitative description of the effectiveness that
10 had been shown for the drugs.

11 Physician-directed ads often have such
12 information, and sometimes we have to send letters
13 about how it's done, but it's not uncommon. But
14 it's extremely unusual to actually show data in a
15 DTC ad. There is usually a statement of some kind,
16 but it's unusual.

17 Do you think a more diligent attempt to
18 do that and to do it in a comprehensible way would
19 be one possible way for PhRMA to do what it is
20 saying it wants to do, which is communicate more
21 accurately and provide more information to patients?

22 MR. DAVIDSON: One of the challenges

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1 that the advertising industry and the pharmaceutical
2 industry have as they work in partnership to try to
3 see how people react to advertising is how they
4 assess this information based on the reader's
5 information. If you are advertising to a medical
6 professional, you can provide a totally different
7 type of information than you can if you're
8 advertising to the general public.

9 The purpose of advertising, remember,
10 the primary purpose, is to first get the attention,
11 certainly be truthful and not misleading, but get
12 the reader or viewer's attention so that you prompt
13 them to take some action and get them to focus on
14 something that is in their personal well-being.

15 The Harvard-Harris study I come back to,
16 one of the interesting features about that is the
17 high proportion of folks who were diagnosed after
18 seeing an ad and going to pursue treatment,
19 diagnosed for the conditions.

20 I think it's one of the questions in an
21 earlier FDA survey suggests that 88 percent of the
22 folks who went in asking for a specific medicine
23 actually suffer from the condition that the medicine

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1 was designed to treat.

2 So there is a good relationship between
3 consumer response. The question is, how much
4 information do you put into the ad without
5 discouraging them, but encouraging them to go seek
6 treatment.

7 Again, one of the values of the whole
8 process is that you have a medical professional
9 assessing the health of the patient, and then
10 deciding what to recommend, whether it's an
11 alternative lifestyle, whether it's a particular
12 prescription, or whatever. That's the intermediary
13 role that is vital to this whole process. But, as I
14 said before, we have such a level of under-diagnosis
15 in this country that getting them to the doctor is
16 one of the biggest challenges.

17 DR. TEMPLE: So you think that is more
18 important, perhaps, especially if the two conflict,
19 than actually giving them a precise or quantitative
20 assessment of what the drug is likely to do?

21 MR. DAVIDSON: It is certainly equally
22 as important. It is certainly equally as important.

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1 Because if you look at the high percentage of
2 people who are not being treated for some very
3 serious conditions, CDC says we have a challenge
4 ahead of us.

5 DR. TEMPLE: So whether you tried to do
6 it could depend on the condition then, too, couldn't
7 it? I mean, if you really just want to be sure they
8 get to the doctor for their lipids, say, you might
9 not worry too much. But if it was some symptomatic
10 condition, maybe it would matter more.

11 MR. DAVIDSON: But what if they go to
12 the doctor, and then are diagnosed with having
13 another condition that they didn't know that they
14 had? That is also part of the side benefits to
15 this.

16 MR. ABRAMS: Ms. Davis.

17 MS. DAVIS: You talked about how
18 industry self regulation will enhance the quality of
19 DTC. And I'm curious, if an ad is misleading, how
20 do you see that self regulation fitting into the
21 overall scheme of regulation, including FDA's
22 oversight of promotions?

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1 MR. DAVIDSON: Well, first of all, let's
2 operate from the presumption that advertisers are
3 not going to put misleading information out there,
4 or are going to put truthful information out there.

5 Now, do judgments vary on that? Of
6 course they do, and that's why you've seen FDA
7 oversight question content of some ads, and send out
8 letters to the advertisers, with a very, very high
9 ratio of compliance.

10 But the going in, what you are trying to
11 do with any self regulatory program, is to set up,
12 as PhRMA has done, a set of guiding principles that
13 advertisers can look to and say, okay, these are the
14 things we either need to do or not do in this
15 advertising, in order to make it more
16 understandable, and to motivate positive behavior on
17 the part of the reader or viewer.

18 It's giving those guidelines, as is
19 done, for example, with the Better Business Bureau's
20 national advertising division has been doing this
21 for years, for general advertising. The children's
22 advertising review unit, which is also part of the
23 Better Business Bureau, has done this for a number

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1 of years.

2 They provide a set of guiding
3 principles, and then they've got a lot of case law
4 that they've built up over the years, and everyone
5 in the advertising community, both advertisers,
6 agencies, councils that advise them, all are aware
7 of how those principles are applied by the Better
8 Business Bureau's national advertising division. And
9 then they use that as their guide for what they
10 prepare in the future. It's been a system of self
11 regulation that's worked extremely effectively in
12 the past for other forms of advertising, and I think
13 can be applied in this area, as well.

14 MR. ABRAMS: Dr. Ostrove.

15 MS. OSTROVE: To follow up on Ms. Davis'
16 point, one of our speakers yesterday talked about an
17 ad that appeared, actually I saw it last night, in
18 Newsweek magazine, that would appear to be, and
19 correct me if I'm wrong, inconsistent with the
20 principles put out in PhRMA guidelines.
21 Specifically, it's a reminder ad, and my
22 recollection is that the guidelines basically do not
23 -- recommend that those not be used.

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1 What -- I understand what you're saying
2 about the Better Business Bureau and their
3 advertising, their national advertising division.
4 Often, my understanding about that is also that it's
5 the competitors that bring kind of complaints in
6 that are looked at.

7 We have a case like this, where clearly
8 there appears to be an ad that is inconsistent with
9 the principles. Where is the force for basically
10 enforcing compliance?

11 MR. DAVIDSON: First of all, it's my
12 understanding that the PhRMA guidelines don't even
13 go into effect until January of next year. So I
14 thin you will hear probably from a representative of
15 PhRMA a little bit later.

16 MS. DAVIS: So it's kind of a technical
17 thing? So even though the guidelines are out there,
18 and the manufacturers know about them, they don't
19 really have to pay attention to them?

20 MR. DAVIDSON: Well, remember how long
21 they've been out there. They've been out there for
22 less than three months right now. And if you have

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1 any idea of what the timeframe it takes to write new
2 scripts and get things filmed and get them out to
3 broadcast entities and print media, there is a huge
4 cycle of change.

5 Hopefully after January you will start
6 seeing ads that will be specifically reflecting
7 those guidances.

8 MS. DAVIS: Thank you.

9 MR. ABRAMS: Thank you, Mr. Davidson,
10 for your presentation and information.

11 Our next speaker is Ellen Liversidge, a
12 speech pathologist, who will be speaking.

13 MS. LIVERSIDGE: Good morning, ladies
14 and gentlemen.

15 My name is Ellen Liversidge from Silver
16 Springs, Maryland. I'm a speech pathologist and
17 board member of AHRP, the Alliance for Human
18 Research Protection.

19 But most of all I'm the parent of a
20 wonderful son who was killed by a prescription drug.

21 Rob died of profound hyperglycemia on October 5th,

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1 2002, back before the FDA had gotten around to
2 placing a warning on the label, back before Eli
3 Lilly had a settlement with 8,000 people harmed or
4 killed by Zyprexa, back before we had any idea that
5 there was any danger.

6 When I found out after his death from
7 Public Citizen that other countries had required
8 Lilly to place warnings on the label, I desperately
9 tried to change the situation in this country.
10 Working with reporters and the Baltimore Sun and the
11 Wall Street Journal trying to get and getting front
12 page articles about the dangers of Zyprexa.

13 Erica Wood of the New York Times
14 followed up with another front page story, and
15 finally, a year later, the FDA ordered all the
16 atypical anti-psychotics to place a warning for
17 diabetes, hyperglycemia, and death.

18 I speak today on behalf of AHRP, and
19 also on behalf of all the parents I have met whose
20 sons and daughters have been lost to psychotropic
21 drugs. We are a band of brothers and sisters when
22 get together, having had the worst possible thing in
23 all the world happen to us and to our innocent

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1 children.

2 Most of all, it is for the innocent
3 children that are alive that I speak today, giving
4 you AHRP's position on the very nefarious direct to
5 consumer advertising scheme called Teen Screen,
6 dreamt up by pharma and funded by the federal
7 government. This plan will give unvalidated
8 questionnaires to all the teens in every high school
9 in the country, providing many of them with false,
10 possibly false, psychiatric labels, and referring
11 them to a doctor for probable medication, thus
12 creating a new market share for the industry.

13 AHRP's position on this scheme is as
14 follows. The Alliance for Human Research Protection
15 opposes government policies requiring or promoting
16 mental health screening of America's infants,
17 toddlers and school children. Our opposition is
18 informed by scientific, legal, ethical and common
19 sense consideration.

20 Number one, the primary catalyst for
21 both Teen Screen and for the prescribing guidelines,
22 known as TMAP, is market expansion. Dr. Peter
23 Weiden, who is a member of TMAP - it stands for the

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1 Texas Medication Algorithm Project - expert
2 consensus panel has charged that the guidelines are
3 based on opinions, not data, and that bias due to
4 funding sources undermines the credibility of the
5 guidelines since most of the guidelines' authors
6 have received support from the pharmaceutical
7 industry.

8 The invalid screening process of Teen
9 Screen ensures that mostly healthy normal children
10 will be brought into government subsidized mental
11 health dragnet. Once children acquire a psychiatric
12 label they may be branded for life. For example,
13 between 55 and 60 percent of foster children in at
14 least three states - Texas, Massachusetts and
15 Florida - are on psychotropic drugs starting as
16 young as age three.

17 Some children are on multiple drug
18 cocktails, as many as 16 drugs. The drugs that are
19 recommended by TMAP are both dangerous and often
20 ineffective. They all carry black box warning
21 labels.

22 Two, the diagnostic criteria upon which
23 mental health screening instruments rest are

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1 scientifically invalid, vague and entirely open to
2 subjective interpretation. Teen Screen was tested
3 on 1,729 children in seven New York City schools
4 using passive parental consent and teen active
5 consent, which is legally invalid.

6 Teen Screen is fraught with suggestive
7 insinuations of failure and self doubt. Such
8 questions can lead vulnerable teenagers to obsess
9 about perceived inadequacies that might lead them to
10 develop low self esteem that could give rise to
11 anxiety, withdrawal and emotional problems.

12 By raising the possibility that suicide
13 may be an option, and that's one of the questions,
14 screening might lead to suicidal thinking, as
15 happens in Japan's Internet suicide clubs.

16 Teen Screen questions are so vague,
17 suggestive and broad that most normal teens are
18 mislabeled as mentally ill.

19 Teen Screen, also known as Columbia
20 suicide screen, is an illegitimate intrusion on
21 privacy which purports to be a suicide prevention
22 assessment tool, but lacks any semblance of

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1 scientific validity.

2 Indeed, the results of the study by Dr.
3 David Schaeffer, chairman of child and adolescent
4 psychiatry at Columbia University who is credited
5 with developing and promoting Teen Screen showed
6 that of 1,729 New York City high school students who
7 were screened using the questionnaire, 475 students
8 tested positive.

9 Number three, mental health screening is
10 gambling with children's normal development. Teen
11 Screen promoters fail to disclose that the risk for
12 children who are screened to be falsely labeled as
13 suicidal or mentally ill is 84 percent.

14 Number four, despite its proven
15 unreliability as a predictive tool, and no evidence
16 that mental health screening prevents suicide, Teen
17 Screen promotes itself in direct to consumer
18 marketing advertisements as a suicide prevention
19 tool, proving that science is no deterrent to a
20 marketing strategy.

21 The Teen Screen website states: We are
22 running public service advertisements in the New

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1 York Times and the Washington Post to raise
2 awareness of our new report, entitled, Catch Them
3 Before They Fall.

4 Catch Them Before They Fall is a
5 marketing pitch much like pharmaceutical company
6 advertisements that refer to unsubstantiated
7 chemical imbalances. Teen Screen promoters are
8 misinforming public health policymakers, school
9 officials, families and teens by mischaracterizing
10 their experimental, scientifically invalid
11 questionnaire as a proven suicide prevention
12 strategy, when their own research refutes such
13 claims.

14 Teen Screen's low predictive level shown
15 to be only 16 percent, will result in falsely 84
16 percent of children who test positive as mentally
17 ill or suicidal.

18 As acknowledged by Dr. Schaeffer, such a
19 high rate of false positives could reduce the
20 acceptability of a school-based prevention program.

21 Number five, coercive mental health
22 screening and forced drugging is already happening

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1 to children in the United States. Current estimates
2 are that each year 8 million American children, or
3 about 10 percent of the school age population are
4 prescribed mind-altering drugs.

5 Finally, a radical proposal contained in
6 the federal mental health action agenda, a follow up
7 to the NFC, is alarming as it is preposterous. The
8 FMHAA's stated goal is to develop mental health
9 promotion and early intervention services targeted
10 to infants, toddlers, preschool and school age
11 children. The action agenda, targeting infants,
12 toddlers and children, is invalid and irresponsible,
13 and disregards the risks, the lack of evidence to
14 support such, quote, early intervention.

15 In 2001 Dr. Benedetto Ditiello, director
16 of child and adolescent treatment and prevention
17 interventions research branch for the National
18 Institutes of Mental Health, acknowledged the
19 diagnostic uncertainty surrounding most
20 manifestations of psychopathology in early
21 childhood.

22 AHRP opposes psychiatric screening of
23 children without active, informed parental consent.

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1 Consent of parents must be documented and given
2 voluntarily without a hint of coercion. Teen Screen
3 has attempted to sidestep parental consent by
4 claiming passive parental consent, which is invalid.

5 Teen Screen is being sued in federal
6 court by the parents of 15-year-old Chelsea Rhodes
7 for violating their constitutional rights by failing
8 to inform them that their child would be screened,
9 and for failing to obtain parental consent.

10 The Rhodes family is represented by the
11 Rutherford Institute.

12 The FDA bears responsibility for failing
13 to stop an unethical drug marketing strategy that is
14 increasing the risk of serious harm for healthy
15 children who are being misprescribed psychoactive
16 drugs on the basis of an invalid screening tool that
17 was being promoted with false claims.

18 According to its website, as of October
19 25th of this year, Teen Screen is actively operating
20 at 460 locations in 42 states and Washington, D.C.

21 Thank you.

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1 MR. ABRAMS: Thank you for your
2 presentation and sharing your thought.

3 Before I open the questions up to
4 questions by the FDA panel, I want to make it clear
5 the rules of a Part 15 meeting, that FDA is here to
6 listen, to get your information. So we are not
7 allowed to respond to comments or answer questions.

8 I think that is important. The purpose of the
9 meeting is to gather information.

10 So with that I'll open it up to the
11 panel members.

12 Dr. Temple.

13 DR. TEMPLE: You mentioned that some
14 direct to consumer ads are mentioning and promoting
15 Teen Screen. I checked. We don't think we're aware
16 of that. Can you either now or afterwards identify
17 those for us so we can look at them?

18 MS. LIVERSIDGE: What I can identify for
19 you now is what is stated in my statement that I got
20 from AHRP. But I do not have any information in any
21 public document.

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1 DR. TEMPLE: Well, even if you went
2 back to them and asked them?

3 MS. LIVERSIDGE: I would be happy to do
4 that.

5 MR. ABRAMS: Thank you for your
6 presentation. And any additional information please
7 submit to the docket, and we will carefully consider
8 it.

9 Thank you.

10 Our final speaker for the panel is Peter
11 Lurie from Public Citizen.

12 MR. LURIE: Good morning. I'm Peter
13 Lurie. I'm a physician, deputy director of Public
14 Citizen's health research group.

15 I want to start off with a housekeeping
16 matter to which our previous speakers have not paid
17 attention which is to make a conflict of interest
18 statement. And that conflict of interest statement
19 is that Public Citizen takes no money from
20 government or industry. I doubt that that is true
21 for the advertisers or for the American Enterprise

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1 Institute.

2 The intellectual background for
3 assessing any intervention in public health is
4 assessing risk and benefit. And those of us who
5 have done that kind of work always ask the question,
6 yes, whose risk and whose benefit?

7 And I think that much of the
8 conversation this morning has in some way been
9 naïve. It's obvious what the risks and benefits are
10 when viewed from the perspective of the advertisers
11 in the pharmaceutical industry. It's all benefit to
12 them, with very little risk. Benefit in the form of
13 increased sales, increased advertising, and so
14 forth.

15 That's the emperor in the room without
16 the clothes, and we should remember that as we go
17 forward. But that's not really the right way to
18 assess the impact of direct to consumer advertising.

19 The right way is to look at it from the perspective
20 of risks and benefits to the public health. That is
21 what we're concerned about.

22 And even if there are any benefits at

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1 all, which I don't concede, the question is if those
2 benefits could be obtained in some other way by a
3 method other than direct to consumer advertising.
4 To that we believe the answer is yes.

5 There was one thing missing from Mr.
6 Calfee's presentation, which is that New Zealand is
7 an interesting example in that, one, it is the only
8 other country that has ever done direct to consumer
9 advertising. European Union gave serious
10 consideration to this awhile ago and decided
11 affirmatively not to do it.

12 But he doesn't mention that there is in
13 fact a moratorium on direct to consumer in New
14 Zealand at this point because they haven't liked the
15 experience, especially the doctors, consumers have
16 not. And so as a consequence they are actually
17 moving toward finalizing that moratorium.

18 So that is really the strongest lesson.

19 I'll make seven points. First, and
20 this point has been made earlier, direct to consumer
21 advertisements bear little relationship to public
22 health needs. Only 14 percent of sales of the top

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1 50 DTC advertised drugs are for acute conditions.
2 And only one of the top 50 DTC advertised drugs is
3 for an antibiotic, presumably because you get cured
4 too quickly.

5 What they are interested in doing is
6 advertising for chronic conditions that make people
7 uncomfortably usually, or that people believe are
8 likely to be dangerous to them, which they will
9 continue to take for a long period of time. That is
10 where the money is to be made.

11 One never encounters ads for generic
12 drugs, even though that would be one way of getting
13 people into drugs, some of which in fact are shown
14 to be the most effective medications for particular
15 conditions, like thiazide diuretics are probably the
16 best way to go for at least the initial treatment of
17 hypertension, but you certainly don't see any ads
18 for them on TV.

19 Least of all do you see ads for any
20 behavioral interventions, like - behavioral
21 interventions such as exercise, weight loss, and so
22 forth, even though these can be safer, less costly,
23 and more effective. That's the first point.

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1 Second, many DTC advertisements are
2 misleading or dangerous. I won't go through the
3 whole experience with Vioxx. I'm sure other people
4 have gone into it. But remember the size of that
5 campaign. The campaign for Vioxx in 2000 was \$160
6 million, larger than the campaigns that year for
7 Pepsi or Budweiser, and the retail sales quadrupled.

8 I don't mind if there are direct to
9 consumer ads for Pepsi or Budweiser, and I don't
10 even mind that much if it isn't true that life goes
11 better with Coke. But I do have a problem with the
12 idea of information being provided in an attempt to
13 get around the doctor and turn the patients in
14 effect into the agents of the drug companies in
15 order to increase prescribing.

16 We provide attached to my testimony as
17 well as in my testimony to the Senate Education
18 Committee a few weeks ago an amazing ad, which is a
19 DTC ad indeed, a direct to children ad, along the
20 lines of what Ms. Liversidge is concerned about.
21 It's an ad for a drug called Differin, an acne
22 product, and it's directed at children. There is a
23 teen survival handbook which includes a self test on

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1 acne which is Zit 101, which is a course, it turns
2 out, on offer at Acme High.

3 And what they are in effect trying to do
4 is get the children to go to their parents, have the
5 parents then ask the doctors for the drug. And in
6 proportion to the success that the children have,
7 they get to download free music on the Internet.
8 And it's proportional to how good you are at it.
9 Two free music downloads if you sign up at the site.
10 Seven free music downloads if you get and fill a
11 prescription, and 10 if you refill it. That really
12 seems completely inappropriate.

13 And a probable new low in direct to
14 consumer advertising was actually misrepresenting
15 the FDA itself, in which AstraZeneca made a claim
16 that FDA had no found no reason for concern with
17 respect to the safety of Crestor, even though Dr.
18 Galson I believe it was on record as saying that the
19 agency was quite concerned about it. So
20 misrepresenting the FDA is really a new low.

21 Three, consumers are being misled. The
22 agency's 2002 survey which we've heard about found
23 that 60 percent of patients thought that

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1 advertisements provide insufficient information
2 about drug risks, and 44 percent felt similarly
3 about drug benefits.

4 And I disagree with the claim that we
5 can't get into detail about benefits. What the
6 industry is concerned about is that for many drugs
7 the benefits, actually laid out in a clear fashion,
8 will turn out to be lower than most people assume,
9 at least based on the visions of people floating
10 around in blue sky fields with butterflies floating
11 above them.

12 If there is going to be benefit
13 information of any kind, let's be quantitative about
14 it, and we'll learn if many drugs, especially for
15 Alzheimer's disease, are barely effective at all.

16 Fourth, doctors are being coerced. In
17 an already classic study that has been discussed a
18 little bit, Dr. Kravitz sent in so-called
19 standardized patients - this is in answer to some
20 earlier questions from the FDA panel - this was a
21 real randomized control trial, they tried to answer
22 this question. And what came out was not at all
23 unexpected: An increase in prescribing for

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1 adjustment disorder, a condition not ordinarily
2 requiring drug treatment, that was much worse, which
3 is to say, more prescribing, when the person, the
4 doctor, was confronted with someone demanding Paxil,
5 55 percent of those who told their doctors they had
6 seen a Paxil ad ended up with a prescription for a
7 drug. And that is an increase in effect over what
8 ought to be in effect zero percent prescribing for a
9 condition like adjustment disorder.

10 Fifth point: The price of health care
11 is being driven up. The GAO agreed that, quote, the
12 DTC advertising appears to increase prescription
13 drug spending and utilization, primarily because of
14 increased utilization, not because of increased
15 prices; that's a separate problem.

16 In a study that separated out the
17 various forms of advertising, i.e. the doctor
18 advertising and the consumer advertising, DTC
19 advertisements for just the 25 largest therapeutic
20 classes were estimated to have accounted for 12
21 percent of the increase in drug sales from 1999 to
22 2000, an increase of \$2.6 billion.

23 Point six, potential benefits of direct

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1 to consumer advertising. The best argument the
2 pharmaceutical companies is the one we've heard
3 repeatedly today, the claim that actually what the
4 industry is interested in is getting under treated
5 people, best of all minority people we seem to
6 believe now, into the care of doctors.

7 The question then would be, if there
8 were a better way than direct to consumer
9 advertising to accomplish that, why wouldn't that
10 industry endorse that instead and use that? In
11 fact, that is what the data from the Kravitz show.
12 What the Kravitz study shows is that the most
13 effective way to get people treatment for
14 depression, arguably an example of an under-treated
15 disease, although whether as in the Kravitz study
16 one ought be getting drug at the first time you
17 present to a doctor is not necessarily correct. But
18 even if one assumed that, the most effective way in
19 that study to get a person on a drug was to have the
20 patient approach them not asking for Paxil or saying
21 that they had seen a Paxil ad, but rather that you
22 approach them saying that they had learned something
23 about depression on television, and isn't there
24 something that could be done for it.

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1 So we'd be seeing far more of the help
2 seeking ads if the real motivation for direct to
3 consumer advertising was to get under-treated people
4 on to drug, or to see them get some sort of help,
5 and we certainly aren't seeing much of that.

6 Finally, point seven, FDA enforcement is
7 lackadaisical. There is an 85 percent decline in
8 overall enforcement actions at DDMAC between 1998
9 and 2004. That didn't just happen. It does go back
10 to the Clinton administration, but it also derives
11 from the requirement to send warning letters through
12 the office of the chief counsel at the FDA, which
13 GAO concluded, that practice of reviewing, had often
14 taken so long that misleading advertisements may
15 have completed their broadcast lifecycle before the
16 FDA issued the letters. According to minority staff
17 at the committee on government reform, the average
18 time from initial placement of prescription drug ads
19 and enforcement action if there was one was 177
20 days, and recidivism was common between companies.

21 So what I believe I've shown, then, is
22 that there are in fact many risks to direct to
23 consumer advertising, and the only theoretical

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1 benefit is one that can better obtained by using
2 help seeking ads, rather than profit-driven direct
3 to consumer ones that link drug and disease.

4 What are our recommendations? Firstly,
5 the former guidelines are unlikely to have any
6 impact as Dr. Ostrow was hinting. It's only the
7 Vioxx debacle that has gotten PhRMA to revise these
8 guidelines at all, and of course they are voluntary,
9 and designed primarily to stave off more aggressive
10 legislation or regulations.

11 The guidelines recommend the company
12 should weigh the quote appropriate amount of time,
13 whatever that means, after launching a new drug
14 before initiating a DTC campaign. Even Senator
15 Frist thinks it ought to be a two-year wait.

16 Second, patient information should come
17 from the FDA. Back in 1979 the FDA proposed to do
18 just this, but the American Medical Association and
19 pharmaceutical industry stopped them from doing it.

20 They were called patient packages in those days.

21 And now we've got a kind of son of
22 patient packages, which is called the medication

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1 guide. But there are only about 75 of those that
2 exist. So those drugs do not get FDA approved
3 information that is provided directly to the
4 patient, and we think this is a massive hole into
5 which the pharmaceutical and advertising industry
6 have stepped and that is why we have the massive
7 growth in DTC advertising that we've currently seen,
8 an increase of \$4.1 billion in 2004 from just \$791
9 million in 1996.

10 Let me point out that that increase did
11 not occur by accident. It occurred because of the
12 1997 deregulation of direct to consumer advertising.

13 That is not the only explanation, but in our view
14 it's the main one. And if the genie can be let out
15 of the bottle by FDA regulations, then it follows
16 that it can be put back into the bottle, at least to
17 a significant extent, by reimposing the regulations
18 that existed or the guidances that existed prior to
19 1997.

20 The problem of course is that there are
21 no regulations at all. And the FDA has been saying
22 for a long time that they've been looking at
23 regulations. They never seem to be people coming;

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1 all we get are a bunch of guidances that are not
2 able to be enforced, and are not enforced, and are
3 frequently violated.

4 The agency is unable to adequately
5 enforce even the weak guidances that it has. It's
6 drastically understaffed, and there is no way that
7 they can keep up with the barrage of print and
8 broadcast ads that are coming out on a daily basis.

9 Federal agencies other than the FDA also
10 have a role in all of this, in particular, the NIH
11 and the AHRQ have an important role in educating
12 consumers, and for that matter, doctors, about many
13 of the conditions that people are concerned about.

14 Finally, if there ought to be
15 regulations, they should provide a pre-review of
16 television advertising and should not allow
17 celebrity endorsements. Most fundamentally the
18 agency is lacking the ability to levy civil monetary
19 penalties. And so it always will be in the
20 interests of the pharmaceutical companies and the
21 advertisers to get an ad out. And should the FDA
22 even learn about it, and if so, should they even act
23 on it, and if so, should it ever emerge from the

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1 office of the chief counsel, by then, the ad will
2 long have run its course, and tens of millions of
3 people will have been exposed.

4 That concludes my comment.

5 MR. ABRAMS: Thank you, Dr. Lurie, for
6 your presentation.

7 You mention in your presentation that
8 you believe that DTC increased utilization of drugs.
9 That could be a positive thing or a negative thing.
10 The negative aspect, it increases costs.

11 But if that increased utilization is for
12 appropriate use, for under-treated conditions,
13 obviously it's positive for public health.

14 Do you have any data or information that
15 could provide some light to tease out what is going
16 on there?

17 MR. LURIE: Well, as I indicated in my
18 testimony, the best data on that are in fact from a
19 randomized control trial unusual in this kind of
20 area of regulation. And I'm sure you are familiar
21 with it. It's the Kravitz study. And what this

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1 Kravitz study shows quite clearly is that direct to
2 consumer advertising - let me explain in case not
3 everybody knows. There were two parts to the study.

4 One had to do with adjustment disorder, assumedly a
5 condition for which little if any treatment was
6 necessary, and the other for depression in which
7 there is at least the possibility that they are
8 under-treating people who could benefit from
9 learning about the dangers of their condition and
10 approaching their physician.

11 With respect to adjustment disorder, DTC
12 advertising massively increased the amount of
13 prescribing the drug, and I would argue that
14 essentially all of that is unnecessary; and that is
15 on the negative side.

16 On the positive side, as I mentioned in
17 my testimony, it turns out that it was more
18 effective to get people onto drugs - if one assumes
19 that that is the right outcome - that the best way
20 to get people onto drugs was not through a drug
21 company-drive DTC ad, but rather by something that
22 came from a more reputable source, like you, right,
23 like the FDA, the NIH, the AHRQ, or even some media

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1 presentation.

2 So if the object is to truly work, which
3 I don't for a moment believe that it is, but if it
4 truly were to get under-treated people onto
5 medication, A, we'd be seeing the best way to do it
6 would through help-seeking advertisement from the
7 industry, and we just don't see much of that at all.

8 MR. ABRAMS: Okay. A speaker in our
9 second panel yesterday morning talked about product
10 specific production versus disease awareness
11 communication. And the point that he made was, you
12 need a call to action. If you don't have a solution
13 or a motivation to have somebody go to a physician
14 like you could get a product to help you, it's not
15 going to be effective.

16 Any thoughts about that?

17 MR. LURIE: Yes. He's wrong. He's
18 wrong, because the data from the Kravitz disproved
19 that. They show that physicians were more likely to
20 prescribe from a help-seeking ad than from the DTC
21 ad for Paxil, as cited by the patient.

22 So that is a theoretical argument. But

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1 to the extent that there are data upon which we can
2 base that, I think it's just plain wrong.

3 MR. ABRAMS: Dr. Temple.

4 DR. TEMPLE: It sounds like the source
5 was a different source, though; it wasn't from the
6 drug company.

7 MR. ABRAMS: It was from something you
8 described as more reputable. I don't know what is.

9 MR. LURIE: No, no. I mean in the
10 study, what the person did was, they said - there
11 were three groups. One was the group that said,
12 hey, I'm feeling blue, or other symptoms consistent
13 with social adjustment disorder. So the depression
14 was, I'm feeling blue.

15 The help-seeking ad type thing was, I
16 saw a program that dealt with depression.

17 And the other one was, I saw an ad for
18 Paxil.

19 So they are different sources, yes. But
20 as I've said, the solution to this is not to turn
21 over the pharmaceutical industry the job of doing

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1 help-seeking ads. I'm merely pointing out that if
2 they were truly interested in the public health,
3 that's what they would do.

4 The best solution is to get the
5 pharmaceutical industry out of the business
6 altogether, because the right people to do the job
7 are you or the NIH or the AHRQ. And it's the
8 failure by the government to act in that way that's
9 leave this gaping information hole into which the
10 industry is stepping.

11 DR. TEMPLE: Let me - it's an
12 interesting suggestion that FDA would become
13 advocates for certain kinds of treatment, getting
14 your cholesterol down after trying exercise and
15 diet. Would you actually be enthusiastic about
16 having the drug regulatory authority responsible for
17 doing that also?

18 We promote generic drug use, but we
19 haven't for the most part actually done what you are
20 describing.

21 MR. LURIE: Yes. I think what we point
22 to in the testimony is really the NIH and the AHRQ.

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1 I think you are a drug regulatory agency. You need
2 to see that information that goes out is honest;
3 sometimes it's not. So no, I don't think it's so
4 much an FDA responsibility as it is that of NIH or
5 CDC for that matter.

6 DR. TEMPLE: Let me ask you a hard
7 question. There already are existing programs for
8 NIH to do that. The ads show up as far as I can
9 tell very late at night. They are never part of the
10 Super Bowl, and it's obviously a matter of money
11 among perhaps other things.

12 Suppose the choices between having the
13 source you prefer to do it and not having it at all,
14 where do you come out?

15 MR. LURIE: I just don't accept the
16 choice.

17 DR. TEMPLE: Oh, you think they are
18 going to come up with several billion to do it?

19 MR. LURIE: No, our recommendation is
20 that the government get on the talks.

21 DR. TEMPLE: Okay.

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1 MR. ABRAMS: Dr. Ostrove.

2 MS. OSTROVE: Dr. Lurie, I'm just
3 confused about one thing, so if you could just
4 clarify it for me. The Kravitz study used simulated
5 patients to talk to physicians. So I'm not sure how
6 that study really addresses Mr. Abrams' question
7 concerning the ability of help-seeking ads to get
8 patients in to see doctors.

9 MR. LURIE: No, I think it goes to the
10 question of the kind of information that is most
11 effective in getting the doctor to prescribe, if one
12 assumes for the moment - which I'm not sure I do -
13 if one assumes that the object is to get people onto
14 drugs.

15 Now, obviously that is a complicated
16 question. But granting for a moment that in
17 depression people coming in without drug treatment,
18 some fraction of them may well have been helped by
19 being put on it, I'm saying that given what the
20 patient described as the source had an impact, and
21 that the less successful source was the direct to
22 consumer ad.

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1 MS. OSTROVE: So what you're saying is
2 that it's what the patient refers to when they go in
3 that may have a more positive impact on the way that
4 the health care professional responds, but it
5 doesn't really say anything about what will actually
6 get the patient in to talk to the physician about
7 their problem?

8 MR. LURIE: Yes, that is correct, and we
9 make that point in our testimony.

10 MS. OSTROVE: Thank you.

11 MR. ABRAMS: Dr. Lurie, you mentioned
12 that you were not real impressed with guidances that
13 were issued by FDA. You didn't think that they were
14 terribly effective. You suggest that we go beyond
15 that.

16 Could you elaborate on that?

17 MR. LURIE: Well, as I said, I thought
18 that guidances are - well, they are voluntary, that
19 is the principal problem. And so however much we
20 might like to see the end of direct to consumer
21 advertising, we do understand that current
22 interpretations as offered by the Supreme Court and

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1 others are not consistent with a ban at this point;
2 we do understand that. It's not something we're
3 happy about particularly, and maybe a Supreme Court
4 less packed than the present one may come to a
5 different conclusion.

6 But nonetheless, that is the case. And
7 so were there to be regulations, which we think
8 there ought to be, I've mentioned a number of
9 elements that would be important, and those would
10 include the celebrity element. The children element
11 is certainly another one. I think that the idea of
12 providing more quantitative, useful, interpretable
13 information about both risks and benefit I think
14 would all be advances.

15 I also think that the agency is lacking
16 the ability - your division in particular - to levy
17 civil monetary penalties. And I think I'd like to
18 see you or anybody else at the FDA approach the
19 Congress looking for that authority. That would
20 make an enormous difference. But right now getting
21 caught putting out a direct to consumer advertising
22 that violates the relevant provisions is just a cost
23 of doing business at this point. It's no great

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1 injury to the industry. They've already had tens of
2 millions of people looking at it.

3 So I think you need more funding so you
4 could have more people that could actually help you
5 to police these, even in a prospective fashion, and
6 that's another point that we'd like to see, more
7 prospective review of ads. And you need to be able
8 to police this much more aggressively than you
9 either have been interested in doing, or that the
10 office of general counsel has allowed you to do.

11 MR. ABRAMS: Okay, Dr. Lurie, thank you
12 for your presentation and the information.

13 I would like to thank the first panel
14 for their presentations and response to questions.

15 (Applause)

16 We have about six minutes before we
17 break, so nobody signed up to make public comments
18 from the floor. I encourage you to do so if you
19 wish to; it makes it a little easier for us.

20 So I invite anybody else who wishes to
21 to come up to a mike, please identify yourself, your

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1 name, and your affiliation.

2 Thank you.

3 MR. SWEENEY: My name is Harry Sweeney,
4 and I am the chairman of Dorland, a global
5 corporation. We are a medical and health promotion
6 communications company.

7 For a point of clarification on the
8 Kravitz study that was just discussed, I'd like to
9 read you a couple of things from that study.

10 First of all, the patient that was
11 characterized as coming in generally seeking some
12 care, this is what that fake patient said: I was
13 watching this TV program about depression the other
14 night. It really got me thinking. I was wondering
15 if you thought a medicine might help me, okay.
16 Nonspecific, but I was wondering if you thought a
17 medicine might help me.

18 The other patient came in and said, I
19 saw this ad on TV the other night that was about
20 Paxil. Some things about the ad really struck me.
21 I was wondering if you thought Paxil might help.

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1 Now this study had kind of a law of
2 unintended consequences result. It happens to be
3 one of the best studies that we've seen so far that
4 indicates that DTC advertising has a very, very
5 positive effect on patient care. And here was the
6 result.

7 Minimally acceptable care which was
8 defined by the authors as receiving a drug or a
9 referral to a specialist or come back in two weeks
10 and see me again - minimally acceptable care -
11 occurred 98 percent of the time when patients made
12 the general request. It occurred 90 percent of the
13 time when patients made the specific drug request.
14 And it only occurred 56 percent of the time if the
15 patients made no request at all.

16 In other words, DTC advertising works to
17 promote better patient care.

18 MR. ABRAMS: Okay, thank you.

19 We have two more people up at the mike,
20 so we're going to take those before the break.
21 Anybody else who wishes to speak at this point,
22 please sign up, and then we'll get to you later in

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1 the day.

2 MS. KASTNER: I'm Kathy Kastner. My
3 company is called the Health Television System. And
4 we produce direct to patient education that is
5 directly related to hospitalized patients, and their
6 life out of the hospital.

7 I have a comment and a question. The
8 comment is related to the various presentations that
9 I've heard that seem to place doctors either as the
10 all-knowing all-seeing interpreters of statistical
11 information and our learned intermediaries, or pawns
12 of the pharmaceutical industry. This was just a
13 comment. And I'll be interested to hear from the
14 American Medical Association later.

15 My question, however, is for Dr. Lurie.
16 I wonder if you --

17 MR. ABRAMS: We are not permitted to
18 take questions from the floor.

19 MS. KASTNER: Oh, just commenting, okay
20 thank you.

21 MR. ABRAMS: You can comment, and make

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1 your comment very thorough, and it will go into the
2 record and we will carefully consider it.

3 MS. KASTNER: Thank you so much. Okay,
4 second comment is that I wonder if the
5 pharmaceutical industry were required to spend a
6 portion of their promotional budget specifically on
7 education with the definition of that being clearly
8 understood by all separate from a promotional
9 budget.

10 MR. ABRAMS: That you for the comment.
11 That will be in the transcript.

12 If you have additional information
13 related to that that you wish us to consider, please
14 include that in your submission to the docket.
15 Thank you. And lastly.

16 MS. SNOW: Good morning. Thank you for
17 the FDA panel and everybody here today.

18 My name is Brenda Snow. I'd like to
19 speak to you on two fronts, first as a patient that
20 has benefited from DTC advertising, and second, as
21 the owner of a medical marketing company that works
22 in this industry called Snow & Associates. That is

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1 my affiliation.

2 I'll start off from the patient
3 perspective. I was diagnosed with multiple
4 sclerosis 12 years ago, and it was by a DTC
5 advertisement that drove me to ask for the first
6 approved therapy for this condition.

7 Obviously you can tell by looking at me
8 today that I'm doing extremely well. Had I not had
9 availability and access to the first biologic for
10 relapsing MS the natural history of the disease
11 suggests that at year 12 I would be ambulating with
12 either canes, devices and/or possibly a wheelchair.

13 So my personal experience has been,
14 while we have heard some very heartbreaking stories
15 over the last couple of days, I felt compelled to
16 provide a perspective where a DTC ad actually
17 impacted my health. For the last 12 years I've been
18 able to raise my family and own a business and be a
19 productive member of society.

20 So that is my personal experience with
21 the DTC advertising.

22 On a business front I'd like to say that

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1 we've heard a lot about Cox-2s, and while again,
2 that is an example, unfortunately a heartbreaking
3 one in the marketplace, I don't think that it is
4 what we should exclusively focus on as we go through
5 this investigative panel, particularly when - and I
6 would thoughtfully like to remind the FDA panel here
7 today - particularly when it comes to ultra orphan
8 diseases, orphan diseases and chronic medical
9 conditions which there are still no cures for - I'm
10 talking about epilepsy, rheumatoid arthritis, lupus,
11 all of these autoimmune diseases where as a business
12 owner now I can tell you, managing patient advocates
13 and testimonials, the majority of these folks - and
14 I would be happy to submit the anecdotal testimony
15 to the board - suggests that had they not had direct
16 patient communication or patient-to-patient
17 communication, they would not know that there are
18 therapeutic agents on the market, in the marketplace
19 today, that affects the outcome of their health

20 And when we are talking about the
21 ability to continue with your life, I think that is
22 a significant one.

23 My final comment is, it's not perfect.

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1 Obviously we are here to look at some changes and
2 make some considerations. But I don't think DTC is
3 to be blamed for everything bad that has happened.
4 I think that there is a lot of other in this
5 treatment paradigm.

6 And I think yesterday the Kaiser
7 Permanente presentation clearly illustrated that
8 there was some grave ownership that should have
9 happened on physicians prescribing those
10 medications.

11 So I think as a broad blanket, at all
12 different stages, there needs to be thoughtful
13 consideration and the physicians certainly play a
14 role in that as well.

15 Thank you for hearing my comments.

16 MR. ABRAMS: Thank you for your
17 comments.

18 I want to again thank the panel for
19 their insightful presentations.

20 We will break now for 15 minutes, and we
21 will resume promptly at 11:15. Again if you wish to

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1 speak from the floor, I encourage you to sign up.

2 Thank you.

3 (Whereupon at 10:57 the proceeding in
4 the above-entitled matter went off the record, to
5 return on the record at 11:16 a.m.)

6 MR. ABRAMS: Welcome back. We will
7 start with our second panel of this morning. And
8 our first speaker is Gary Ruskin from Commercial
9 Alert.

10 MR. RUSKIN: I'm sorry to have my back
11 to you here. Hello, is this working?

12 Hi, my name is Gary Ruskin. I'm the
13 executive director for Commercial Alert. Thank you
14 very much for inviting me to testify today.

15 I'd like to start by quoting three
16 letters sent to the subcommittee on oversight and
17 investigations of the U.S. House of Representatives
18 Committee on Energy and Commerce some two decades
19 ago.

20 Quote, Scheering Plough believes there
21 is a fundamental flaw in the concept of advertising

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1 prescription pharmaceuticals directly to patients,
2 and that is the inability to provide them complete,
3 meaningful and useful information.

4 That quote did not come from a critic of
5 the industry, or some consumer watchdog; it came
6 from Allen S. Cushion, who was then senior vice
7 president for public affairs for Scheering Plough.
8 Most of his peers in the pharmaceutical industry
9 agreed.

10 Quote: We do not believe that
11 prescription drug advertising to consumers is a good
12 idea, wrote Thomas M. Collins, president of Smith-
13 Kline-French laboratories. The likelihood - quote -
14 the likelihood that meaningful patient education
15 will occur is small.

16 Quote: It can inform, but it is not
17 education, and it should not be portrayed as a part
18 of the education process.

19 Here is another one, quote: We do not
20 believe that prescription drug advertising to
21 consumers is in the public interest, wrote Robert
22 Schellhorn, chairman of Abbott Laboratories.

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1 We believe that direct advertising to
2 consumers introduces a very real possibility of
3 causing harm to patients who may respond to
4 advertisements by pressuring physicians to prescribe
5 medications that may not be required.

6 Today I want to explain why those three
7 gentlemen are exactly right. First, just a quick
8 word about Commercial Alert and why I'm here. We're
9 a nonprofit organization that protects children and
10 communities from commercialism. We're a watchdog
11 group for the advertising industry, and my job is to
12 study commercialism and the advertising industry,
13 and to mitigate the damage they do the American
14 public.

15 I'm going to respond directly to the
16 questions that you have posed, excellent questions.

17 But at the outset I just want to emphasize that
18 under current prescription drug laws and the
19 principles that underlie them, there is no basis at
20 all for allowing direct to consumer prescription
21 drug advertising. By law only doctors may prescribe
22 prescription medicine, and there is no legitimate
23 purpose in advertising what consumers may not

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1 directly purchase.

2 For this reason alone, direct to
3 consumer drug advertising should be prohibited.

4 Now I'd like to focus my testimony today
5 on questions one and three in the notice of public
6 hearing. Question one asks, does current DTC
7 promotion underlie - present the benefits and risks
8 of using medical products in an accurate
9 nonmisleading and balanced and understandable way?

10 And the answer is no. Direct to
11 consumer drug advertising is inherently misleading;
12 inherently misleading. And there are a few reasons
13 for this.

14 Pharmaceutical companies have conflicts
15 of interest that keep them from presenting unbiased
16 information about their products. Pharmaceutical
17 companies exist to make a profit. That is their
18 duty under the law, to yield maximum returns to
19 their shareholders.

20 In order to do that they have to sell
21 drugs, and the more drugs they sell the better the
22 shareholders will do. Every piece of information

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1 that a pharmaceutical company sends out must be
2 geared to that end. And that's why pharmaceutical
3 companies are not a good source of information about
4 their own prescription medicines. Their financial
5 interests directly conflict with any intention to
6 provide unbiased information about their products.

7 Because of these financial conflicts of
8 interest, pharmaceutical companies are perhaps the
9 least trustworthy sources of information about their
10 own products.

11 By their very nature drug companies hype
12 the benefits or alleged benefits of their drugs and
13 downplay the negatives. And they encourage people
14 to see their problems and diseases as diseases that
15 require medication. And the result is a public that
16 is increasingly drugged and pathologized.

17 You know in a candid moment two DTC
18 advertising executives at FCB Healthworks wrote,
19 quote: The ultimate goal of DTC advertising is to
20 stimulate consumers to ask their doctors about the
21 advertised drug, and then hopefully get the
22 prescription, unquote.

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1 Please read that - I'll say it again,
2 because I think it will answer most of the questions
3 that are prompted by this hearing: The ultimate
4 goal of DTC advertising is to stimulate consumers to
5 ask their doctors about the advertised drug and then
6 hopefully get the prescription.

7 Now question three asks, could changes
8 in the requirements for disclosure of certain
9 information in broadcast advertising improve the
10 usefulness of this information for consumers.

11 And the answer is, no. Because
12 broadcast DTC ads are inherently misleading. And
13 another reason why is it's just important to examine
14 the nature of television, to think about the nature
15 of television for a second and what it's good at.
16 Television is great at entertainment. It excels at
17 bringing show business into the homes of millions
18 of Americans each day. It excels at presenting
19 visual images to people and visual images that are
20 what television does well.

21 And it is especially good at selling
22 products, and this is why advertisers migrated to TV
23 in the early days, even before most Americans did,

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1 and to see a smoker taking a big drag on a cigarette
2 was much more provocative than a jingle on a radio.

3 We want what we see. And so television
4 is a magnificent selling medium. But it's not - you
5 know it's great at conveying images of happy tummies
6 and smiling people who are relieved because they
7 don't have irritable bowel syndrome anymore, but
8 it's not so good at conveying complex information.

9 And the main reason is that television
10 teaches us primarily with images and not with words.

11 And images are inefficient ways to convey most
12 information. While some things you can learn through
13 images, anything that is complicated or requires
14 conceptual analysis or is typically taught very
15 poorly through television.

16 Neal Closeman wrote that, quote: It is
17 in the nature of television that it must suppress
18 the content of ideas in order to accommodate the
19 requirements of visual interest.

20 We need words and symbols to understand
21 what is complicated. Printed words are far better
22 for teaching what is complicated.

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1 Another problem is that television also
2 encourages us to absorb passively what we see, but
3 real education, whether it's about drugs or anything
4 else, it's active; it's not passive.

5 Television is excellent at spreading
6 these fantasyland images to people - fantasyland
7 images is what Senate Majority Leader Frist called
8 them. But it is simply incapable of presenting the
9 depth and richness of information that people need
10 about pharmaceuticals, and it's certainly not in 30
11 or 60 second spots.

12 And much the same is true for radio.
13 The high cost of buying ads on the media makes it
14 impossible to convey the extensive information that
15 consumers need about prescription drugs. And while
16 radio is better suited for conveying information,
17 it's still far inferior to print.

18 I wanted to talk for a second about
19 actors and celebrity endorsements. The advertising
20 industry uses actors in ways that are plainly
21 deceptive. For example, it uses actors who do not
22 and have never used the drug they are advertising,
23 but it doesn't disclose that fact, and that is - and

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1 it doesn't disclose that the actors really are
2 deliberately falsifying any improvements in health
3 that they are portraying or implying.

4 And that deception is so plain and
5 outrageous, it can only be described as fraudulent.

6 Now celebrity endorsements can be deeply
7 deceptive. For example, there is the famous story
8 of Wyeth hiring Lauren Hutton to promote its drug
9 for hormone replacement, and in an article in Parade
10 magazine, Hutton said, my number one secret is
11 estrogen, quote, it's good for your moods, it's good
12 for your skin. If I had to choose between all my
13 creams and makeup for feeling and looking good, I'd
14 take the estrogen, unquote. But there was no
15 mention that she'd been hired by Wyeth, and that
16 Hutton was a hired shill, and the promotion of
17 Wyeth's drug had nothing to do with education at
18 all.

19 So at best paid celebrity endorsements
20 have virtually no educational value. They come from
21 paid shills with anecdotal stories that tell a story
22 that may have no relationship whatever to the
23 relevant merits of the drug.

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1 All right, so I want to talk for the
2 last couple of minutes here about the minimum
3 requirements for protecting the public from DTC ads.

4 Now we certainly believe that DTC ads should be
5 prohibited. But if the FDA believes that it cannot
6 at this time fully prohibit DTC prescription drug
7 marketing, we strongly urge the FDA to expand its
8 interpretation of the term, misleading.

9 Any DTC ad should be accompanied by the
10 full FDA-approved label. At a minimum, DTC ads
11 should not exist without the full FDA-approved
12 label. The reason is, the label is the minimum
13 amount of information for any pharmaceutical
14 marketing communication to not be misleading.

15 Anything that presents less than that,
16 because it is dangerously incomplete.

17 The FDA should consider the entire label
18 as material information to consumers' decision-
19 making process. And it's probably worth thinking
20 about the Federal Trade Commission's policy
21 statement on deception just to kind of help you
22 think about a similar situation.

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1 Their policy statement said, quote, the
2 practice of offering a product for sale creates the
3 implied representation that it is fit for the
4 purposes for which it is sold. Failure to disclose
5 that the product is not fit constitutes a deceptive
6 omission. Omissions may also be deceptive when the
7 representations are not literally misleading, when
8 those representations create a reasonable
9 expectation or belief among consumers which is
10 misleading absent the omitted disclosure.

11 So in essence here DTC prescriptions
12 make an implied representation that the drug is fit
13 for use by consumers, who view the ads, and such an
14 implied representation is misleading if it's not
15 accompanied by the full FDA-approved label.

16 All right, then it's very important to
17 remove the loophole for broadcast ads. As you all
18 know prescription drug ads have to have a brief
19 summary, but regrettably in your guidance to
20 industry on consumer direct to broadcast
21 advertisements, the FDA created a devastating
22 loophole by interpreting adequate provision to mean
23 broadcast DTC ads may refer merely to print ads or

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1 websites or the like.

2 There is no basis for this loophole,
3 which establishes a stronger standard for DTC
4 prescription drug advertising in print and a weaker
5 one for broadcast. It's not merely enough to tell
6 people viewing the broadcast DTC ad to see the label
7 elsewhere.

8 Essentially this allows a broadcast ad
9 itself to be misleading, with the hope that
10 consumers will be able to seek out and read
11 information elsewhere.

12 This is completely inadequate, and it
13 does not meet the requirement under the act that DTC
14 ads must in themselves be nonmisleading.

15 There is no public policy justification
16 for lax standards on broadcast medium, merely
17 because the print standards are almost impossible
18 for broadcast media to meet.

19 In fact, it is a compelling reason to
20 prohibit DTC ads on TV and radio, because these
21 media are simply poorly suited to convey complicated
22 information. At a minimum there should be a uniform

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1 standard for all DTC advertising, the current print
2 standard.

3 Okay.

4 MR. ABRAMS: Thank you for your
5 presentation. Dr. Aikin.

6 DR. AIKIN: Thank you for your
7 presentation today. You advocate including the full
8 labeling in print advertising, if we can just stick
9 to print advertising. In those cases where the
10 particular product might have patient labeling,
11 would you advocate printing the physician labeling
12 in that case, or reprinting the patient labeling?

13 MR. RUSKIN: Well, I guess the physician
14 labeling -- in my mind the patient labeling is
15 quite thin in many case. I'm sorry.

16 So I would advocate for the physician
17 labeling, just because I think if - we don't think
18 there should be DTC ads, but if there must be the
19 ads, I think it is absolutely incumbent upon the
20 pharmaceutical industry to produce extensive
21 information in their ads so that people can read and
22 understand what these ads are and what these drugs

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1 are.

2 DR. AIKIN: Do you think it's helpful to
3 reprint physician labeling that patients might not
4 understand?

5 MR. RUSKIN: Well, I think that that's
6 part of the problem here with promoting things that
7 are very complicated. So I think at a minimum you
8 have to produce all the information to people to
9 read, and then they'll understand it as best they
10 can.

11 But to me your question just explains
12 one more reason why this is a crazy idea to drug
13 marketing; we just shouldn't do it at all.

14 MR. ABRAMS: Dr. Behrman.

15 MS. BEHRMAN: I guess two questions to
16 follow up on Dr. Aikin's point.

17 I believe you mentioned that in a
18 broadcast ad you would somehow convey the entire
19 physician labeling. Have you given any thought to
20 how you would do it? Would you scroll it?

21 MR. RUSKIN: I don't think it's

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1 possible, and that is kind of our point, is that
2 there is - it is inherently misleading. There is
3 just no way to pack that information in there in a
4 way that you could do that.

5 All media have limitations, and they are
6 inherent in the media. And that is just inherent in
7 TV; it's a lousy way of conveying information. So I
8 don't think it can be done.

9 MS. BEHRMAN: And are you aware of
10 research or data that speak to how much of the
11 entire prescribing information that is captured in
12 official labeling is important for a consumer to be
13 exposed to during DTC ads so they can fully - or as
14 much as you believe it is possible to balance the
15 information in that ad?

16 MR. RUSKIN: I'm not aware of any such
17 research.

18 MR. ABRAMS: Ms. Davis.

19 MS. DAVIS: Hi, thank you for your
20 presentation.

21 Towards the beginning of your

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1 presentation you indicated that there was no
2 legitimate purpose to advertising directly to
3 consumers since they can't directly buy prescription
4 products.

5 I think we've heard a lot during the
6 course of this meeting about some positive impact
7 that direct to consumer advertising can have on
8 actually getting people into the doctor when they do
9 have an undiagnosed or untreated condition.

10 How would you suggest that we make these
11 consumers aware of the fact that they have this
12 condition, and that there is something that can help
13 them/

14 MR. RUSKIN: Well, it's a great
15 question. I mean look, it's obvious that we need to
16 get people to understand what their own health
17 conditions, and we need to people to understand how
18 drugs work and what they are and what's out there.

19 But there are other entities that could
20 accomplish this much better, because they are not -
21 they don't have these inherent conflicts of
22 interest. So for example, I wrote about this a

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1 little bit in my written testimony. But for
2 example, the NIH could do such patient education
3 very well, or universities without - which take no
4 money from drug companies, or media organizations
5 could easily do such a thing, provided they don't
6 take ads, could all be harnessed to do much better
7 patient education.

8 Personally I think NIH would be great
9 for this sort of thing.

10 MS. DAVIS: And if I could just follow
11 up, how would you motivate these entities such as
12 universities that may not have a conflict of
13 interest to actually do this?

14 MR. RUSKIN: Well, I think there has to
15 be some stream of revenue, either from the federal
16 government or from states. I don't know exactly
17 where that revenue would come from.

18 But I think it's obviously desperately
19 needed. Then DTC advertising simply wouldn't be
20 needed at all.

21 MR. ABRAMS: Okay, our last question
22 would be from Dr. Temple.

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1 DR. TEMPLE: As you point out, the
2 purpose of an advertisement is to sell the product.

3 Do you think that invariably means that an ad must
4 be misleading even if it captures the essentials of
5 the currently approved labeling?

6 Let me say, I recognize that the imagery
7 can be powerful, and one has to take into account
8 all of those things. But if we were diligent about
9 those things, and I must say, I'm assuming that
10 nobody is going to give NIH \$4 billion or whatever
11 it takes to promote some of the good things we'd
12 like them to do, but maybe I'm too pessimistic.

13 But if that doesn't happen, do you think
14 that it is not possible under this present system to
15 have ads that are in fact balanced?

16 MR. RUSKIN: I think so. I really
17 encourage you to look back at the 1984 staff report
18 that the House Committee on Energy and Commerce
19 subcommittee on oversight and investigations did,
20 because Chairman Dingle went through that argument
21 quite extensively.

22 And basically his conclusion was, look,

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1 advertisers are very sophisticated. There are so
2 many ways to have shadings of tone and lighting and
3 intonations of voice to make this just inherently
4 impossible for the FDA to regulate, because there
5 are just too many innovations and ways of getting
6 around any simple rule. And for that reason alone
7 it just won't work. And that's why the whole class
8 is a bad idea. And that's what Chairman Dingle
9 argued.

10 DR. TEMPLE: All those things apply
11 equally, I assume, to physician directed advertising
12 who are the actual prescribers.

13 You argued that direct to consumer
14 promotion is sort of obviously illegal because
15 consumers can't prescribe for themselves, and you
16 could say that the fact that they can't prescribe
17 for themselves, and there is a learned intermediary
18 could allow for some greater tolerance of the
19 possibility that the ad isn't perfect, because the
20 perfect person to prescribe is still going to have
21 to make the decision to do it.

22 You are not impressed by that?

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1 MR. RUSKIN: No, I mean look, we either
2 believe in the law that's on the books or we don't.
3 I mean the law says, only physicians can prescribe.
4 So there are logical consequences that follow from
5 that.

6 One of those is that means the decision
7 maker is the physician, and therefore, there is just
8 no point of advertising to consumers.

9 MR. ABRAMS: Thank you, Mr. Ruskin, for
10 your presentation.

11 Our next speaker is Richard Stamp from
12 the Washington Legal Foundation.

13 MR. SAMP: Good morning. My name is
14 Richard Samp. I am chief counsel of the Washington
15 Legal Foundation, a nonprofit public interest law
16 and policy center based here in Washington, D.C.

17 WLF devotes a considerable portion of
18 its resources to opposing unwarranted government
19 restrictions on commercial speech. Thus our
20 interest in the topic being considered in today's
21 hearing.

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1 WLF has for several years tracked DDMACs
2 oversight of prescription drug promotional
3 activities. In 1995 WLF files a citizen petition
4 calling on FDA to relax restrictions on DTC
5 advertising, and I repeated that call in testimony I
6 gave at an FDA hearing in October, 1995.

7 I understand that our citizen petition
8 is part of the record in this proceeding, so I won't
9 go into all of the reasons which we focused on in
10 our citizen petition, which I think are still valid
11 today.

12 In 1998 we prevailed in a federal court
13 challenge to the constitutionality of FDA
14 restrictions on the ability of doctors and patients
15 to receive truthful information about off-label uses
16 of approved drugs.

17 And I emphasize, the court injunction
18 against FDA remains in place today.

19 In June of this year, WLF launched a
20 new program called DDMAC watch. Under this program,
21 WLF reviews and responds to warning and untitled
22 letters issued by DDMAC or by its counterpart in the

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1 biologics center, OCBQ.

2 To date WLF has responded to 12 DDMAC
3 and OCBQ letters. To date we have received no
4 response from the agency. We nevertheless have no
5 intention of stopping the program. WLF is firmly
6 convinced that FDA regulation of speech about
7 therapeutic products must be the subject of a
8 searching inquiry, both because of the public health
9 importance of public access to scientific
10 information about FDA-approved products, and because
11 FDA's current policies and practices present grave
12 statutory and constitutional problems.

13 The public health benefits of DTC
14 advertising are by now well known. Those benefits
15 are well illustrated by the data from the FDA's 2002
16 national telephone survey. The survey included both
17 health care practitioners and adult patients who had
18 visited a health care provider within the last three
19 months and sought access to - their exposure to,
20 perception of, and attitude toward FDA advertising.

21 I will skip over all the results of that
22 survey, which I think are well known to most of the
23 people here.

24 The conclusion of this study, however,

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1 is that DTC advertising encourages patients to seek
2 health information; increases awareness of possible
3 treatments; and reinforces health care practitioners
4 as authoritative sources of information.

5 These findings are consistent with
6 earlier research.

7 In light of the enormous benefits of DTC
8 advertising, WLF does not understand DDMAC's
9 apparent hostility. Rather than help manufacturers
10 fulfill their potential to be valuable sources of
11 health information for patients, DDMAC often works
12 actively to repress speech that it has no basis for
13 deeming to be false.

14 Most alarming to WLF, DDMAC has taken to
15 attacking scientifically valid clinical study
16 reports, and prohibiting manufacturers from
17 disseminating study data to help care practitioners
18 and patients.

19 For example, on June 28th of this year,
20 DDMAC sent a warning letter to Endo Pharmaceuticals,
21 objecting to the presentation of data from a
22 clinical investigation of lidoderm. The data were
23 published in a reputable medical journal.

24 Nonetheless, DDMAC demanded that Endo,

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1 quote, immediately cease the dissemination, end
2 quote, of information about the study, because DDMAC
3 did not like the study design.

4 On July 15th of this year, DDMAC sent an
5 untitled letter to Abbott Laboratory, objecting to
6 the presentation of data from a clinical
7 investigation of Cervanta. The data were published
8 in a reputable medical journal.

9 According to DDMAC, the study did not
10 constitute, quote, substantial evidence, end quote,
11 and therefore could not be relied upon by Abbott to
12 substantiate its claims.

13 These are but two examples of a well
14 established policy within DDMAC of prohibiting
15 manufacturers from sharing valid clinically relevant
16 scientific information.

17 It's paternalistic in the extreme for
18 DDMAC to purport to forbid speech based on peer
19 reviewed scientific journal articles. And WLF asks
20 the division to change its policy immediately.

21 This is precisely the type of
22 information that DDMAC should encourage
23 manufacturers to share, not only with health care
24 practitioners, but also directly with patients.

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1 That is what is mandated by the First
2 Amendment, and that is what is good for the public
3 health.

4 I want to speak briefly about corrective
5 advertising, but I'm going to skip over a number of
6 my prepared comments in the interest of time.

7 WLF is responding to FDA's request for
8 comments on its practice of, quote, asking, end
9 quote, sponsors to run corrective advertisements, or
10 issue corrective promotional materials, to remedy
11 impressions created by potentially false or
12 misleading materials.

13 Let's be clear what we're talking about.

14 DDMAC does not ask the sponsors to run corrective
15 advertisements. Although the agency uses language
16 to suggest that a sponsor has a genuine option to
17 reject a request for corrective messaging, what goes
18 on between DDMAC and sponsors is not exactly an
19 arms-length transaction.

20 Sponsors know that if they resist
21 DDMAC's request, they run the risk of souring their
22 relationship with DDMAC to the detriment of the
23 company.

24 This is not merely speculation on WLF's

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1 part. Within the past month we have learned that
2 DDMAC has told two sponsors that if they press their
3 rights, DDMAC will give strict scrutiny to every
4 single one of their promotional pieces.

5 Let there be no doubt: DDMAC expects
6 companies to engage in corrective messaging whenever
7 the division desires it.

8 It's a bedrock principle of
9 constitutional law that the First Amendment limits
10 not only government restrictions on speech but also
11 government compulsion to speak.

12 WLF has seen no indication that FDA has
13 considered whether its requests for corrective
14 advertising comport with the First Amendment as a
15 general matter. And we view it as highly unlikely
16 that anyone in FDA engages in a First Amendment
17 analysis each time DDMAC sends a warning letter
18 seeking corrective advertising.

19 Not only do we believe that it is highly
20 unlikely that this practice at DDMAC comports with
21 the First Amendment. We also believe that DDMAC
22 lacks statutory authority to demand such corrective
23 advertising.

24 Turning to what we believe is a

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1 deficiency in DDMAC's establishment of written
2 guidelines, it is abundantly clear to us that DDMAC
3 has in place many policies and procedures that drive
4 its decisions on promotional materials but that have
5 not been made available for public review.

6 The FDCA and FDA's own regulations
7 require the agency to announce new regulatory
8 expectations to regulated industry by going through
9 the notice and comment rulemaking or guidance
10 processes.

11 Anyone conversant with DDMAC regulatory
12 practice knows that you could be an expert on the
13 statute, the regulations, and the guidance documents
14 and still know only a tenth of the rules governing
15 drug promotion.

16 For example, it is clear from DDMAC's
17 warnings and untitled letters that there are
18 limitations on the length of the time a company can
19 say that a product is new. But you would be hard
20 pressed to find any authoritative document in which
21 that rule appears.

22 It is also obvious that there are
23 circumstances in which breakthrough is not allowed.
24 We learn from recent directive messaging required

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1 with respect to Embril that breakthrough can only be
2 used if sponsors conduct head-to-head comparative
3 studies.

4 WLF has pointed out numerous examples of
5 de facto rules in our correspondence to DDMAC under
6 the DDMAC Watch program.

7 We expect and hope that FDA will
8 reexamine DDMAC's modus operandi, and ensure that
9 the only rules that are lied upon in reviewing
10 promotional materials are those that have gone
11 through the statutorily prescribed procedures.

12 Much of the citizen petition we filed 10
13 years ago addressed excessive information that is
14 often required by FDA in advertising, and
15 unfortunately, many of those problems persist.

16 To take one example, suppose a
17 manufacturer wishes to convey the following message:

18 You have been prescribed drug X for your disease.
19 Take drug X exactly as your doctor prescribes.

20 It makes little sense that under current
21 FDA rules the manufacturer who conveys that message
22 will also have to provide the full PI as well as
23 comply with fair, balance and FDA's many other
24 requirements.

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1 FDA needs to streamline its disclosure
2 requirements in order to ensure that the information
3 being conveyed to patients is useful and meaningful.

4 Some suggestion reforms: WLF has
5 repeatedly communicated with FDA concerning our
6 views on the ways in which the agency's regulation
7 of speech should be changed. We are submitting for
8 the record copies of those previous suggestions.

9 Our main message for you at this
10 important meeting is that there remains much
11 important work to be done to ensure that DDMAC's
12 policies and procedures respect the First Amendment
13 and are consistent with the agency's statutory
14 authority.

15 Rather than clamp down on consumer
16 directed advertising, as the meeting notice implied
17 should be done, FDA should find ways of getting more
18 health information to patients.

19 That is the only approach that accords
20 with the administration's express commitment to
21 treating consumers as partners in their own health
22 care.

23 It is the only approach that accords
24 with the First Amendment.

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1 And it is the only approach that truly
2 promotes the public health.

3 Thank you for this opportunity to speak.

4 MR. ABRAMS: Dr. Temple?

5 DR. TEMPLE: Let me ask you about one
6 particular thing, which is what studies can be
7 referenced.

8 Do I understand that you think, oh,
9 anything that is published, say, in a peer review
10 journal is more or less automatically good enough,
11 and that there isn't any further criterion that
12 could be acceptable? For example, does a study have
13 to be a controlled trial?

14 MR. SAMP: If it has appeared in a peer
15 review journal, to me that is prima facie evidence
16 that the study has some validity.

17 Now for example many studies that are in
18 peer reviewed journals are open studies, and
19 therefore, don't meet the criteria that FDA would
20 normally apply for drug approval.

21 And if somebody wants to include the
22 results from those studies in some sort of
23 promotional piece, I think FDA would be well within
24 its rights in requiring that doctors be informed

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1 about some of the shortcomings of the study.

2 They should be told for example, this is
3 an open study, therefore this is perhaps not the
4 same well controlled study that the FDA requires for
5 product approval.

6 But so long as those kinds of
7 disclosures are made, doctors are much better off
8 knowing about those kind of studies than not knowing
9 about them at all.

10 DR. TEMPLE: Okay, so one of the
11 examples you gave on lidoderm plainly represented an
12 uncontrolled study. That's why we didn't allow them
13 to do it.

14 We would have probably said the results
15 aren't meaningful. But your remedy would be that we
16 would make the sponsor say this is a completely
17 uninform - we're telling you this, but it's
18 completely uninformative because there is no control
19 group.

20 Is that the idea?

21 MR. SAMP: The idea is that FDA knows a
22 lot about medicine, but so do the editors of peer
23 reviewed journals. And if they thought that the
24 article was good enough to be published, chances are

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1 that it does provide some information.

2 And FDA may disagree, but FDA's remedy
3 for that is to say it's not a well controlled study;
4 therefore proceed at your risk. But on the other
5 hand, as they have been told many times by federal
6 judges, we are not the masters of the universe when
7 it comes to medical knowledge.

8 A few editors of peer reviewed journal
9 magazines know something about medicine as well.
10 And therefore, when they think that the article is
11 good enough to be published, and there is no
12 indication at all that these particular editors have
13 a bias in favor of the company, that FDA ought to
14 allow this information to be conveyed to doctors,
15 provided that some sort of disclaimers are allowed.

16 And a disclaimer that requires people to
17 say, by the way, this is a worthless study, would be
18 wrong, because FDA doesn't know that in comparison
19 to the editor of the journal.

20 If FDA wants to say, require that it be
21 said, the study that we're showing you, FDA thinks
22 it's worthless. However, the New England Journal of
23 Medicine thinks differently, and we ask you to make
24 up your mind after reading the article.

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1 MR. ABRAMS: Dr. Behrman.

2 MS. BEHRMAN: I gather you've commented
3 unfavorably on all the letters that DDMAC has issued
4 since you started your program in June?

5 MR. SAMP: That's not correct. On most
6 of them we have.

7 MS. BEHRMAN: Do you believe that in
8 aggregate that the majority or totality of the ads
9 out today are neither false nor misleading? Or
10 DDMAC, are we just finding wrong in them?

11 MR. SAMP: First of all, I suspect that
12 the vast majority of ads that are out there DDMAC
13 does not comment on. So I assume you agree with me
14 that most ads out there are not inherently
15 misleading.

16 MS. BEHRMAN: That was really my
17 question. You believe that the majority of the ads
18 out there are not either false or misleading?

19 MR. SAMP: That is my belief, and I
20 suspect that there probably are some misleading ads
21 out there that unfortunately DDMAC probably has not
22 uncovered just because it doesn't have the resource
23 to fully examine every ad.

24 I do think in the aggregate, though,

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1 that the most important health care problem that we
2 have in the country is a lack of information
3 arriving to consumers rather than too much and
4 potentially misleading consumers.

5 So it ought to be the case that DDMAC
6 looks at ways to get more information to consumers
7 rather than stopping it.

8 MR. ABRAMS: We will have one more from
9 Dr. Behrman, and then one question from Ms. Davis,
10 and then we'll end.

11 MS. BEHRMAN: So if it did happen that
12 we found a false and misleading ad, and we felt it
13 was an egregious message, a very damage message,
14 what do you suggest we do about that? What would be
15 the appropriate remedy?

16 MR. SAMP: Well, first of all, as a
17 first thing to be doing, I would hope there would be
18 clearer guidance in written documents from DDMAC so
19 companies presumably wouldn't be doing this if they
20 knew in advance that what they were doing was
21 proscribed.

22 In terms of remedies, I think that if a
23 company persists, there are many unfortunately
24 powers that the agency has, up to and including

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1 criminal enforcement and seizing of product, and
2 there are any number of products that are being
3 peddled that perhaps have absolutely no scientific
4 value and have never been approved by FDA, and are
5 being advertised, and I certainly encourage FDA to
6 go after those kinds of products.

7 But if you are referring to my comments
8 about corrective advertising, it seems to me that in
9 the absence of evidence that the advertising that
10 you believe is false has in some way so totally
11 poisoned a well that people will never be able to
12 accurately view that drug again, I think the
13 appropriate remedy in most cases is simply an
14 injunction against further running of that ad. And
15 if people do, taking appropriate enforcement action.

16 MR. ABRAMS: Ms. Davis.

17 MS. DAVIS: Thank you. I just wanted to
18 follow up on some of the questions Dr. Temple was
19 asking.

20 It's my understanding that scientific
21 literature is full of examples of adequate and well
22 controlled studies disproving something that might
23 be thought to be true from a published study that
24 was not adequate and well controlled.

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1 So if a manufacturer was promoting
2 something from a published study, when the weight of
3 the evidence in adequate and well controlled studies
4 show that what they were promoting was false or
5 misleading, how would you suggest that the agency
6 and the sponsors, the company promoting it, react in
7 that situation?

8 MR. SAMP: Well, particularly if the
9 study that is well controlled contradicts what is
10 being said, to me that would be first of all pretty
11 good evidence that the study you're talking about is
12 false, and would therefore fall well within the
13 realm of FDA's ability to prohibit false
14 advertising.

15 What we're talking about is - what I'm
16 talking about anyway is information which is
17 arguably true, which FDA has no basis for thinking
18 is false, but which FDA wants to prohibit because it
19 has its doubts about the adequacy of the study that
20 produced that information.

21 And to the extent there is contrary
22 information, FDA is well within its rights in
23 requiring the disclosure of that contrary
24 information.

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1 MS. DAVIS: If I could just follow up
2 real quickly, if that contrary information comes out
3 after that's already been promoted, how would you
4 suggest the agency react?

5 MR. SAMP: Well, I suspect that in part
6 of wanting to look at the good faith of the
7 manufacturer. If the manufacturer in good faith was
8 advertising a study that is later contradicted by a
9 study that the manufacturer knew nothing about, I
10 would certainly hope that an agency using discretion
11 would take much less severe action than a company
12 that knowingly used a study that they knew was
13 extremely doubtful.

14 MR. ABRAMS: Thank you, Mr. Samp, for
15 your presentation.

16 Our next speaker is Alex Sugarman-Brozan
17 from the Prescription Access Litigation.

18 MR. SUGARMAN-BROZAN: Good morning.
19 Thank you for the opportunity to speak.

20 I am director of the prescription access
21 litigation project, which is a coalition of 115
22 organizations representing consumers in 35 states.
23 PAL, as we're known, works to end illegal
24 pharmaceutical price inflation and deceptive

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1 marketing through the use of class action litigation
2 and public education.

3 First I want to start by saying that we
4 need to put direct to consumer advertising in the
5 larger context of drug promotions generally.
6 Although the industry spends over \$4 billion a year
7 on DTCA they spend over \$5 billion a year on
8 physician promotions. So the entire universe of
9 transactions and information exchange that takes
10 place isn't just a question of a consumer who is
11 influence by an ad approaching a doctor who hasn't
12 been influence. The 80,000 or more than 80,000
13 pharmaceutical sales people who descend on doctors'
14 offices everyday have an influence over what
15 physicians know about prescription medications as
16 does the influence of the drug industry in
17 continuing medical education, journal articles, and
18 published guidelines. And we need to think about
19 DTCA in that context.

20 We see deceptive marketing by
21 pharmaceutical companies as one of the primary
22 factors driving up cost and inappropriate use of
23 prescription drugs in the United States.

24 This in turn is a major contributor to

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1 the health care crisis in this country. We strongly
2 feel that the net effect of DTCA is negative.

3 Initially we feel that as other speakers
4 have described the DTCA interferes with the doctor-
5 patient relationship. It creates unrealistic
6 expectations of drug efficacy, and risk and severity
7 of side effects. We call it the fields of flowers
8 effect, referring to one of the common images in
9 drug ads of happy people frolicking through fields
10 of wildflowers, given the impression that the drug
11 being promoted will make the user just as happy as
12 the people shown in the ads.

13 We feel that DTCA promotes brand name
14 drugs as a panacea, while undermining genuine public
15 health messages that promote lifestyle changes such
16 as diet and exercise, and as well as generic drugs.

17 We never see ads that say, ask your
18 doctor about diet and exercise. Or, ask your doctor
19 about hydrochlorothiazide, one of the diuretics that
20 is one of the most effective treatments for
21 hypertension, but which costs only pennies a day.

22 DTCA also furthers the notion that newer
23 is better, and that a brand name drug is better than
24 a generic or over the counter, thus over-promoting

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1 expensive brand name drugs whose real-world side
2 effects long term are unknown, at the expense of
3 generics whose long term safety and efficacy may be
4 more well documented.

5 Obviously, it drives up cost by
6 promoting inappropriate use of brand name
7 prescription drugs to users who either don't need
8 that particular drug, or who could use a less costly
9 intervention.

10 And finally we feel that it skews
11 research priorities of the industry towards - in
12 favor of so-called me-too and lifestyle drugs.

13 Every year PAL holds an event called the
14 Bitter Pill awards, exposing drug company
15 manipulation of consumers. And I just want to
16 highlight two of our awardees in this past year that
17 we think demonstrate some of the harms of DTCA.

18 And the first is one we've all heard a
19 lot about this year. Vioxx and Celebrex were the
20 joint winners of the Speak No Evil Award for
21 concealing drug risks and benefits in the name of
22 profit.

23 Vioxx in particular was a drug taken by
24 over 20 million people due almost entirely due to

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1 the advertising promotion, both to consumers as well
2 as to physicians. Despite the fact that only one to
3 two of patients were at risk for the kind of
4 gastrointestinal complications for which the only
5 advantage of this drug was.

6 And the Archives of Internal Medicine
7 did a study showing that 70 percent of the users of
8 Cox-2s in the first three years didn't need, because
9 they didn't fit this extremely narrow profile.

10 And this obviously raises the issue of
11 how many heart attacks and deaths were caused by the
12 inappropriate use of these drugs that later were
13 discovered to be dangerous, but also, how many
14 billions of dollars in the health care system were
15 wasted.

16 The second award I want to highlight is
17 Nexium, which one our award for the Least Extreme
18 Makeover award for dressing up an old drug with a
19 new name and a new price tag.

20 I think most people in this room are
21 aware that Nexium is merely an isomer of Prilosec,
22 AstraZeneca's previous heart burn and reflux
23 blockbuster. But at comparable doses, Nexium is
24 clinically no more effective than Prilosec, yet it

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1 is seven times more expensive.

2 They have estimated sales from 2005 to
3 reach \$4.6 billion. This is a drug that simply has
4 no reason for anyone to take it, and owes its entire
5 existence to the promotions around it.

6 Both of these examples I think
7 demonstrate that the function of drug ads is not to
8 educate but to sell. And I'd like to offer a quote
9 by dr. Marsha Angell, author of The Truth About the
10 Drug Companies, who said: To rely on the drug
11 companies for unbiased evaluations of their products
12 makes about as much sense as relying on beer
13 companies to teach us about alcoholism. The fact is
14 that marketing is meant to sell drugs, and the less
15 important the drug, the more marketing it takes to
16 sell it.

17 Important new drugs do not need much
18 promotion. Me-too drugs do. Any educational
19 benefit is significantly outweighed by the negative
20 effects previously described.

21 As other speakers have stated, there are
22 other ways of educating the public about medical
23 conditions, and the need for treatment that do not
24 carry the baggage of DCTA.

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1 Now, PhRMA recently released its own
2 voluntary guidelines on DTCA to much fanfare. My
3 recommendation is that the FDA should take no heed
4 of these whatsoever. Voluntary guidelines, which do
5 not require compliance, which have no enforcement
6 mechanism, and which carry no penalties for
7 violation, are a public relations measure and
8 nothing more.

9 We would urge the FDA to take the
10 following actions. First, to increase enforcement.

11 And this mostly requires adequate staff to review
12 promotions.

13 As other speakers have said, the level
14 of enforcement in the form of untitled warning
15 letters has decreased over the past seven years.
16 The number of letters issued in 2005 is
17 approximately 20 percent of the number issued in
18 1998.

19 It's been stated that the FDA has 40
20 staff members to review all drug promotions,
21 including both DTCA and promotions to medical
22 professionals. And there are approximately almost
23 53,000 drug promotions in 2004.

24 This required each and every of those 40

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1 staff people to review 1,320 pieces of promotion per
2 year, or 5.5 per day, which is simply impossible to
3 give the level of scrutiny necessary at that kind of
4 rate.

5 Second, we would encourage ending the
6 requirement that all enforcement letters be reviewed
7 by the office of the chief counsel. Others have
8 referred to the GAO report which showed that this
9 policy change has resulted in often letters taking
10 so long to reach the sponsoring company that the
11 drug promotion has already run its course. This is
12 the epitome of closing the barn door after the horse
13 has gone, and completely undermines the
14 effectiveness of what little enforcement authority
15 has to police DTCA.

16 Third, we would encourage requiring pre-
17 broadcast submission of all ads. Again, this would
18 require adequate staff to review those, sine the
19 time necessary to review them before broadcast would
20 be shorter.

21 And the FDA should require not only TV
22 ads but all radio, print and online advertisements
23 should be submitted prior to broadcast. And
24 obviously this relates to my next recommendation,

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1 which is, we encourage the FDA to seek congressional
2 authority to impose civil monetary penalties, as
3 other speakers have also recommended.

4 Currently there is a huge gap in the
5 FDA's enforcement authority that renders its
6 untitled warning letters ineffective. At best such
7 a letter will prompt a manufacturer to stop running
8 the ad in question, and possibly to run a corrective
9 ad if that is requested.

10 But manufacturers know that the more
11 severe sanctions that FDA can impose, such as an
12 injunction or criminal enforcement or seizure are
13 very blunt instruments that the FDA seldom if ever
14 uses, and that therefore there is almost always
15 nothing to back up the untitled warning letters.

16 It is akin to what the comedian Robin
17 Williams has said about unarmed British police, and
18 what they shout to fleeing criminals, which is:
19 "Stop or I'll shout stop again."

20 The FDA should therefore seek
21 congressional authority to impose civil monetary
22 penalties on manufacturers who violate the FDA
23 standards on DTCA, particularly those that are
24 repeat offenders.

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1 Finally, I would recommend prohibiting
2 reminder advertisements. Although the PhRMA
3 guidelines would seem to prohibit this, again, those
4 are voluntary, and it remains to be seen whether all
5 manufacturers will sign up, and whether their
6 compliance to those guidelines will be effective in
7 the long term when the heat is off.

8 A message that says nothing more than,
9 ask your doctor if drug X is right for you does
10 absolutely nothing to educate the consumer. Its
11 only purpose is to increase the name recognition of
12 the drug, and bolster those longer advertisements
13 for the drug that do list the benefits and risks.

14 The FDA should issue a regulation
15 prohibiting reminder ads as a violation of the
16 relevant FDA standards on DTCA. Any advertisement
17 including the name of a drug should be required to
18 disclose the same risk information as an ad
19 describing the drug's use in more detail.

20 Now it has been discussed widely in the
21 industry and the press that so-called disease
22 awareness ads are going to begin to replace more
23 drug-specific promotions, and I think we need to
24 give this type of advertisement careful scrutiny,

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1 because I think that disease awareness is going to
2 become the new reminder ad.

3 Disease awareness ads in theory just
4 describe a medical condition, and don't mention a
5 particular medication. And while educating
6 consumers about medical conditions is of course
7 extremely valuable, we should not entrust that
8 education to such self-interested parties as the
9 companies that stand to make billions from the
10 increased use of brand name prescription drugs.

11 This is one example of not disease
12 awareness ads, but the additional source to which
13 the disease awareness ad referred. And there is a
14 television commercial featuring Lorraine Bracco,
15 star of the Sopranos, in which all she does is talk
16 about her experience with depression and no mention
17 is made of any drug.

18 She then refers viewers to a website,
19 Depression Help dot com. When you visit that
20 website, it's an untrammelled promotion of Pfizer's
21 SSRI Zoloft.

22 The link between the originally
23 supposedly nonpromotional ad and the website
24 promoting Zoloft belies the claim that disease

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1 awareness ads are some benign form of public
2 education.

3 These awareness ads, such as this one -
4 and not all of them have this characteristic of
5 referring people to a website that is purely
6 promotional - but awareness ads such as this
7 function as barkers steering consumers to
8 promotional materials that do discuss the particular
9 risks and benefits of a particular drug.

10 When there is such an explicit link
11 between a disease awareness ad and another DTCA
12 source that is subject to regulation, we believe the
13 original ad should be considered part of the same
14 promotional materials to which it links and subject
15 to regulation as well.

16 Now, Dr. Peter Laurie from Public
17 Citizen mentioned the promotion for Differin. And I
18 put a copy of the advertisement to which he referred
19 right here. And I think you will see just how
20 reprehensible this is.

21 This is a disturbing trend for
22 advertising drugs for children, particularly for
23 acne medications. Children and teenagers are simply
24 not able to fully appreciate and balance the risks

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1 and benefits of a prescription drug. But marketers
2 know how effective children and teens are at
3 pressuring their parents to get them what they ask
4 for. And anyone in the room who is a parent will
5 attest to that.

6 This ad campaign creates completely
7 inappropriate incentives by offering free music
8 downloads for every prescription you have. Such
9 linked promotions, if not already illegal - and I
10 would argue that they are - should certainly be made
11 illegal by the FDA through regulation.

12 All right, I'm going to make my other
13 regulations very quickly. We feel that coupons for
14 prescription drugs have no place in our medical
15 system and should be flatly prohibited as they
16 completely skew the incentives of the consumer even
17 more so that DTCA already does.

18 And finally we'd agree with other
19 speakers that it is time to return to the pre-1997
20 requirements, and require the full brief summary in
21 all broadcast, and not just the major statements and
22 adequate provision at some other source.

23 Thank you for the opportunity to speak
24 to you today.

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1 MR. ABRAMS: Thank you for your
2 presentation.

3 Dr. Temple?

4 DR. TEMPLE: The full brief summary in a
5 TV ad, you mean like scrolling it or something? Or
6 is this just to block them?

7 MR. SUGARMAN-BROZAN: Well, again, again
8 --

9 DR. TEMPLE: Or is this just to block
10 them?

11 MR. SUGARMAN-BROZAN: No, I think that
12 for many drugs, if not most drugs, it would not be
13 possible to portray the full brief summary in an ad
14 that didn't last 10 minutes. And that just
15 demonstrates the inappropriateness of advertising
16 drugs on TV or radio.

17 If a manufacturer was able to find a
18 consumer-friendly and understandable way of
19 including the full brief summary, then I suppose
20 they should be permitted to do that. But if they
21 can't, then it shouldn't be on TV or on the radio.

22 DR. TEMPLE: Okay, let's take a print
23 ad. Our guidance - our post-guidance - suggested
24 that the so-called brief summary, which is of course

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1 neither brief nor a summary, is impenetrable because
2 it's very long, very small print, and is not written
3 in consumer friendly language.

4 And we proposed a number of alternatives
5 that we thought would communicate that, some of
6 which would depend on the so-called highlights of
7 what will eventually be revised physician labels and
8 things like that.

9 But the goal of all those is to make
10 them comprehensible. Just considering now the print
11 ads, do you think that is in the wrong direction or
12 the right direction?

13 MR. SUGARMAN-BROZAN: I think any
14 information distributed to the public about
15 prescription medications, whether it's product
16 specific or more general, obviously needs to be
17 understandable by the public.

18 We also think it's noteworthy that only
19 New Zealand is the only other country that uses
20 DTCA, and even they have a moratorium. And we think
21 on balance DTCA is a negative thing, but we just
22 don't see it becoming illegal or substantially
23 restricted.

24 So in light of that, I think the

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1 regulatory system needs to do the best it can. The
2 impenetrable six-point type that lists every detail
3 that even physicians have a hard time getting
4 through is obviously not consumer friendly, and I
5 think the FDA needs to take steps to ensure that
6 print ads are understandable.

7 DR. TEMPLE: So let me see if that has
8 any potential translation to the broadcast setting.

9 Obviously even a consumer friendly version of
10 highlights would be difficult to get into a
11 broadcast setting, but you could pick the highlights
12 of the highlights.

13 Would you think that's not good enough?

14 MR. SUGARMAN-BROZAN: I think that's not
15 good enough.

16 DR. TEMPLE: Or you'd rather see it go
17 away?

18 MR. SUGARMAN-BROZAN: I think for many
19 consumers, they will refer to the outside sources,
20 and that their only information would be what they
21 saw in the ad. And we've seen the studies, many of
22 which have been cited today, about the inappropriate
23 effects of DTCA on prescribing, not just on
24 consumers seeking particular prescriptions, but on

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1 them getting them.

2 And therefore, I don't think it's
3 possible to summarize information in a one-minute
4 ad. Maybe the industry needs to purchase larger
5 blocks of time, where they can lay out all that
6 information. But I highly doubt that any consumer
7 would want to take a drug after seeing that.

8 DR. TEMPLE: Yes, I think our thought
9 would have been that they won't. They'll just tune
10 out. So you probably can't do it that way.

11 MR. ABRAMS: Dr. Behrman?

12 MS. BEHRMAN: Can I just clarify your
13 answer to Dr. Temple's question? I believe you said
14 in your presentation that it was quite clear that
15 you thought the entire group summary be included in
16 a print ad, and then Dr. Temple referred to our
17 February '04 draft guidance which talked about ways
18 of summarizing a subset of that information.

19 Are you in agreement with that approach?

20 MR. SUGARMAN-BROZAN: I think that there
21 needs to be a consumer-friendly summary. But an
22 inclusion of the brief summary for those who have
23 the inclination to wade through it is appropriate.

24 MR. ABRAMS: Okay, thank you for your

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1 presentation and information today.

2 Our next speaker is Wallace Snyder from
3 the American Advertising Federation.

4 MR. SNYDER: Good afternoon. I am
5 Wallace Snyder, I am president and CEO of the
6 American Advertising Federation.

7 Formerly, I was the associate director
8 for advertising practices at the Federal Trade
9 Commission.

10 The AAF represents all facets of the
11 industry - the agencies that create the
12 advertisements, the companies that market and sell
13 them, and the media companies who run the ads.

14 I'm very proud to represent an
15 organization as diversified in its viewpoints and as
16 open-minded in its discourse.

17 I think the FDA for its regulation of
18 DTC advertising, and I thank you for this
19 opportunity to present to you this morning.

20 I think that my statement will be very
21 clear, no mistake about it. And it will be: Do not
22 impose a moratorium on direct to consumer
23 prescription drug advertising.

24 The criticism of DC advertising has been

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1 blunted in these hearings by a number of experts,
2 including conclusions contained in the annual survey
3 by Prevention magazine, and I quote: The increasing
4 presence of DC advertising has not resulted in a
5 surge of requests about or for advertised
6 prescription drug.

7 No one is going to strong arm consumers
8 in this country about medicines or any other
9 product, and the advertising industry does not want
10 citizens taking medicines simply for the sake of
11 taking medicines.

12 And as a result, as the polls show, the
13 American people are quite capable of deciding if and
14 when they want a prescription drug, when provided
15 with balanced information.

16 Ultimately the issue is not about
17 moratoriums. It is about regulation. It is about
18 the process of regulation. If a drug is not ready,
19 by all means keep it off the market. But once
20 approved, once the stringent requirements of
21 critical trials and other testing are done, and the
22 drug is approved, please do not send a mixed message
23 by delaying advertising. Regulate the drug, but do
24 not impose or impede the flow of truthful

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1 information.

2 We support ads that provide the clearest
3 explanations of risks and benefits, and are
4 presented to consumers in the clearest possible
5 fashion.

6 Consumers with good information will
7 make good health decisions.

8 The regulatory scheme now in effect
9 relies on the Food and Drug Administration to
10 approve drugs for patient use, and to review all the
11 advertising for those drugs. A moratorium will gut
12 this viable oversight, and it would minimize any
13 influence the FDA has over prescription drug
14 advertising.

15 The FDA chance to influence the first
16 message received by consumers would be gone.

17 Now I have to tell you in advertising
18 there is an old statement about businessman R.J.
19 Wrigley. It goes like this: An acquaintance seated
20 next to Wrigley on a flight to Chicago asked the
21 multimillionaire why he continued to advertise his
22 chewing gum since it was already so successful. And
23 Wrigley replied, the same reason the pilot keep this
24 plane's engines running, even though we are already

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1 in the air.

2 Wrigley understood the value of
3 advertising to his business and to consumers, and he
4 understood the value of an informed public, as does
5 the Supreme Court, which acknowledge that the free
6 flow of advertising could be as important as the
7 free flow of news to Americans.

8 An advertising great, David Ogilvy, in
9 our industry, said that what this is all about, this
10 advertising, he said that I do not regard
11 advertising as entertainment or as an art form but
12 as a medium of information.

13 And that is what this is all about:
14 getting the information to the American public.
15 Advertising is just one instrument in our quest for
16 better health, but advertising is a partner in this
17 mission.

18 I believe contemporary advertising is
19 disciplined, and an ethical industry that believes
20 in good citizenship. The most memorable slogans and
21 enduring social changes can be credited to the
22 advertising industry.

23 Our critics may be well intentioned, but
24 they are misguided and just plain wrong when they

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1 claim that DTC advertising doesn't promote public
2 health in this country, that they say it is
3 misleading, that it omits specifics about the side
4 effects, and that it drives a wedge between medical
5 professionals and patients, is false on all counts.

6 Here are some of the traditional bottom
7 lines.

8 A recent survey of 900 African-American
9 physicians revealed a majority believes DTC
10 advertising promotes increased communication between
11 physicians and patients.

12 More than 60 percent felt no pressure to
13 prescribe a specific medicine, and the vast majority
14 denied changing their prescribing habits because of
15 DTC.

16 The Prevention poll says caregivers rely
17 on DTC, not as a final word but as a starting point
18 to help manage ailments, and to help learn more
19 about new treatments for people in their care.

20 The Prevention poll also found that DTC
21 advertising, and I quote: Does not appear to
22 overstate and understate the risk of advertising
23 medicines. The poll says consumers are likely to
24 equally remember both.

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1 A study by the FDA found that DTC
2 advertising prompted 23 million people in America to
3 see a doctor and talk about a condition they never
4 discussed before.

5 The Prevention poll says 21 percent who
6 say DTC advertising made a lifestyle change,
7 improving diet and exercise habits. And yesterday
8 you heard Professor Andrew Clyde (phonetic) of Penn
9 State discuss his research that finds that ads
10 appear to encourage patients to seek medical care.

11 Now I have to tell you personally that
12 those of us with solid incomes, a good education,
13 have options in this country for health maintenance
14 - insurance, Internet access, and visits to medical
15 and allied specialists.

16 I am blessed with easy access to good
17 health care. I talk with doctors about my asthma,
18 pulmonary specialists. And the new pharmaceuticals
19 that are available to me for this illness.

20 But too many low income Americans of
21 all colors have no such recourse. For too many
22 underprivileged Americans, health care means a trip
23 to the emergency room. And we have an epidemic in
24 this country of inner-city asthma sufferers among

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1 our youth.

2 DTC advertising can help them avoid this
3 by connecting them to the health care system before
4 a crisis situation arises.

5 Many critics of DTC advertising are
6 upset because they believe the advertising is
7 causing a rise in the use of prescription drugs.

8 Pharmaceutical usage is something that
9 should be celebrated, and not lamented. If
10 physicians are doing their jobs properly, and we
11 have no reason to believe they are not, increased
12 usage means more patients are getting needed
13 treatments for their illnesses.

14 DTC advertising represents a first step
15 toward gaining information, going to a clinic, or
16 adopting a healthy lifestyle. Why send a mixed
17 message by approving a drug but blocking information
18 provided by ads?

19 How many patients will suffer a reduced
20 quality of life because public policy deliberately
21 limits the information they can receive about
22 potential treatments?

23 If a drug is not deemed safe, delay
24 approval and require additional clinical trials.

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1 But once approved, we should do all we can to make
2 sure that those who might benefit learn about it,
3 talk to a physician and decide the best course of
4 treatment for them.

5 DTC advertising is a valuable source of
6 information about the benefits and the risks of new
7 treatments. It promotes a healthy diet and
8 exercise, and it encourages people to talk to their
9 doctors. It leads to more cost-effective health
10 care through early detection, and it provides a
11 resource to under serviced caregivers who need
12 accurate drug-related information to manage their
13 health care of people who are in their charge.

14 The statement made by the cardiac
15 surgeon, Christian Bernard, summarizes, our view
16 point on this issue. Dr. Bernard, who performed the
17 world's first heart transplant on a human said,
18 suffering isn't ennobling, recovery is.

19 Thank you very much for your attention.

20 I'd be happy to answer any questions.

21 MR. ABRAMS: Ms. Davis.

22 MS. DAVIS: Hi, thank you for your
23 presentation.

24 I have a question. You had cited an

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1 example of inner city people suffering from asthma
2 as an example of underprivileged people who aren't
3 getting treatment.

4 Currently there is direct consumer
5 advertising going on. What would you suggest needs
6 to be done in order to get people into the doctor in
7 addition to what we've seen already?

8 MR. SNYDER: Well, what we have really
9 encouraged is that the companies that manufacture
10 these drugs - for example, the Advairs, the products
11 that can avoid the bronchial dilation, that they
12 really focus a good portion of their budget on their
13 city consumers.

14 And I think that you will see that
15 happening more and more. But what I would urge is
16 that they really make those consumers, parents,
17 grandparents, guardians, aware that there are
18 products other than bronchial dilators that can be
19 taken. Because if it's too late, the child is going
20 to go into the emergency room.

21 MR. ABRAMS: Okay, Mr. Snyder, thank you
22 very much for your presentation and information.
23 Thank you.

24 MR. SNYDER: Thank you for the

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1 opportunity.

2 MR. ABRAMS: Okay, our final speaker on
3 the panel is Kim Witczak, a consumer.

4 MS. WITCZAK: Hello. My name is Kim
5 Witczak, and I am not affiliated with any other -
6 with any group or company.

7 I have come here today as a private
8 citizen, and unfortunately, a widow. I have also
9 worked in the ad business for over 15 years.

10 On August 6th, 2003, my husband, Woody,
11 was found hanging dead at the age of 37 of a Zoloft-
12 induced suicide after being on a drug a total of
13 five weeks.

14 It is because of what happened to my
15 family today, and my professional experience, that I
16 am here today. I'd first like to tell you a little
17 bit about my husband and his story.

18 Woody and I were married a few months
19 shy of 10 years. Woody was a person who cherished
20 life, and the people in his life. He had a
21 successful sales career, and attained the position
22 of national sales manager with a manufacturing
23 company before leaving to pursue his dream of
24 starting a new business from the ground up.

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1 With the challenges of this new
2 opportunity he had trouble sleeping. He was excited
3 about the opportunity but would wake up thinking
4 about work in the middle of the night.

5 He went to his family doctor, and was
6 given samples of Zoloft to help him sleep. He was
7 not depressed nor ever diagnosed with depression by
8 his doctor.

9 I happened to be out of the country on a
10 photo shoot for the first few weeks he was on the
11 drug. He experienced several side effects including
12 diarrhea, heavy sweating, akathisia, which is a
13 neurological condition that causes severe internal
14 restlessness and agitation, as well as a feeling of
15 being outside his body looking back at him.

16 Unfortunately, the Pfizer three-week
17 sample pack doubled the dose. We tried many things
18 during this period trying to figure out why Woody
19 suddenly went from sleeplessness to having all these
20 new problems. We were unaware, unwarned, that
21 Zoloft is the drug that is touted and sold to help
22 millions was actually causing Woody harm.

23 Woody was told that it would take four
24 to six weeks for it to work. On August 4th, I left

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1 on an advertising shoot in Detroit, and Woody seemed
2 to be doing better. We were discussing our overseas
3 trip for our ten-year anniversary and making plans
4 to have children.

5 And in fact the day before he died, we
6 booked two trips for the following week, and one a
7 month later.

8 The next day Woody was found hanging in
9 my garage by my dad. Woody had no history of
10 depression or any other mental illness. His death
11 was a complete shock to his family, his friends, his
12 doctor, and me.

13 The man who loved life was gone. While
14 still struggling to cope with this loss, I have
15 chosen to use my experience to try and make a
16 difference.

17 I have often asked myself why Woody, a
18 guy who didn't like taking medications, went to the
19 doctor and ended up on Zoloft.

20 I do believe that DTC advertising had a
21 role. Before August 6, 2003, I never gave Zoloft a
22 second thought. I had seen Zoloft ads everywhere,
23 and just assumed it was safe and effective since it
24 was being advertised on TV and in magazines.

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1 Although Woody didn't go to his doctor
2 specifically looking for Zoloft, I believe DTC has
3 affected the culture that ultimately led him to
4 Zoloft.

5 DTC advertising has influenced the
6 American prescribing habits on many levels.
7 Americans of all economic, social and educational
8 backgrounds are now trained to run to general
9 physician and ask them if whatever drug is right for
10 them.

11 Harvard Business School actually did a
12 case study. The marketing of antidepressants is one
13 successful example of how advertising can drive a
14 market. From a professional standpoint this is what
15 every advertiser strives for, advertising that
16 changes consumers' perception, to motivate them to
17 believe or behave in a certain manner.

18 From my personal perspective, I think
19 it's a tragedy. DTC advertising has created a
20 mindset that there is a pill for every problem.
21 Antidepressant advertising is a perfect example.

22 This is one drug that is supposed to
23 work for anxiety, social phobia, TMS, depression.
24 One has to wonder how a drug that was originally

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1 approved for major depressive disorder can
2 distinguish between these various mental disorders
3 as it supposedly balances out the so-called chemical
4 imbalances in the brain.

5 DTC advertising has shifted the
6 diagnosing paradigm away from the physician to the
7 consumer to self-diagnosing medical problems and
8 conditions before seeing their doctor.

9 We heard today that that is a good
10 thing, to encourage people to go. However, before
11 going in, already diagnosing themselves.

12 DTC advertising is driving more and more
13 people to GPs for medication they may or may not
14 need.

15 Ultimately we as the American public are
16 the real clinical study. DTC advertising has
17 created disorders and their solutions.

18 In a 2000 Ad Age article, Paxil's
19 product director said, every marketer's dream is to
20 find an unidentified and unknown market and develop
21 it.

22 Interestingly, soon after Paxil was
23 approved by the FDA for a new indication, social
24 anxiety disorder. As Elliot Valenstein, professor

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1 of psychology and neuroscience at the University of
2 Michigan said, shyness can't be marketed because
3 people recognize it as a normal variance on
4 personality. But social phobia sounds like a
5 disease.

6 Just recently an article titled "A
7 Disease for Every Pill" ran in the October 17th
8 issue of the Nation. It talks about the creation of
9 a disorder call PMDD, premenstrual Dysphoric
10 Disorder. Eli Lilly's blockbuster antidepressant,
11 Prozac, was about to lose its patent exclusivity
12 when they found a new use for Prozac, and renamed
13 and repackaged it under the name of Seraphim,
14 targeted to women who suffer premenstrual cramps and
15 emotional ups and downs that go along with monthly
16 periods.

17 This is a perfect example of a company
18 using the creation of a condition and aligning it
19 with the product.

20 It's interesting to note that not every
21 regulatory body around this world recognizes this as
22 a disease. In 2003 a panel from a European agency
23 for evaluation of medicinal products noted that PMDD
24 is not a well established disease entity across

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1 Europe. Patients might erroneously receive
2 diagnosis of PMDD resulting in the widespread
3 inappropriate long and short term use of fluoxetine,
4 which is the generic name for Prozac or Seraphim.

5 We are the only westernized country
6 besides New Zealand that allows DTC advertising.
7 The drug companies have been lobbying like crazy in
8 the EU to open up their market and allow DTC
9 advertising.

10 According to the labor health
11 spokesperson in the European parliament, if we open
12 the door to direct advertising it is a slippery
13 slope down the American road where pink pills and
14 television advertisements for a miracle solution for
15 everything from baldness to chronic fatigue.

16 Not long ago prescription drugs were
17 marketed primarily to help train health care
18 professionals. It is now being replaced by drug
19 companies promoting their ads in mass market print
20 and television advertisement targeted to us, the
21 general public.

22 This new marketing environment begs for
23 enhanced consumer protection.

24 At the minimum, direct to consumer

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1 advertising of drugs must be held at a higher
2 standard. This is serious business with products
3 that can have serious or sometimes failed side-
4 effects.

5 It needs to, at the minimum, treat it in
6 a serious manner as Dr. Janet Woodcock said
7 yesterday, as truthful, balanced and not misleading.

8 Prescription drugs are not like other
9 consumer products. They should not be treated in
10 the same way as cars, soap or fast food. DTC ads
11 must be grounded in truth, absolute truth, no
12 variance from the truth. Safety has to be number
13 one.

14 Drug companies have the ethical
15 responsibility to communicate all serious side
16 effects, whether known as a result of the initial
17 clinical study, or after the drug is on the market,
18 and the side effects are starting to pop up, given
19 the large number of people on the drug, in a clear,
20 concise and honest manner.

21 Not just those that seem palatable to
22 the public and won't scare people away from thinking
23 twice about taking the drug. If you notice most
24 side effects for all drug ads are pretty much the

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1 same.

2 Let's take a look at a few Zoloft print
3 ads to see if they follow this principle. Do you
4 often get nervous around people? The use Zoloft as
5 the bouncing oval cartoon character, looks like the
6 white M&M. Social anxiety might be overwhelming.
7 You might shake, sweat, or feel panicky. I know I
8 am right now.

9 Here are the ones that I think are
10 really interesting. Earlier somebody was saying
11 that they were using real testimonials from people.

12 Well, these are really interesting. We've Kathy
13 story's here. She is age 41 from Irvine,
14 California. It's in a cartoon. Her daughter said,
15 mom, you are no fun anymore. It hit me that it was
16 time to get help.

17 This one is Molly's story, age 28,
18 Cincinnati. She wasn't feeling in love.

19 Well, the best part of these ads, if you
20 look at the very tiny type in the bottom, last
21 little cartoon, it says, story not based on actual
22 person.

23 What other industry could you do this
24 in?

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1 And then this last one, it's a
2 disclaimer, on June 30th of 2005, the FDA came out
3 with a public health advisory warning that all
4 patients, adult and children, need to be closely
5 monitored on a daily basis when first going on this
6 for any emergency suicidality or changes in
7 behavior.

8 Where does it get put in - you can see
9 this tiny green highlight. That is where it's at.
10 But to me - I mean I wish that was available when my
11 husband got put on it. I was out of the country.

12 I ask, is this responsible advertising?

13 In my opinion, no.

14 You know we talk about balance and risk.

15 Maybe one thing - I'm in the ad business, and I
16 can't believe I would even remotely suggest this -
17 but maybe if the advertisers are buying two pages
18 anyway, let's put the ad and disclaimer side by
19 side, instead of putting it on the back side of the
20 page.

21 I mean yesterday somebody in here said
22 that her daughter never even knew that there were
23 even any side effects on the back, because most of
24 them skip over it. It looks like editorial. Put it

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1 side by side. I know that's not going to be
2 popular.

3 But most supporters of DTC claim that
4 advertising is one of the best ways to inform,
5 educate and encourage choice about treatments
6 available. Not everyone agrees. Even a deputy
7 director at JAMA, Dr. Drummond Ray, said, direct to
8 consumer advertising has nothing to do with public
9 education, and it's got everything to do with
10 boosting a product's sales.

11 In conclusion, I'm going to leave you
12 with a compilation of drug TV commercials. If the
13 FDA had the ability to preapprove these ads, I
14 wonder if they would have even passed. While some
15 of these have been removed from the marketplace,
16 they stand as a good example of why we need to keep
17 improving and evaluating the DCT advertising.

18 Prescription drugs are serious business,
19 and the advertising of them needs to reflect it.

20 Thank you. We're going to show the
21 video.

22 MR. ABRAMS: Okay, first - oh, I'm
23 sorry.

24 (Videotape presentation of TV

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1 commercials:

2 MALE VOICE: All I want are nights with
3 less pain, mornings with less stiffness. So I can
4 get out here early and show these clams whose boss.

5 MALE VOICE: The guy who wanted to spend
6 the entire honeymoon indoors. Remember the one who
7 couldn't resist a little mischief? Yeah, that guy.
8 He's back. Viagra.

9 FEMALE VOICE: If you are one of the
10 many who suffer from overwhelming anxiety and
11 intense fear of social situations with unfamiliar
12 people, now there is Paxil CR. Paxil CR helps
13 relieve the symptoms of social anxiety disorder all
14 day, so the real you can come through.

15 FEMALE VOICE: Tonight, will you be able
16 to catch a great night's sleep, or will it once
17 again elude you? Your restless mind keeps chasing
18 sleep away.

19 MALE VOICE: I've got to remember that
20 appointment tomorrow. Did I send the car payment?
21 What made me volunteer for that assignment?

22 FEMALE VOICE: Introducing Lunesta.

23 MALE VOICE: You know that feeling of
24 suddenly being very nervous? Maybe you're scared

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1 of being criticized, or imagine that others are
2 judging you. You are embarrassed, and don't know
3 why. Your heart thumps and races. So you stay
4 back. You worry that you are the only one who ever
5 feels this way. Actually you could be one of 16
6 million Americans with symptoms of social anxiety
7 disorder. Zoloft, a prescription medicine, can
8 help. It works to correct chemical imbalances in
9 the brain which may be related to symptoms of social
10 anxiety disorder. Someday soon you could overcome
11 those nervous anxious moments. Only your doctor can
12 diagnose social anxiety disorder. Zoloft is not for
13 everyone. People taking MAOIs or Pimozide shouldn't
14 take Zoloft. Side effects may include dry mouth,
15 insomnia, sexual side effects, diarrhea, nausea, and
16 sleepiness. Zoloft is not habit forming. Talk to
17 your doctor about Zoloft, the number one prescribed
18 brand of its kind. Zoloft, when you know more about
19 what's wrong you can help make it right.

20 End of videotape presentation)

21 MR. ABRAMS: Thank you, Ms. Witczak, for
22 your presentation and thoughts. First, we convey
23 our condolence on your loss. We know this
24 presentation wasn't easy to do.

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1 So I'll open it up to the FDA panel for
2 questions at this point.

3 Dr. Aikin.

4 DR. AIKIN: Thank you. Thank you for
5 your presentation.

6 You raised a very interesting point, in
7 that DTC is changing the environment and not just
8 individual behaviors, and I think that's something
9 that perhaps we don't consider very often that DTC
10 might be influencing physicians, not just physician
11 advertising, but physicians.

12 Do you have any suggestions for us as an
13 agency as to how we might be able to distinguish the
14 relative impact of those two forms of promotion?

15 MS. WITCZAK: It's interesting. I think
16 we all forget doctors are consumers also, because
17 they see commercials. But I think the culture that
18 we have created is that people go in, and a doctor
19 doesn't have that much time, especially when our ads
20 are driving to general practitioners. And the
21 samples, we've got doctor cabinets that are packed
22 with samples, they have maybe seen other people who
23 have come in there, and they only have a few minutes
24 to spend with you, and it's like the easy thing to

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1 do. Here, I know this has maybe helped other
2 people.

3 I don't know if that really answers your
4 question.

5 MR. ABRAMS: Dr. Behrman.

6 MS. BEHRMAN: If I could follow up on
7 that, based a little bit on your advertising
8 experience and your personal experience. Your
9 husband was prescribed this medication, and you feel
10 that neither you nor he were adequately informed,
11 and given that as we discussed the bulk of the
12 advertising dollars are spent advertising to
13 practitioners who are increasingly busy, and also,
14 away from the specialist community to the general
15 community.

16 Can you give us any thoughts about how
17 to address the advertising to that population as
18 well, so the professional population?

19 MS. WITCZAK: To which population?

20 MS. BEHRMAN: Well, in other words, two
21 points you brought up - or one point, that you and
22 your husband did not receive adequate warning. And
23 you talked about changing the environment based on
24 promotion. And if you assume that that's happening

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1 in the professional environment as well, what fixes
2 might you see in terms of professional ads? I know
3 that we are focusing primarily on DTC, but --

4 MS. WITCZAK: Well, I think the first
5 thing you have to assume that the drug companies
6 are giving you all the information. Because I don't
7 believe that Woody had the suicidal - was not told
8 at that point by the doctors.

9 So I think you have to make sure that
10 that is first and foremost, that the drug companies
11 are telling us.

12 In terms of, I think there is a lot of
13 detail in the message. It's almost as much money
14 being spent on that end. It's really important that
15 maybe these ads that - I don't know if they would
16 ever show the ads to the doctor. I know we had no
17 information. We weren't even told to do close
18 monitoring. I applaud the FDA for coming out with
19 that advisory this summer.

20 But I'm not sure how much it goes back,
21 or how much of the advertising really gets shown to
22 the doctors, and actually getting their input. Is
23 this responsible advertising to your consumers that
24 have been coming in to you?

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1 MR. ABRAMS: Thank you again for your
2 presentation and your thoughts.

3 This concludes this morning's panels. I
4 want to thank the panel members for their
5 presentations and their responses to the FDA panels.

6 (Applause)

7 MR. ABRAMS: This has been a very full
8 morning, and we are running over unfortunately, so
9 we are going to have a shortened lunch so we can get
10 back on track. We are going to reconvene here at
11 1:35.

12 (Whereupon at 12:45 p.m. the proceeding
13 in the above entitled matter went off the record, to
14 return on the record at 1:37 p.m.)

15 MR. ABRAMS: Good afternoon.

16 And welcome back to the afternoon of day
17 two, the final two panels of this hearing.

18 We will start right away. The first
19 presenter will be Emily Alfano from Genetic
20 Alliance.

21 MS. ALFANO: Thank you.

22 My name is Emily Alfano. I am from
23 Genetic Alliance, which is an international
24 coalition comprised of more than 600 advocacy,

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1 research and health care organizations that
2 represent approximately 14 million individuals with
3 genetic conditions.

4 First I just want to thank you for the
5 opportunity to address this panel.

6 As you examine the issues surrounding
7 direct to consumer promotion of regulated medical
8 products, it's vital that you consider the
9 perspectives of all the different stakeholders.

10 Because my organization's members
11 represent individuals with genetic conditions, many
12 of them rare genetic conditions, our concerns
13 related to direct to consumer marketing focus
14 primarily on genetic topics.

15 Specifically, two related but distinctly
16 different areas of concern: the current state of
17 regulatory oversight of genetic tests. Are the
18 tests safe and accurate? Are there gaps in the
19 regulatory process?

20 And the second, the potential for
21 irresponsible for misleading promotion of genetic
22 tests. Do the tests do what the advertisements say
23 they do? Do consumers have enough information to
24 make informed decisions about these tests?

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1 As a representative of a community of
2 people concerned about safety, accuracy and
3 accessibility of genetic tests, I can say that the
4 current state of regulation poses significant
5 problems.

6 At present the oversight mechanisms
7 associated with genetic tests have gaps, a fact that
8 makes direct to consumer marketing of these tests a
9 serious concern.

10 That is, the marketing a genetic test
11 presents two discrete areas of concern: the claims
12 made in the advertisement, and the validity and
13 utility of the test itself.

14 Currently, there are more than 1,000
15 genetic tests available, but only a handful, those
16 packages tested, are regulated by the Food and Drug
17 Administration.

18 As a result the vast majority of genetic
19 tests available are only regulated by the oversight
20 of the laboratory under the clinical laboratory
21 improvement amendment.

22 Under CLIA, laboratories are held to
23 certain standards, standards based on the complexity
24 of the test performed.

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1 But in this age the more rigorous
2 regulations, performed either by FDA or by CLIA or
3 some complement of both, is necessary.

4 To ensure that nothing falls through the
5 cracks, a coordinated effort across agencies would
6 be ideal.

7 That said, an onerous system of
8 regulation for genetic tests, one that discourages
9 testing, is also unacceptable.

10 Just as important to our organization
11 and it is members as safety and accuracy is the
12 accessibility of genetic tests. Overregulation and
13 the implications that follow would likely make
14 genetic tests, specifically those for rare genetic
15 conditions, inaccessible to most individuals and
16 their families.

17 This is an equally problematic outcome,
18 one that must not be ignored or underestimated. The
19 safety and accuracy of testing is essentially
20 irrelevant, if the tests are not accessible to the
21 individuals who need them.

22 Once genetic tests have received the
23 regulatory attention they require, direct to
24 consumer marketing of those tests, with appropriate

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1 information and support, could be acceptable for
2 some tests.

3 As science continues to move forward,
4 and as more and more genetic tests become available,
5 access to these tests may be the key to improved
6 health outcome.

7 However, it is irresponsible to simply
8 offer genetic tests to the public with no validation
9 or without context or explanation. Genetic tests
10 offer predictive information, and information about
11 the health of both individuals and their families.

12 Like many other medical tests and
13 procedures, this information can be confusing and
14 intimidating if not appropriately translated by a
15 health care professional.

16 As such, genetic tests offered directly
17 to consumers should include opportunities for
18 genetic counseling, opportunities that provide an
19 individual with all the information needed to make
20 the most appropriate decisions about his own health
21 care and the health care of his family.

22 On behalf of Genetic Alliance I urge
23 this panel to consider both concerns - concerns
24 about the adequacy of oversight and concerns

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1 regarding the potential for irresponsible direct to
2 consumer marketing and sales of those tests.

3 Genetic tests should be accessible to
4 consumers in a form that is safe, reliable and
5 accurate. But above all else, they must be
6 accessible. They must find a balance between
7 regulations that accomplishes the desired goals,
8 quality genetic tests that improve public health,
9 and excessive regulation that places too onerous a
10 burden on laboratories, and limits the availability
11 of tests.

12 Genetic Alliance has made the quality of
13 genetic testing a priority for the upcoming year.
14 We will be working with patient groups, industry
15 members, policy organizations and government
16 officials to craft a sensible solution to ensure
17 quality tests are accessible.

18 Until this is accomplished, direct to
19 consumer marketing of these tests is dangerous.

20 Thank you.

21 MR. ABRAMS: Any questions from the FDA
22 panel? Ms. Wolf?

23 MS. WOLF: Do you have any specific
24 kinds of information that you want consumers to have

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1 in the direct to consumer marketing of the tests?

2 MS. ALFANO: There are a lot of -
3 genetic tests, because they implications for not
4 just the individual but for the family as well, we
5 recommend some form of genetic counseling that
6 doesn't necessarily mean it has to come from a
7 genetic counselor, but some information ahead of
8 time before the test to tell you what the test is
9 going to tell you, because it is predictive
10 information. It's not necessarily a diagnosis. And
11 then what your treatment options would be. What are
12 the implications for your family? That sort of
13 thing too, to help people through the process, so
14 that they are not just getting a test rule.

15 I mean even health care professionals
16 often don't know how to interpret a lot of the
17 genetic tests for various diseases, and so to give
18 that information to a consumer without any
19 information that they can then look at and figure
20 out would be irresponsible.

21 MS. WOLF: So you want that to be
22 required information?

23 MS. ALFANO: Yes.

24 MR. ABRAMS: Okay, Ms. Alfano, thank you

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1 very much for your presentation.

2 The next speaker is Meg Columbia-Walsh
3 with Faith Popcorn's BrainReserve.

4 (Off-mike comments)

5 MS. CUNNINGHAM: I'd like to remind
6 people to please turn your Blackberries off and not
7 use them during the presentations. That noise that
8 we keep getting is somebody using their Blackberry.
9 Thank you.

10 And now I have the presentation up.

11 MS. COLUMBIA-WALSH: Hi, I'm Meg
12 Columbia-Walsh. And I am from the industry, both on
13 the inside and the outside, really just pointing out
14 today - my main point is, with great passion, the
15 current consumer that we have in the general public,
16 and the cultural context in which they're living,
17 which I hope both in industry and the FDA side will
18 really consider as we think about regulation of any
19 sort of information as we talk to them.

20 I think right now even in just pharma,
21 big pharma, bad pharma, the FDA is also under
22 attack. I really believe full disclosure, openness,
23 communication, accountability, is the only way that
24 we are going to restore trust in our industry, in

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1 our regulatory bodies, and in health care in
2 general.

3 Provide education on the risks and
4 benefits of products and encourage consumers to
5 become the knowledgeable empowered managers of their
6 health. They are more empowered than they have ever
7 been.

8 We cannot regulate their ability to seek
9 or gather information regarding their health.

10 I also would like us to think about that
11 DTC means advertising to a lot of people, and if
12 anything, I wish that what we came out of this,
13 which is convincing industry to spend less than 50
14 percent of their money on television, and think
15 about how else we can educate in the true culture
16 which we're living in.

17 The cyber cat is out of the bag. DTC
18 is, what, 15 years old? We created this environment
19 of empowered information seeking consumers. We
20 cannot reverse that. Every person diagnosed goes to
21 the Internet for information. If we regulate that
22 information for six months before, once we release a
23 product they're going to find it out, and it could
24 be misinformation. So let's provide it in an open

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1 way. Let's just do it in better taste. Maybe that's
2 what happened, we just became bad taste, so people
3 are reacting to that. Let's do it in better taste,
4 and advertise benefits with full disclosure of
5 everything that is going on.

6 Accenture reports in the next five years
7 27 billion - this is where we're living right now,
8 this is the culture, and especially the youth that
9 is coming behind us. So let's not worry about
10 regulating advertising; not everybody is going to be
11 watching it anyway.

12 All communication is DTC. We can't hide
13 behind any word. The FDA and the pharmaceutical
14 industry, every single word we print is public, so
15 don't let them have to find information that may be
16 inaccurate.

17 This is the culture that we're living
18 in. It's Wiki, it's the podcast, it's webcast, it's
19 the Internet, it's print, it's across culture. We're
20 one color, one language. WE must think about this.

21 This isn't just affecting us as we've seen.

22 So who are our consumers? They don't
23 know who to trust. They don't want their brands to
24 embarrass them. They don't want to be lied to.

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1 This is very big. We're in a full
2 culture of icon toppling. The pharmaceutical
3 industry, the tobacco industry, the Martha Stewarts
4 of the world, the Enrons, consumers are turning to
5 each other, not to us.

6 Let's fix that and restore that trust.
7 They want to do the right thing. People embrace
8 right now and respect companies that are open about
9 their corporate flaws. We have a problem with
10 methamphetamines right now. Don't take upper
11 respiratory off the shelves. Let's educate
12 consumers. Let's be honest. This is what children
13 are doing with meth; this is the place that we play
14 in this; this is what we are going to do about it.

15 Here are some examples outside of our
16 industry. Whole Foods, slaughtering ducks in an
17 inappropriate way. Immediately stopped the
18 practice, changed the way that their process
19 throughout the world, and open up a foundation to
20 fix it.

21 McDonalds comes under attack, they have
22 open disclosure, people come into our kitchen, see
23 what we do.

24 The Gap releases a social responsibility

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1 report. That's right, we're overseas. We're not
2 doing a great job, so let's go in and do a better
3 job; this is what we're going to do to fix it.

4 This is what we all should be talking
5 about today, how we're going to restore this trust.

6 Here is our public resume. We can
7 advertise, but we cannot hide. This is the point of
8 not regulating it.

9 This is PhRMA, just matched on Google
10 against these terms. Evil, corrupt, unethical, and
11 inhumane. So clearly we're sliding.

12 And since I've started to track this, it
13 increases on a weekly basis. We have a phenomenal
14 regulatory body that we are sitting in front of. We
15 have an incredible industry. Let's reverse that
16 trend.

17 And the only way that we are going to do
18 that is being transparent to our consumers, exposing
19 our flaws, educating properly, and putting that
20 information and education everywhere, not taking it
21 away or limiting access to it.

22 So what is our public resume, and how
23 can it be managed? This is what I'd love us to
24 think about. How can the FDA and the pharmaceutical

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1 industry earn the unconditional trust of our current
2 information empowered consumer?

3 Listen to the consumers - they trust
4 each other. They grew up in the world of cyburbia.
5 They're networked, they're connected, and they're
6 united.

7 People turn to connected peer groups
8 right now. They are not looking only at the
9 institutions for this information. So what does
10 this mean? We must show up where they are. We must
11 make sure that we are in their peripheral lives,
12 that we're presenting this information everywhere,
13 and if sometimes that means television advertising
14 because it's mass media, great.

15 But we have to show up everywhere that
16 they are. AlphaMom, 24-hour video on demand for
17 birthing and parenting. Epinions, this is
18 everywhere. They don't come to ask about the
19 products; they go to each other, and then they rate
20 each other on how they're rating the products.

21 This is our world too. Daddytypes.com,
22 a blog for new dads to exchange information. So if
23 we're not providing the right information, then they
24 are in there talking about us without us giving our

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1 proper information.

2 Institutions are being marginalized,
3 therefore, as the trusted source of information.
4 How can the FDA and the pharmaceutical industry stay
5 relevant to its well-connected consumers and
6 gatekeepers, a question that I would love for us to
7 really discuss, and which peer communities should we
8 join so that we make sure they have the proper
9 information?

10 They value their health, but a second
11 opinion is not embarrassing anymore. They'll go
12 second, third, look at doctors right now to do it.
13 So again if we are going to provide information, and
14 they are going to walk in with a stack of paper, it
15 should come from us, and we should be encouraging
16 that.

17 Benefits, risks, full disclosure,
18 everything about it so they can help decide with the
19 help of their doctor.

20 Self-prescribed wellness is what you are
21 concerned about. Access to information empowers
22 people to diagnose, prescribe and treat themselves,
23 but not if they have the proper information.

24 So consumers have StriVetin, so they

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1 start to use it for facial wrinkles, because they
2 figure that on their own, they talk to each other on
3 the net. That's how they discover it.

4 So if this was to be released today,
5 should we therefore take the information away so
6 they can't figure the real use and why that is not a
7 good idea? Or the benefits and risks of that
8 product, that should come from us. We don't want
9 them to have misinformation, or to be medical
10 students on their own.

11 Sales of mangosteen juice, the minute
12 you mention health benefits, the minute you mention
13 this, they are going to take off. It is going to
14 sell; we know that.

15 So again, let's make sure we have the
16 proper information. We are a nation of first-year
17 medical students thirsty for information and quick
18 to judge, but the problem is that we're
19 overconfident and under-qualified to do that.

20 So who better to provide that but us
21 here? Okay, so we can't release a product and not
22 tell them about it, because then they'll go on the
23 web or anywhere else that they can particularly if
24 they are suffering from something.

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1 And I'm not saying that careful
2 regulation doesn't have its place. I'm just saying
3 that you can't limit. That shouldn't be one of the
4 things that we are talking about here. These are
5 the things we should be considering together.

6 How can we help consumers become more
7 accurate, and educated better, when diagnosing their
8 family and their own well-being? How can the FDA
9 and the industry stay indispensable to a generation
10 of overconfident and self-prescribing doctors?

11 Full disclosure, open communication,
12 transparency, authenticity, accountability, doing it
13 together for all the different constituencies, are
14 the only values that are going to restore trust in
15 our system, in the FDA, and in the industry.

16 Do not regulate or limit access to
17 information. Let's just do a better job at it.
18 More information about the pharmaceutical products
19 from the people who develop them. Let's make sure
20 we do marketing in good taste, but let's still make
21 sure we disclose everything when we have that
22 information - not six months later, not a year
23 later, but the minute we know, and maybe even
24 before.

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1 Maybe we should start to have CME for
2 consumers. Consumers will find out the information
3 anyway, so it should come from us. It should come
4 from the most knowledgeable source in the most
5 authentic way.

6 Thank you.

7 MR. ABRAMS: Thank you, Ms. Columbia-
8 Walsh, for your presentation.

9 You just - we do have questions, I'm
10 sorry. I wasn't quick enough with my follow up.

11 You mentioned that we should have proper
12 information about drug products and the conditions.

13 A speaker this morning made a point of saying that
14 this information, if it's coming from the drug
15 company, is viewed as biased, it's not really good
16 information, other folks should be doing it.

17 If you were advising industry, what
18 specific steps should they take? And if you were
19 advising the agency, what specific steps should we
20 take to improve the quality of this information?

21 MS. COLUMBIA-WALSH: I think my main
22 point is that the consumers are going to find it.
23 So level citing us both on the same team. You know,
24 the point is that consumers are more empowered and

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1 information hungry than ever before. So for a
2 marketer - this is a capitalist society. There is
3 nothing wrong with them marketing, or making money,
4 but they must do it in a way that gives the best
5 education.

6 And I think that is what we've gotten
7 away from. I think we've lost the educational
8 value, and we haven't put enough emphasis on that.
9 I love the ads that you see like Evra or Tylenol if
10 you are going to take my product, and you are going
11 to OD on it, don't take it. We'd rather you didn't
12 use it.

13 I mean I think consumers can really
14 respond right now to that type of transparency, and
15 on the FDA side, I think we should demand that. So
16 instead of regulating and removing information, or
17 limiting information, I'd much rather see us put
18 some sort of rigor behind the type of education or
19 information and rules around that, instead of only
20 saying, oh, we're not going to do it, or we're going
21 to ask the industry to self-regulate themselves, and
22 the answer from the industry is, okay, well, I'm
23 going to launch a drug and I'm not going to run any
24 ads. Because then we're promoting these over-

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1 confident people to go get information that doesn't
2 come from us.

3 MR. ABRAMS: What exact information
4 would you like to see in these advertising pieces?

5 MS. COLUMBIA-WALSH: I think it should
6 be as much as we can in the time we have, depending
7 on the format. That is part of my issue - I'd like
8 to see more formats, more of us doing blogs, us
9 doing websites, et cetera.

10 But I think it has to be a more
11 educational open view of the whole positive and
12 negative. Full disclosure of the risks and
13 benefits. I think consumers are smart; we have a
14 gatekeeper anyway in the physician. But as I showed
15 examples of transparency, I think the more
16 transparent they are, the more they're going to
17 trust us, that we say here are the good and bad.
18 Consumers are fairly smart about that now.

19 And then be able to go in a more
20 educated way, because I firmly believe that all the
21 time in DTC, that even if we get annoyed at a
22 consumer walking into a doctor with a stack of
23 Internet papers, that level of conversation, for as
24 short as it is, starts at a higher level of

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1 dialogue. And if we did send people into the
2 doctor, and we did all that, then we'd fund a really
3 great thing. And maybe we just need to reexamine
4 it, because we've gone down a path that wasn't
5 positive.

6 But not take it away.

7 MR. ABRAMS: Dr. Ostrove?

8 MS. OSTROVE: You mentioned that we need
9 full disclosure of risks and benefits. One of our
10 earlier panelists talked about feeling that it was
11 important to have the full FDA-approved package
12 insert associated with all advertising.

13 What is your sense of, would that get at
14 what you are talking about? Is there something else
15 you would be looking at in terms of full disclosure?

16 Can you just kind of expand a little on that?

17 MS. COLUMBIA-WALSH: Yes, I would love
18 to see us do, if we were going to do an
19 instructional bulletin for a VCR, we wouldn't only
20 give the industrial specs of that machine. So when
21 you look at a package insert, even if you're in the
22 industry, you get blurry after a few columns into
23 it.

24 Certainly a consumer cannot understand

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1 all of that, so why don't we do that? That would be
2 a great idea. Let's take that package insert, and
3 talk about what it is, what is in it, and teach them
4 how to use it and how to read it.

5 In other words, making it part not only
6 of attached in three pages of print ads, or running
7 a commercial that is so confusing because there is
8 too much. Why don't we teach them exactly what that
9 package insert is, and make that part of the
10 education, and pull out things both positive and
11 negative, that they should be talking to their
12 doctors about.

13 MS. OSTROVE: So you're saying translate
14 it so that it's more understandable to the consumer?

15 MS. COLUMBIA-WALSH: That's right.

16 MS. OSTROVE: And you also seem to be
17 saying something beyond that, which is somehow some
18 kind of meta-education in terms of how to use the
19 information?

20 MS. COLUMBIA-WALSH: Yes, I think that's
21 true. I think our consumers are really ready for
22 that. I mean they are hungry, and I have a bias
23 because I founded CBS Health Watch, which became the
24 largest consumer site on the web. I saw hundreds of

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1 thousands, millions of people, coming in and out of
2 there, and same with oncology.com, the minute we
3 provided them information they were voracious about
4 getting it.

5 And they stayed on line with us with
6 expert interviews and so forth for hours. For an
7 hour and half. We had to like kick them off. I
8 would love us to do a better job of that.

9 MS. OSTROVE: What about patients and
10 people who are not especially literate? If you like
11 at the NALS, the National Adult Literacy Survey - I
12 think there should be some new stuff coming out soon
13 - you've talking about 40 percent of the population
14 that has some problems in terms of literacy.

15 MS. COLUMBIA-WALSH: That's right, and I
16 think we have to go at them in different ways.
17 Television isn't the answer to that either. When we
18 reach out to them, we do it in ways just like you
19 have corporations where you put money aside for low
20 income housing.

21 Our pharma companies do a tremendous
22 amount of work in that way. Maybe we need to work
23 together in how we educate better. Is it visual
24 then? How are we promoting that, but don't not show

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1 up.

2 You know, again, I still don't think the
3 thing is then that we just simply withhold
4 information. Let's become transparent and give it
5 to them in a way that they can understand, or their
6 support system, whether it's their community center,
7 or whatever it is, can help them to understand it.
8 I guess that's how I feel.

9 I mean I'm a fan of both sides. I have
10 20 years here. It's a big passion. But because of
11 what I've seen consumers respond to, both in DTC and
12 on the net, I don't think we can reverse that.

13 So if anything I just want it to become
14 more educational. I think we if we were more CME
15 about it, without just rules, but I mean literally
16 how we educate, I think consumers will respond.

17 I don't think they need only dancing
18 objects and fancy pictures to get the point across.

19 I think we could educate them.

20 MR. ABRAMS: Dr. Behrman.

21 MS. BEHRMAN: I'm a little confused.

22 Are you talking about the information coming from us
23 or that we're doing this. Who is this "we", the
24 "us"? Is it the pharmaceutical manufacturers? Or

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1 do you believe FDA should be producing the
2 information in the ads?

3 MS. COLUMBIA-WALSH: No, I mean industry
4 clearly is the one in the game. They are going to
5 be producing, we're talking about products here. I
6 mean I think there are a lot of wonderful things you
7 could do just in health care overall.

8 When we are speaking in this forum about
9 products, the FDA certainly understands. People
10 read about you in the press, too. They are seeing
11 that our entire industry is under siege. You are
12 part of that.

13 So I'm really talking in combination
14 together, that the regulation you're imposing is
15 sitting in a coalition to better educate about
16 products instead of what rules can we put in to make
17 it harder, or this constant kind of tension that
18 we've been in, well, this word is good but this one
19 isn't.

20 Because there is certainly marketing
21 against it. I understand that. But I just think we
22 can, within this country, I've shown work together
23 in a better way to provide that.

24 I think we are on the same team. I

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1 don't think it's like you against the industry. I
2 guess that's my point.

3 MR. ABRAMS: Thank you for your
4 presentation.

5 The next speaker is Joseph Cranston from
6 the American Medical Association.

7 MR. CRANSTON: Good afternoon. My name
8 is Joseph Cranston, and I'm a pharmacologist by
9 training, and I currently serve as the director of
10 science research and technology at the American
11 Medical Association, and I'm speaking on behalf of
12 the AMA at this Part 15 hearing.

13 The AMA commends the FDA for holding
14 this hearing to determine the positive and negative
15 consequences of direct to consumer advertising, and
16 whether the agency should consider modifications in
17 the way it regulates it.

18 DTC has been a topic of debate among our
19 member physicians for over 20 years. And this
20 debate continues. At our annual meeting last June,
21 six new resolutions on DTC were considered by our
22 House of Delegates, which is our policymaking body.

23 The resolutions ranged from doing a
24 study to greater federal regulation of DTC to two

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1 resolutions which called for an outright ban on this
2 type of advertising.

3 All six resolutions were tabled for
4 report back to our House of Delegates next June in
5 2006. I'm providing this information up front,
6 because I think the FDA needs to understand that
7 current AMA policy on direct to consumer advertising
8 could change once the new report is considered at
9 the 2006 meeting.

10 Back in 1993, with the help of the FDA,
11 the AMA developed guidelines for an acceptable DTC
12 advertisement. The guidelines remain a key part of
13 our official policy today in 2005, and they are
14 applicable to both prescription drugs and medical
15 devices.

16 In brief, the AMA currently believes
17 that a DTC ad is acceptable if it is disease
18 specific, it enhances patient education, it presents
19 a scientifically accurate message, and exhibits fair
20 balance between benefit and risk information, is
21 understandable by consumers, promotes discussion
22 between patient and physician rather than
23 encouraging self diagnosis and self treatment, and
24 is run only after physicians have been appropriately

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1 educated about the drug.

2 Current AMA policy also calls for more
3 independent research on the effects of DTC ads, as
4 well as adequate funding for the Food and Drug
5 Administration to effectively regulate this kind of
6 advertising.

7 My focus today will be to present the
8 AMA's perspective on some of the important questions
9 raised by the FDA in its Federal Register notice
10 announcing the meeting.

11 The first question I'd like to address
12 is whether television DTC ads exhibit fair balance
13 as is required in federal regulation

14 The AMA has expressed concern both to
15 Congress and to the FDA that DTC ads shown on
16 television often are very effective at using
17 pleasing if not distracting visuals as the major
18 risk information is being discussed on audio.

19 And we believe that there is now - that
20 our concern about a lack of fair balance now is
21 supported to some extent by both of the well
22 designed research.

23 At the FDA's September, 2003 meeting on
24 DTC research, and again yesterday morning, Dr. Ruth

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1 Day of Duke University described her research on the
2 cognitive accessibility of prescription drug
3 information.

4 At the 2003 meetings she described a
5 study where they evaluated 29 TV DTC ads. And what
6 they found was that when compared to information
7 about benefits, information about risk received
8 fewer sentences, was placed in locations where it
9 would be more difficult to remember, had a much
10 higher level grade level for readability, and was
11 disadvantaged from a semantic perspective.

12 When these researchers then tested the
13 ads on real people, they found that people remember
14 information about indications and benefits far
15 better than they remember information about risk.

16 Thus the conclusion was that because of
17 the way television DTC ads are constructed, people
18 are much better able to understand benefit
19 information than risk information.

20 In formal comments to the FDA in both
21 late 2003, and again, in May of 2004, the AMA
22 encouraged the agency to consider modifying its 1999
23 final guidance on broadcast advertisements, to
24 ensure that television DTC ads are structured in a

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1 way that fairly balances the benefits and the risks
2 of prescription drugs.

3 A second question is, can consumers
4 understand and accurately assess claims regarding
5 the efficacy of prescription drugs in DTC ads?

6 One of the AMA's main tenets for
7 appropriate DTC is that the advertisement should
8 have some educational value. There is a growing
9 body of evidence to suggest this may not be the
10 case. Bell, et al, in an article published in the
11 Journal of Family Practices, 2000, review over 300
12 print DTC ads for 101 drugs that were published in
13 18 popular magazines. They found that while the ads
14 were informative, they lacked important educational
15 information about those conditions, and the
16 treatment for which the drug was being promoted.

17 Similarly, Rollisch and Schwartz and
18 colleagues wrote an article in the Lancet, reviewed
19 the contents of 67 DTC print ads from ten magazines
20 published between 1998 and 1999. They found that
21 the ads rarely quantified a medication's expected
22 benefits, and instead made what they considered an
23 emotional appeal.

24 In contrast, over one-half of the ads

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1 used actual data to describe the drugs risks.

2 The authors suggested that these print
3 DTC ads leave readers the perception that the drug's
4 benefit is large, and that everyone who uses the
5 drug will enjoy the benefit.

6 AT the 2003 FDA public meeting, and
7 again in a subsequent publication in 2004 in the web
8 edition of Health Affairs, the same researchers
9 provided further evidence that print DTC ads present
10 benefit information in a way that tends to
11 overestimate the benefit to consumers.

12 They created what was called a
13 prescription drug benefit box for three actual ads
14 in which only the name of the drugs were fictitious.

15 And the purpose of this benefit box was to present
16 actual data on a drug's benefit in a concise and
17 understandable way that directly reflected the
18 clinical trial used for the drug's approval.

19 Consumers were then asked to rate the
20 efficacy of each of the three drugs based on the
21 printed DTC ads that did or did not contain this
22 benefit box.

23 Consumers were far more likely to rate
24 the drugs as extremely effective when the ads lacked

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1 the prescription drug benefit box, compared to ads
2 to contained it. Thus these researchers concluded
3 that quantitative data about drug efficacy, as
4 presented in this prescription drug benefit box
5 reduced perceived efficacy of the advertised drug,
6 and helped people more accurately gauge the true
7 benefit of the drug.

8 The AMA encourages the FDA to give
9 thoughtful consideration to these research studies,
10 because they do raise the question of whether
11 commercially-driven DTC is really as educational as
12 its proponents would like you to believe.

13 While the AMA recognizes the
14 difficulties in creating prescription drug benefit
15 classes for all drugs, as was pointed out by a
16 senior FDA official both at the 2003 public meeting,
17 and I think yesterday morning as well, there may be
18 ways for FDA to guide the pharmaceutical industry in
19 designing DTC ads that will more objectively present
20 benefit information.

21 What is the impact of DTC on the
22 patient-physician relationship? Much of the
23 research has come from surveys of consumers, and to
24 a lesser extent, physicians. There does appear to

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1 be consistency across the surveys that DTC may have
2 the positive effect of increasing diagnoses of
3 previously undiagnosed conditions, and promoting
4 better communication between physician and patient;
5 these are good things.

6 On the other hand, surveys consistently
7 show that there is a subset of patients who demand
8 specific advertised drugs from their physicians.
9 The impact of this on the patient-physician
10 relationship remains unclear. Many physicians
11 continue to complain that less time is available to
12 effectively diagnose and treat patients who have a
13 fixation on a particular drug as a result of a
14 commercial.

15 Furthermore, there is the potential to
16 create this trust in the physician-patient
17 relationship when the physician is put in the
18 uncomfortable position of having to defend why the
19 requested drug is unnecessary.

20 A recent randomized control trial,
21 published by Kravitz, et al, in the Journal of the
22 American Medical Association, alluded to earlier
23 today in one of the presentations, the study that
24 used professional actors to pose as patients, showed

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1 that patients' requests have a profound effect on
2 physician-prescribers, both good and unfortunately
3 also bad.

4 Patients who made a general or brand
5 specific, that is, based on a DTC ad, request for an
6 antidepressant resulted in both increased
7 appropriate prescribing of antidepressants for major
8 depression but also increased inappropriate
9 prescribing for antidepressant for adjustment
10 disorder.

11 The researchers conclusion were that DTC
12 seem to both avert underutilization - a good thing -
13 and promote overuse - maybe not so good.

14 Thus like all the surveys, this
15 controlled study suggested that DTC has both
16 positive and negative effects on the patient-
17 physician relationship.

18 In summary, I'd like to make the
19 following points. One, current AMA policy considers
20 DTC ads that satisfy the AMA's DTC guidelines as
21 acceptable. However, the AMA is preparing a new
22 report on DTC and its policy will be revisited in
23 June, 2006.

24 Second the AMA is pleased that there is

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1 a growing body of independent - and that should be
2 underlined - independent research on the impact of
3 DTC, and it encourages more research of this type be
4 done.

5 But finally, based on what we would
6 consider to be the best evidence from available
7 research, the following conclusions can be drawn.

8 First, fair balance in television DTC
9 ads clearly could be improved.

10 Second, the educational value of DTC ads
11 could be improved if benefit information were
12 presented more objectively.

13 And finally, there seems to be both
14 positive and negative consequences of DTC on the
15 patient-physician relationship, although more
16 research is needed.

17 Thank you, and I will be happy to answer
18 any questions.

19 MR. ABRAMS: Dr. Cranston, you mentioned
20 that people, consumers, remember more about the
21 benefits than the risk information, it should be
22 structured in a better format. One of the things
23 that you discussed was the prescription drug benefit
24 box, and you alluded to the challenges of that,

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1 because drugs are different as far as standardizing.

2 What are your thoughts about the box?
3 What first would be the objective of the box, what
4 do you want that to convey? And generally, what
5 should go in there?

6 DR. CRANSON: I don't know whether it's
7 doable or not. Dr. Temple was the FDA official who
8 made those comments. And I really suspect he's
9 confused. I think it would only really be useful in
10 a print ad. I really think it would be very
11 difficult on television. I think that the
12 information that would go in there would be
13 information that really reflects the true value of
14 the drug based on the actual clinical data that was
15 used for a previous trial.

16 To me, that dealt with the issue of
17 providing information about - more information about
18 the actual benefit of the drug.

19 MR. ABRAMS: Thank you. And my second
20 point is, you mentioned that consumers take away the
21 benefits more than the risks. What can be done so
22 they take away the risk information, the risk
23 concepts?

24 DR. CRANSON: Well, I think Dr. Day has

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1 presented at two of these meetings now, and I think
2 her work is fairly compelling that there are ways
3 using cognitive psychology to structure the ads.

4 And it may be to your benefit to bring
5 in some consultants from the outside who do have the
6 expertise to look at this and see whether it is
7 possible to provide guidance for the industry in
8 that regard.

9 It would be nice if there were
10 convergence, if in fact something like this were
11 doable, if you folks would provide some further
12 guidance on content to improve these things as the
13 industry as you bring forth the new guidelines this
14 year.

15 MR. ABRAMS: Mr. Byrd.

16 MR. BYRD: Just to clarify one point you
17 made regarding the use of visuals in conflict with
18 presentation of risk information.

19 It is the AMA recommendation that
20 visuals not be used, or just appropriate - or
21 inappropriate visuals be avoided?

22 DR. CRANSON: I think avoiding
23 inappropriate visuals make sense. I personally am
24 not an expert, and the AMA has not specifically

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1 addressed that. I have said off the cuff to people
2 that they should take out and scroll the major - not
3 the whole thing that people are talking about - but
4 the major risks as they discussed.

5 I don't know if that is good or not. I
6 don't know if they'll remember that. I really
7 don't. I think you really need to talk to experts
8 like Day and others who have an understanding of
9 people will in fact remember this information and
10 move forward accordingly.

11 MR. ABRAMS: Ms. Wolf.

12 MS. WOLF: If patients come in after
13 they've seen an ad, are they willing - are they
14 responsive to a physician's efforts to try to
15 clarify what some of the benefits and risks are?

16 DR. CRANSON: I think probably most are.
17 Obviously, we have no evidence of monitoring
18 physician-patient relationships. And what we hear
19 we hear from our members, and a lot of that is
20 anecdotal.

21 But I'd have to think that most patients
22 are probably fairly reasonable. If the physician
23 provides them with a justification for an
24 alternative drug, or for no drug at all, most

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1 patients would say fine.

2 MR. ABRAMS: Thank you, Dr. Cranston,
3 for your presentation and the information you
4 provided.

5 The next speaker is Rima Laibow from the
6 National Coalition of Organized Women.

7 MS. LAIBOW: Thank you. I'm also
8 representing the National Solutions Foundation, of
9 which I am the medical director.

10 We will watch an edited version, a
11 shorted version of "Comfortably Numb," and then I
12 will speak for the remaining time.

13 [Video presentation:

14 FEMALE VOICE: Think before you take the
15 stuff, because you really can't get happiness from a
16 pill. It doesn't work like that.

17 MALE VOICE: Anti-depressants,
18 stimulants, the whole gamut that we have been
19 developing over the past 50 years for adults and the
20 elderly are now being shifted to children as young
21 as two.

22 MALE VOICE: Giving medication to
23 children is an absolute last resort. It borders on
24 being unethical not to try 15 things before you do

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1 it try to address it in more creative ways rather
2 than the magic pill.

3 FEMALE VOICE: The panacea for
4 everything is here, pop a pill, and it'll make you
5 feel better, instead of counseling, instead of
6 taking the time to find out what's really bothering
7 the person.

8 FEMALE VOICE: A little kid, so young,
9 like four, five, taking medicine at the doctor's
10 office. These developing minds, and we're just
11 pouring chemicals into them.

12 MALE VOICE: Parents just want to do the
13 right thing. So they want to make sure that they
14 are getting treatment if it's needed. And the
15 result is that we have a lot of people that are too
16 quick to pull the trigger of medication.

17 FEMALE VOICE: Don't we have an
18 obligation as a parent? I mean isn't that why you
19 took on the obligation of having children is to
20 spend the time with them and work with them? But
21 no, it's so much easier to give them a pill.

22 FEMALE VOICE: You can't treat us like
23 this little adults, because we're not.

24 MALE VOICE: Ding dong, it's a bell,

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1 it's ringing. This is an alarm for what is likely
2 to occur later on.

3 FEMALE VOICE: The drug is numbing the
4 emotions. SSRIs or other drugs that numb emotions
5 like alcohol, cocaine, opiates --

6 FEMALE VOICE: Today, we are facing a
7 crisis of epidemic proportions. Over 8 million
8 American children, some as young as two years old,
9 are being given stimulant and anti-depressant drugs
10 to control hyperactivity.

11 MALE VOICE (singing): Take two
12 amphetamine, and put them in my hands --

13 FEMALE VOICE: Michael loved the
14 outdoors. He loved surfing, fishing, he especially
15 liked anything to do with salt water. February 8th,
16 2001, was the day that he died. It's been 3-1/2
17 years and I still have some real hard times. I
18 always will. That was the day that my life changed
19 forever.

20 These doctors have got to know, or they
21 certainly should know, what these potent medications
22 are all about.

23 MALE VOICE: We know the drug trials to
24 be ineffective. We know the drug trails show the

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1 drugs to carry a substantial risk of adverse
2 effects, including suicidal ideas, self mutilation,
3 other aggressive types of behavior.

4 MALE VOICE: Some kids it causes this
5 terrible thing called akathisia, or where you get
6 this intense emotion that you got to do something,
7 and it's dangerous.

8 FEMALE VOICE: I just had an impulse to
9 just like go and grab the medicine, and that is what
10 I did.

11 MALE VOICE: They will do something
12 really stupid. They will hurt themselves. They
13 will hurt other people. They will do things out of
14 character.

15 FEMALE VOICE: On March 31st, I took a
16 lot of my pills and I tried to kill myself.

17 MALE VOICE: Drugs interfere with the
18 normal functioning of the brain. They do that; that
19 we know as an uncontrovertible fact. That's why we
20 give them. We want to change the way the brain
21 works. We want to interfere with the communication
22 of chemicals. We want to slow something down. We
23 want to speed something up. We want to put
24 something to sleep - in the brain.

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1 MALE VOICE: Those are mind altering
2 drugs. It changes the chemical balance in your
3 brain.

4 MALE VOICE: The classic picture is, kid
5 goes on Ritalin, and the kid sometimes responds by
6 being irritable, crabby, maybe even depressed, so
7 then they add an antidepressant to the mix, and the
8 kid is on that, and they get really aggressive,
9 maybe impulsive. Then oh my gosh, they are bipolar
10 disorder, and they are put on not usually lithium
11 but depakote or one of the anti-seizure medications.

12 Now you have a kid on poly-pharmacy, and it's just
13 like, who is this child? By the time they're ten
14 years old, they are mental health invalids, walking
15 around with three or four different diagnoses to
16 justify the medications that they are on.

17 MALE VOICE: She changed drastically
18 when she was with these drugs. She wasn't the same
19 person that she was all her life.

20 FEMALE VOICE: When I went to the
21 psychiatrist, she was saying that since I was
22 starting to feel lower that I needed more. So she
23 would like keep giving me more, and I kept getting
24 worse. And then this morning I'm supposed to be

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1 taking it like an adult.

2 MALE VOICE: For a child who is five
3 years old everyday to take a potent drug like
4 Ritilan or Aderall, which are stimulants, which we
5 know are drugs that affect the brain that lead some
6 people to be completely dependent on them, that lead
7 some people to become psychotic on them and so
8 forth, what happens when everyday you give that
9 child a dose for five to six years?

10 Well, what doesn't happen?

11 MALE VOICE: Saying "biochemical
12 imbalance" is like a marketing slogan that everybody
13 seems to know. People go into their doctors and
14 say, I think I have a biochemical imbalance.

15 MALE VOICE: Are we telling our kids
16 that happiness is going to be within the pill, but
17 we don't tell them what the pill is doing, the
18 manufacturer of those pills.

19 MALE VOICE: It is a fact now that drugs
20 are being given younger and younger, and
21 pediatricians are using psychotropic medications as
22 their first line of defense for a lot of complaints
23 about their children.

24 And it is very unfortunate because there

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1 is no data about children under six years old. We
2 have not a clue about how this affects the
3 developing brain, and whether or not these drugs
4 have any efficacy at all, because the efficacy
5 studies are of older children, and they are
6 questionable.

7 MALE VOICE: For the first four to five
8 years, we're all ADHD, most of us that is cannot
9 control ourselves. Most of us want things and blurt
10 out answers before the question is over and
11 interrupt adults. And most of us grow out of that
12 phase, which is totally normal.

13 MALE VOICE: Children are like rivers,
14 you can't step in the same part of them twice, they
15 are changing so rapidly that you can rely on
16 development to take care of a lot of problems, in an
17 earlier age child, like 4-1/2. So it's a travesty
18 to give a child that young any drug when
19 developmentally they may mature out of the problem
20 anyway with proper guidance and support.

21 FEMALE VOICE: One of the biggest thing
22 I noticed about them was, they all knew they had
23 attention deficit disorder, and they all were on
24 some form of medication for it. And they were able

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1 to say to me, oh, I'm on medication, and I have
2 attention deficit disorder.

3 And the interesting thing was, they also
4 were able to say to me, and you can't do anything to
5 me if I don't do my work.

6 MALE VOICE: That child will get a
7 diagnostic label even at such a young age, terrible
8 two or three, might get the label, ADHD.

9 MALE VOICE: I mean years ago the
10 terrible twos were a normal expected part of
11 development, and now, it may be the beginning signs
12 of oppositional disorder or ADHD, or bipolar
13 disorder, or you name it.

14 MALE VOICE: The experts who have
15 diagnosed that child think that, well, if that child
16 has this diagnosis, then the child has a disease,
17 has a disorder in their physical body, in their
18 brain, and we need to intervene on that disorder
19 within that child.

20 We don't have to really understand why
21 that child is that way.

22 FEMALE VOICE: They know there is no
23 consequences for their actions, because they are
24 protected under that labeling. And that to me is

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1 the biggest disservice they've ever done to these
2 kids.

3 MALE VOICE: Don't drink and drive, but
4 okay, take drugs and drive. That's okay; that
5 doesn't impair your ability to drive. But of
6 course it does.

7 FEMALE VOICE: I was taking it, and I
8 was just feeling like horrible. I felt like a
9 walking zombie.

10 MALE VOICE: Maybe we should get some
11 answers.

12 FEMALE VOICE: If this helps like one
13 person, then I've accomplished my goal and I've done
14 what I wanted to do.

15 MALE VOICE: Good marketing can overcome
16 bad data any day of the week. Because when you have
17 unlimited resources you can market any idea. I mean
18 the public has been convinced that every single
19 problem in living or challenge in life is a disease,
20 a disorder, or a deficit of some kind.

21 And parents have really bought into
22 this.

23 MALE VOICE: We let her down. Because
24 she came to us for help. And this time we almost

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1 cost her her life.

2 MALE VOICE: Nothing gets taken away by
3 a drug. A drug only adds a layer. The original
4 stuff is always there.

5 MALE VOICE: We need to look at the
6 process through which drugs become available to the
7 market, especially for children.

8 MALE VOICE: I know how big a business
9 the pharmaceuticals are. I mean the lawmakers have
10 studied that. But when you are talking about
11 millions of kids, literally, five years, four years,
12 being prescribed this, how are you affecting these
13 kids? How are we changing their lives? What is
14 going to happen 15 or 20 years from now when all
15 these million of kids and how long are we going to
16 keep them on these drugs?

17 End of video presentation]

18 MS. LAIBOW: I should tell you that I am
19 a child and adolescent psychiatrist, and I've
20 practiced drug-free medicine for 35 years, so that
21 gives me a distinct bias.

22 I have no commercial or industry ties.
23 But I have a question. And on this issue, my vote
24 is with the CEOs alluded to earlier of the

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1 pharmaceutical industry who said that DTC is not
2 about education.

3 So my question for the FDA is, is its
4 mission to protect and promote the pharmaceutical
5 industry as it was stated in Article 16 of the
6 initial enabling legislation that created this body,
7 or is it to promote and protect the well-being or
8 patients?

9 Every year in this country hundreds of
10 thousands of people, at a minimum, suffer
11 preventable harm and death from pharmaceuticals.
12 The regulation of pharmaceuticals is impacted by the
13 impact on this agency of economics and therefore
14 power.

15 No long term studies have been done on
16 the pharmaceutical drugs that were used for years on
17 end with our children and our adults. No long term
18 safety studies have been done, but we do know a few
19 things about these drugs.

20 We know that they have mutagenicity and
21 carcinogenicity as part of their profile of impact.

22 We know that there is neurological damage. We know
23 that there is endocrine damage. We know that there
24 is growth inhibition and skeletal damage.

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1 We know that there is suicidality. In
2 fact, Dr. Temple of this panel said in September of
3 2004 that looking at 15 clinical trials, some of
4 which were suppressed, and the negative information
5 therein - that there is serious, serious damage and
6 suicidality in psychotropic medication, and the
7 risks are considerable.

8 I would simply conclude by saying that
9 when a long-term experiment, when a human
10 experiment, is carried out without adequate informed
11 consent, and Dr. Grace Jackson has written about
12 informed consent in her book, reconsidering
13 psychoactive medication, we are looking at something
14 that violates the Helsinki Accords and the Nuremberg
15 Protocols of experimentation on subjects who have
16 not given informed consent, because the information
17 has not been made available to them, and the safety
18 and efficacy have not been established.

19 I consider DTC a dangerous and
20 unnecessary precedent, and I think that physicians -
21 the money, the \$4 billion - would be far better
22 spent adequately educating physicians, not educating
23 physicians to be essentially drug-dispensing units.

24 And consumer education of the real risks

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1 and the real benefits, I agree with Ms. Columbia-
2 Walsh, it's absolutely essential. But that is not
3 marketing information. That is real information.

4 Thank you.

5 MR. ABRAMS: Thank you, Dr. Liabow, for
6 your presentation.

7 The final speaker for this panel is
8 Kathy Kastner with Health Television System, Inc.

9 MS. KASTNER: Hello. I've just decide
10 to change my entire talk as a result of listening to
11 everyone today.

12 My name is Kathy Kastner. I'm the CEO
13 of the Health Television System, which is a direct-
14 to-patient television network in hospitals that has
15 been established for 12 or 13 years, first in
16 Canada, and then across North America.

17 We have been in the privileged position
18 of learning from consumers what their needs are, and
19 what the gaps are, in the way of information and
20 education around drugs, really.

21 Even though we have reached hospitalized
22 consumers, and the intent is to keep everybody out
23 of the hospital, one would hope that the
24 hospitalized patients would not be dismissed for

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1 their input into the relevancy of health education
2 and information, and that the understanding is, it's
3 not just the patients when you are in the hospital,
4 it's family and the community, their community, that
5 are involved.

6 So there is an exponential reach of any
7 education or information that's being provided by
8 whomever.

9 So before I tell you more about what
10 we've learned through our educational service and
11 developing education that meets the needs of
12 patients who will likely be leaving the hospital
13 with one or more prescriptions, I wanted to just
14 tell you three things I've learned from my work with
15 the American Academy of Family Physicians in their
16 patient education conference.

17 And that is, that according to the ASP
18 doctors only spend about three minutes on education,
19 which is asking a lot, I think - it's putting a lot
20 on doctors who have a number of different things to
21 do already. Not that they shouldn't educate, but
22 education isn't coded. It's not billable, you know.

23 So doctors who I think are the most well
24 intentioned health care professionals - after nurses

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1 - you have to take the business of being a doctor
2 into account.

3 And the other thing is that doctors are
4 not necessarily statistically educated to evaluate
5 the clinical studies and the data that is put
6 forward in these ads. It's a whole area of
7 statistical analysis that doctors are not - should
8 not be expected necessarily to have taken.

9 The same thing with consumers of course,
10 and the final thing that I learned is that doctors
11 are human.

12 Okay, on to some of the things that we
13 have learned. The first thing is that information
14 is not education. And to turn information - well,
15 the definition of education as opposed to
16 information is to turn information into something
17 that is going to resonate with the end user.

18 So you have to know what the end user
19 needs or is missing from the end user's scope of
20 understanding or scope of experience.

21 It is not what either the health care
22 professional thinks the consumer needs, nor is it
23 what the pharmaceutical company thinks the consumer
24 needs, and with all due respect, it may not even be

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1 what the FDA thinks the consumer needs.

2 But the - one of the benefits of having
3 dealt with consumers who were highly motivated never
4 to be in that hospital again is that often they
5 don't know what questions to ask of their doctor,
6 even if they had been prescribed something, and that
7 the language beyond plain language and bringing
8 things down to a grade six level, the language of
9 health care is not the language of consumers. It
10 may not even be the language of any of the people in
11 this room.

12 And I would urge everyone in this room
13 to take a look at the AMA website, AMA hyphen ASSN
14 dot org. And on that website is a fantastically
15 insightful video called, help your patients
16 understand.

17 It's meant for their constituents, but
18 in it are physicians who acknowledge that consumers
19 should not be expected to understand medicalese.
20 They've never been to medical school.

21 And the doctors should try and effect
22 three changes within their practice: create a shame-
23 free environment - I thought that was enormously
24 powerful, no matter how educated or literate you are

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1 - create a shame-free environment; speak slower; and
2 use living room language.

3 So the AMA is trying to enact change in
4 the communications style and the sensitivity within
5 their constituents.

6 But the AMA video also has real people
7 in there. And one of them is a woman who is clearly
8 highly educated, and it says she has a high level
9 job with computers, and her husband is a scientist.

10 And in this testimonial, this anecdote,
11 she said, I went to my doctor because I had a
12 problem down there, and my doctor said, no, no
13 problem, we can help you. And I went to the
14 hospital the next - or whatever the day was to go to
15 the hospital, and there she was confronted with five
16 two-page forms.

17 And in spite of her level of education,
18 or level of literacy, she was not a quick reader,
19 nor was her cognitive level such that she easily
20 understood forms. But she was not in any way going
21 to admit that when she was being admitted for a
22 procedure.

23 And the next day when her nurse came and
24 asked how she felt after a hysterectomy, she said, I

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1 couldn't believe out of embarrassment I had a part
2 of my body removed, and I want to go on the road
3 kind of thing and let people know.

4 Likewise her husband who was an engineer
5 came out of the doctor's office saying, I did not
6 understand anything that my doctor said.

7 So in the area of direct to consumer
8 advertising, which I mean it's been established that
9 it is advertising. But I believe that it can take
10 on a role of educating areas which have been
11 identified, which have not yet been identified, but
12 areas that should be identified, that it includes
13 saying, as a point in this latest video was, no pill
14 can give you happiness.

15 No drug can change your life
16 irrevocably. There are so many other factors that
17 are involved in making you happy, changing your
18 life. And the fact that changing behavior for any
19 of us I feel like I can speak fairly confidently
20 that a change of behavior, even if you are well and
21 healthy, and intending upon changing your diet or
22 getting more exercise involved in your life, or
23 distressing, is hard.

24 So that to ask people who are - have

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1 been diagnosed with something, and have to look at
2 their lives completely differently, to ask them to
3 enact that change instantly is unrealistic and sets
4 up a cycle of defeat.

5 So that for a direct to consumer ad,
6 whether it's print or broadcast - and our medium is
7 broadcast, and I'm going to be providing some
8 statistics on how our medium, introducing direct to
9 consumer advertising, and prescriptions at time of -
10 prior to leaving the hospital, makes a big huge
11 difference to compliance, the length of term of
12 compliance, especially in the area of statins, which
13 this study concentrated on.

14 That if you can help consumers
15 understand that, in the area, say, of hypertension,
16 for which we produced an educational segment, and
17 the first thing we had to determine was, were our
18 viewers going to understand what hypertension. And
19 in doing that, we conducted informal focus groups
20 just asking people what their definition of
21 hypertension was. And man, the results could go
22 into a Monty Python skit.

23 So it was determined that before any
24 education could be developed, we had to acknowledge

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1 that the language of this particular condition was
2 not understood by consumers for whom the benefits of
3 controlling high blood pressure through medication
4 and diet would be lost because they thought
5 hypertension meant a tense heart, or whatever it was
6 that they thought it meant.

7 So that to determine first off if
8 consumers understand what is being spoken of,
9 whether in a direct to consumer ad - actually, there
10 is a recent example with Plavix that talks about
11 plaque, and because Plavix is part of a recommended
12 therapy for patients leaving the hospital with
13 certain CV conditions, we just undertook to say, do
14 you know what plaque is? And it wasn't - I was not
15 surprised to hear that the understanding of plaque
16 was either a thing that you receive if you have won
17 an award, or the thing you brush off your teeth,
18 that clots and plaque are not everyday language.

19 And in Toronto, in fact, which is where
20 I'm originally from, there is a mini-med school that
21 is put on by University of Toronto that is designed
22 to help consumers understand the biologics and the
23 way the body interacts, and the language of health
24 and prescription drugs.

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1 And at the conference last year for
2 health literacy that is put on by the Institute for
3 Health Care Advancement, there was another language
4 example brought up by a doctor who said he was
5 visiting his patient. And he said, you know, you
6 have heart failure, not whatever it was that the
7 patient was admitted for. You're on the wrong
8 floor. I'm going to make sure you get up to the
9 right floor this afternoon.

10 And the patient later on said, aren't I
11 going to be cold on the floor? Are they going to
12 provide me with blankets?

13 So what we who are not only educated but
14 educated in the field of health language may take
15 for granted is a huge missing element out there that
16 would, in our belief, help all stakeholders,
17 including pharmaceutical companies who could use
18 their dollars, which is why I suggested this before,
19 if there was a percentage of the money going for
20 promotion or a separate category for education,
21 which is very hard to quantify admittedly.

22 You know the ROI on education can be
23 determined, is immeasurable because of all those
24 various doctors involved. Be that as it may, we

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1 provide education, we believe education is an
2 important factor in schools.

3 And there are people who are educated to
4 the educators. So from the FDA point of view, I
5 wonder if a suggestion might be, in addition to the
6 social scientist, to possibly add the master's of
7 education to the mix, so that any promotions can be
8 viewed to see if they follow principles of adult
9 education, which are very different from principles
10 of - oh my God, I've done it.

11 Well, that was a lot of fun. I think
12 that's it. I got my lipid study. Got the AMA thing
13 in. Okay. Are there any questions.

14 MR. ABRAMS: Dr. Behrman.

15 MS. BEHRMAN: I have two. One is, then
16 is your advice to us - you focused a lot on
17 language, and comprehension - that in order to
18 improve the educational value of DTC ads we should
19 focus on the language that's used and the lack of
20 communication? Is what I should glean?

21 MS. KASTNER: Meaning, identifying words
22 and concepts that are not familiar yet to consumers,
23 and ensuring that they are clarified somehow.

24 I too don't think that a 30-second ad

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1 can accomplish that. But for a self-directed adult,
2 and not all of us are, to be able to tell consumers
3 who are reading or watching the ad that there are
4 places to learn more about the terminology, whether
5 it's hypertension or lipid reduction or whatever, to
6 have that incorporated into it, I think that
7 component could be looked at more closely.

8 MS. BEHRMAN: And just to follow up, you
9 mentioned the AMA's notion of a shame-free
10 environment. Does that have an analogy if you will
11 in an ad?

12 MS. KASTNER: Well, I don't know if
13 there is an analogy per se, but to be addressing the
14 fact in the - checking, some ads do - that you are
15 not alone, or that there is no shame in asking
16 questions, and here are some of the questions to
17 ask. We've also found consumers don't even know
18 what questions to ask.

19 MS. BEHRMAN: Thank you.

20 MR. ABRAMS: Thank you for your
21 presentation.

22 MS. KASTNER: Wait, Lisa is supposed to
23 ask me a question.

24 MR. ABRAMS: Ms. Moncavage?

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1 MS. MONCAVAGE: We are FDA are not
2 compelled to speak.

3 MR. ABRAMS: I withdraw my statement.

4 MS. MONCAVAGE: You mentioned the lipid
5 study. Could you talk about that a little it?

6 MS. KASTNER: Yes, there was a study
7 done which I will provide which shows that if a
8 prescription is initiated in the hospital - and for
9 our purposes it means to have communication or
10 direct to consumer advertising in the hospital so
11 that patients are aware of this - if a prescription
12 is initiated in the hospital the compliance rate, if
13 that is what one says, increases to - they follow
14 these patients for six months, patients who have
15 been prescribed in a hospital versus in a follow-up
16 doctor's visit. And the patients in the hospital
17 were still compliant six months later.

18 Would you like me to provide that data?

19 MR. ABRAMS: Sure. If you could submit
20 it, it would be very useful.

21 MS. KASTNER: I will provide it. Thank
22 you very much.

23 MR. ABRAMS: Thank you for your
24 presentation.

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1 Okay, we are going to break in a minute,
2 and then have a final panel come back.

3 I request that anybody who wishes to
4 speak from the floor. We probably will have time
5 after the next panel.

6 So I'd like to thank this panel for
7 their excellent presentations.

8 (Applause)

9 MR. ABRAMS: And we will break now and
10 resume at 3:15.

11 (Whereupon, the proceeding in the above-
12 entitled matter went off the record at 2:50 p.m. to
13 return on the record at 3:13 p.m.)

14 MR. ABRAMS: Good afternoon, and welcome
15 back. We are at the home stretch now, panel #8, the
16 final panel of the hearing.

17 We will start off with our first
18 speaker, Mark Tosh from DTC Perspectives.

19 MR. TOSH: Good afternoon, and thank
20 you. I'm representing DTC Perspectives. My name is
21 Mark Tosh. And I'd like to thank this FDA for the
22 opportunity to present here today.

23 DTC Perspectives publishes DTC
24 Perspectives, and develops educational conferences

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1 for the DTC industry.

2 We have tried to be an objective
3 observer of DTC trends and issues, and our position
4 is that the DTC industry benefits most by
5 understanding the points of view of both supporters
6 and critics.

7 Indeed, the weekly newsletter written by
8 our chairman, Bob Ehrlich, often takes the drug
9 companies to task for actions he feels are not in
10 the public interest.

11 Let's turn to the matter at hand. First
12 we'd like to say that we think DTC has been a net
13 positive for the American public. We must recognize
14 that our health system is not objective, and was not
15 objective, before DTC appeared.

16 Physicians are not always neutral. They
17 are influenced by drug companies through medical
18 meetings, samples, and detail reps.

19 Insurance companies are not neutral, and
20 often try to influence drug choices to less
21 expensive drugs, not necessarily the best drugs.

22 OTC products try to influence consumers
23 and compare themselves to Rx drugs.

24 Therefore, consumers benefit by having

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1 all the facts available to them, even with a sales
2 orientation as a part of branded DTC advertising.

3 Second, we think the industry has taken
4 some positive steps in 2005. Many new ads are more
5 straightforward, more sober, and easier to
6 understand. The new trend is positive for
7 consumers, because risk information is now presented
8 in many ads as part of the main actor portrayal, not
9 as a voiceover. In some ads, doctors provide the
10 risk and benefit information.

11 Drug companies also have significantly
12 increased disease education ads in 2005, in response
13 to both critics and the FDA guidance.

14 We also see an attempt at self
15 regulation through the PhRMA code that was adopted
16 this past August. It is not perfect, but it does
17 provide two major changes. Most importantly, it
18 brings the end of branded awareness reminder ads,
19 and it also talks about the age-appropriateness of
20 advertising targets.

21 Now let us turn to what we think should
22 still be done to improve DTC. First, we were
23 greatly disappointed that the PhRMA code did not
24 deal with medicalese brief summaries. This is a

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1 major problem that still exists in about half of
2 print ads. Despite the FDA draft guidance issued
3 almost two years ago, few drug companies have
4 changed to a patient-friendly format. We think this
5 is absolutely wrong. Consumers, now more interested
6 in understanding risk, deserve to have that
7 information in understandable terms. Drug companies
8 owe that to consumers any time they run an ad in a
9 consumer magazine or refer to that information on a
10 television ad.

11 We urge the FDA and DDMAC to get
12 whatever regulatory authority it needs to ban these
13 medicalese brief summaries. Many marketers and drug
14 companies have told us that they want these patient
15 friendly summaries adopted, but are vetoed by
16 company lawyers who somehow believe a flood of
17 incomprehensible information will protect them from
18 liability lawsuits.

19 I hope they are proven wrong, and that
20 American juries react negatively to medicalese brief
21 summaries.

22 Therefore DDMAC should consider getting
23 specific authority to mandate patient-friendly
24 summaries, or alternatively, make the typeface

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1 requirement larger, so that these medicalese types
2 of summaries are cost inefficient for drug
3 companies.

4 Also, one of the drug companies that
5 does deserve praise for making patient friendly
6 summaries available years ago is Merck. Given the
7 negative press that Merck has gotten on Vioxx, at
8 least they do deserve credit for their brief summary
9 policy.

10 Our second recommendation is to develop
11 a guidance that encourages ads that deal with
12 retention and compliance. Most DTC is for brand
13 awareness. We are now glad to see more disease
14 education ads, but we also think the public needs to
15 see ads on the proper use of drugs.

16 We know that poor retention and
17 compliance is a major contributor to
18 hospitalizations and other illnesses.

19 We think that a good use of reminder ads
20 would be for this purpose, a 15 or 30-second ad that
21 would be impactful for current or lapsed users.

22 Third, we recommend Congress or DDMAC
23 develop a panel to oversee the PhRMA code, an
24 independent assessment of self regulation is

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1 critical to determine if drug companies have done
2 the job well.

3 This panel should issue a public report
4 on how well the industry has followed its 15
5 points.

6 Fourth, we do not think we need
7 additional regulation on use of celebrity spokesmen.

8 We know a few major branded drug ad campaigns that
9 still use celebrities, and there is no evidence that
10 celebrities work better than noncelebrities, at
11 least that we know of.

12 Clearly the public identifies with
13 celebrities who announce they, too, may have an
14 embarrassing condition. And therefore, celebrities
15 can be effective in disease education.

16 Fifth, we would recommend DDMAC not try
17 to ban special offer type promotional ads, which was
18 one of the things raised in the background to this
19 meeting. While we do not feel brands help their
20 image through such couponing, or through buy-a-few-
21 get-a-few-free product type promotions, we do not
22 think there is any harm to consumers by offering
23 them.

24 We are not aware of any evidence that

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1 these discounts lead to inappropriate use or result
2 in physician pressure to prescribe. The discounts
3 are usually small, and not a major incentive to ask
4 doctors to prescribe.

5 In summary, we think the drug industry
6 has come a long way in 2005 toward making DTC more
7 in the public interest. We believe no major changes
8 are needed, except as noted above, and 2006 should
9 be a learning year on self regulation, and a year to
10 determine if the industry will continue on its trend
11 toward more disease education, and less branded ads.

12 We do however believe DDMAC should act
13 on medicalese brief summaries through new
14 regulations. We also would like to see an
15 independent panel to monitor self regulation as soon
16 as next year.

17 DTC Perspectives would be happy to
18 assist in that effort, as we feel we are able to
19 objectively review drug company compliance with the
20 PhRMA code.

21 Thank you for your time.

22 MR. ABRAMS: Dr. Aikin.

23 DR. AIKIN: Thank you for your comments.

24 You suggest that the FDA develop

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1 guidance on retention and compliance advertising.

2 Companies could certainly do this form
3 of advertising now. What do you envision such a
4 guidance saying?

5 MR. TOSH: Well, perhaps some type of
6 guidance on the balance of advertising to go
7 retention of the amount.

8 DR. AIKIN: Could you be more specific,
9 by amount?

10 MR. TOSH: Well, whether it should be 10
11 percent of the advertising or 25 percent, or just
12 how it would break down.

13 MR. ABRAMS: Dr. Behrman.

14 MS. BEHRMAN: You had mentioned a board,
15 an independent board to oversee or at least evaluate
16 the PhRMA, the voluntary code. Do you envision FDA
17 creating that board or outside organization?

18 MR. TOSH: I think it would be an
19 outside organization, an independent panel. But DTC
20 Perspectives would be offering its assistance to
21 help set up such a board and develop the names of
22 the people who would serve on such a board.

23 MS. BEHRMAN: And you would envision
24 then PhRMA taking initiative to do that? Or is that

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1 a recommendation to us on the board?

2 MR. TOSH: Well, we think that the board
3 needs to be independent, and it could perhaps work
4 in conjunction with PhRMA on its findings. But we
5 think that the board should be set up independently
6 of PhRMA.

7 MR. ABRAMS: Thank you, Mr. Tosh, for
8 your presentation.

9 The next speaker is Scott Lassman from
10 PhRMA.

11 MR. LASSMAN: Good morning. It's
12 already afternoon. And thank you for on behalf of
13 the Pharmaceutical Research and Manufacturers of
14 America, also known as PhRMA, I'm pleased to appear
15 this afternoon at this public hearing on direct to
16 consumer advertising.

17 My name is Scott Lassman, and I'm
18 assistant general counsel at PhRMA.

19 PhRMA represents the country's leading
20 research based pharmaceutical and biotechnology
21 companies. PhRMA member companies are devoted to
22 inventing medicines that allow patients to lead
23 longer, healthier, and more productive lives,
24 investing more than \$30 billion annually in

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1 discovering and developing new medicines, PhRMA
2 companies are leading the way in the search for
3 cures.

4 But PhRMA don't just do the important
5 work of discovering and developing new medicines.
6 They also devote substantial time and effort to
7 informing health care professionals and patients
8 about the availability, proper usage, and benefits
9 and risks associated with those medicines.

10 This communication provides tremendous
11 value to health care professionals and patients by
12 making them aware of the benefits and risks of the
13 new drugs; empowering patients to play a more active
14 role in managing their own health; encouraging
15 patient compliance with the physician-directed
16 treatment regimens; and perhaps most important,
17 encouraging patients to seek treatments for diseases
18 that currently are underdiagnosed or undertreated.

19 DTC advertising in particular can be a
20 powerful tool to reach millions of people about
21 health care treatments. Because of this reach, DTC
22 advertisements can be a tremendous value in
23 conveying useful health information to patients.

24 An important benefit of DTC advertising

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1 is that it fosters informed conversations about
2 health, disease and treatments between patients and
3 their health care providers.

4 Because of DTC advertising large numbers
5 of Americans are prompted to discuss illnesses with
6 their doctors for the first time. Because of DTC
7 advertising, patients know where to find additional
8 information about disease states and treatment
9 options.

10 Because of DTC advertising, patients
11 become more involved in their own health care
12 decisions, are proactive in the patient-doctor
13 dialogue.

14 Because of DTC advertising, patients are
15 more likely to take their prescribed medicines.

16 In short, DTC advertising plays an
17 essential role in meeting the needs of an
18 increasingly sophisticated information-seeking
19 health care consumer.

20 DTC advertising also serves a valuable
21 role in educating patients about the limitations and
22 risks associated with certain therapies. Now
23 obviously DTC advertising cannot and should not
24 replace the health care professional as the most

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1 authoritative source of information about the risks
2 and benefits of particular drugs for a particular
3 patient. But it can and does encourage patients to
4 talk to their physicians about their medical
5 conditions or treatment options, including the risks
6 of treatment.

7 This dialogue results in better educated
8 patients, more active in their own health care, who
9 generally comply with their treatment regimens.

10 PhRMA and its member companies have long
11 understood the special responsibility we have to the
12 patients that use our innovative medicines. Despite
13 the very positive role DTC advertising plays in
14 helping to educate patients - I think we've heard a
15 lot about that over the last two days - we have
16 heard concerns expressed over the past couple of
17 years about DTC advertising, and we do take those
18 concerns very seriously.

19 In order to address these concerns and
20 improve the value of DTC advertising, on July 29th,
21 2005, PhRMA's board of directors unanimously
22 approved PhRMA's guiding principles on direct to
23 consumer advertisements about prescription
24 medicines.

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1 Although the guiding principles are
2 voluntary, consistent with PhRMA's state as a
3 voluntary trade association, since July, 26 PhRMA
4 member companies have stated publicly that they
5 intend to follow the guiding principles.

6 We are proud of this commitment by our
7 members.

8 Our principles recognize that
9 prescription drugs are different, and should be held
10 to a higher standard; that there are important and
11 powerful products that have both benefits and risks,
12 and thus must be used with care; that they require
13 the supervision and oversight of a trained health
14 care professional; in short, our principles
15 recognize that prescription drugs are not like light
16 bulbs or toothpaste or underarm deodorant or any
17 other consumer product. DTC advertising thus should
18 be responsibly designed to provide accurate,
19 accessible and useful health information that
20 encourages the appropriate use of these special
21 products.

22 And this is precisely what the primary
23 goal of PhRMA's new DTC guiding principles are.

24 Because prescription drugs are

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1 different, DTC advertisements already are subject to
2 stringent regulatory requirements and oversight by
3 FDA. These requirements are more stringent than the
4 requirements that apply to virtually any other type
5 of DTC advertising.

6 For instance, advertisements for cars
7 don't need to spend any time at all discussing the
8 dangers of driving or the risk of a rollover.

9 Pharmaceutical ads, by contrast, are
10 required to talk about risks. And this is
11 appropriate, because drugs are different. The
12 guiding principles recognize that FDA regulations
13 already set a very high standard.

14 According to those regulations, all DTC
15 information must be accurate and not misleading; to
16 make product claims only when supported by
17 substantial evidence; must reflect the balance
18 between risks and benefits; and must be consistent
19 with the FDA-approved labeling.

20 Our members are committed to meeting
21 these existing high standards, and the guiding
22 principles reiterate that commitment.

23 But the guiding principles go further.
24 They reach beyond existing regulatory requirements,

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1 in order to help promote an educated dialogue
2 between physicians and patients. For example, the
3 guiding principles state, the company should spend
4 appropriate time educating health care professionals
5 about a new medicine before it's advertised to
6 patients.

7 This will help to ensure that physicians
8 know about a new medicine first, so that they are
9 prepared to answer questions that they get from
10 their patients.

11 In addition, companies that sign onto
12 these guiding principles agree to submit all new
13 DTC television ads to the FDA before releasing these
14 ads for broadcast. This commitment again goes
15 beyond existing regulatory requirements, which
16 require companies to submit DTC television ads at
17 the time they're first aired.

18 This additional lead time should provide
19 the agency the opportunity to review new TV ads
20 before they're aired, consistent with its priorities
21 and resources. It also should provide FDA and
22 sponsors a better opportunity to communicate
23 expectations and identify and address issues before
24 a DTC ad is viewed by the public.

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1 The guiding principles also state that
2 DTC television ads that identify a product by name
3 should clearly state its approved indications and
4 major risks.

5 Critics contend that reminder ads on
6 television often leave patients guessing about the
7 nature of the advertised product, its intended use,
8 and whether the patient should follow up with his or
9 her physician.

10 While PhRMA believes that reminder ads
11 can help familiar consumers with product names, we
12 also believe that television ads should facilitate a
13 more informed dialogue between patients and health
14 care providers.

15 To achieve this goal the DTC principles
16 call for companies to provide all relevant benefit
17 and risk information when a product is named in a
18 television ad.

19 The guiding principles also go beyond
20 existing legal requirements by asking companies to
21 focus more closely on the intended audiences, as a
22 result of concerns that certain prescription drugs
23 may not be suitable for all viewing audiences, the
24 guiding principles state that DTC television and

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1 print ads should be targeted to avoid audiences that
2 are not age appropriate for the messages involved.

3 If an advertisement contains content
4 that may be inappropriate for children, the
5 advertisement should be targeted to predominantly
6 adult audiences.

7 This means programs or publications that
8 are reasonably expected to draw an audience of
9 approximately 80 percent adults.

10 PhRMA believes that DTC advertising is
11 important, even for these types of health conditions
12 that may be embarrassing or sensitive.

13 By the same token, PhRMA's member
14 companies recognize that these ads should be
15 disseminated with sensitivity and respect for the
16 feelings of parents and children.

17 The guiding principles contain many
18 other important provisions intended to enhance the
19 value of DTC. For instance, should new and reliable
20 information concerning a serious previously unknown
21 safety risk be discovered? Companies commit to work
22 with the FDA to responsibly alter or discontinue a
23 DTC advertising campaign.

24 In addition, the principles encourage

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1 companies to include, where feasible, information
2 about help for the uninsured and underinsured. Our
3 member companies host a host of programs that assist
4 needy patients, and DTC ads can help spread the
5 word.

6 PhRMA's board also unanimously approved
7 the creation of an office of accountability to
8 ensure the public has an opportunity to comment on
9 companies' compliance with these principles.
10 Periodic reports will be issued by the PhRMA office
11 of accountability to the public regarding the nature
12 of the comments.

13 Each report will also be submitted to
14 the FDA.

15 PhRMA's board also agreed to select an
16 independent panel of outside experts to review
17 reports from the office of accountability after one
18 year, and evaluate overall trends in the industry as
19 they relate to these principles.

20 The panel will be empowered to make
21 recommendations in accordance with the principles.
22 And the principles go into effect in January of
23 2006.

24 We believe these new principles will

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1 help patients get the information they need to make
2 informed health care decisions in consultation with
3 their health care practitioners.

4 Given the progress that continues to be
5 made in society's battle against disease, patients
6 are seeking more information about medical problems
7 and potential treatments. The purpose of DTC
8 advertising is to foster an informed conversation
9 about health, disease and treatments between
10 patients and their health care practitioners.

11 Our guiding principles, we believe, are
12 an important step in facilitating that conversation.

13 My comments today have focused on
14 PhRMA's guiding principles, which we believe address
15 many of the issues raised by FDA in its meeting
16 notice.

17 We also intend to submit written
18 comments to the docket addressing these and other
19 issues in more detail.

20 In closing, though, I would like to
21 mention that PhRMA strongly supports FDA's efforts
22 to increase the effectiveness of DTC advertising to
23 impart meaningful health information to patients
24 including risk information.

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1 PhRMA specifically supports efforts to
2 improve the usefulness of the brief summary to
3 consumers, as stated in our previous comments to the
4 docket on FDA's draft guidance.

5 However, this should be accomplished in
6 a way that does not create unnecessary product
7 liability concerns.

8 As a final comment, PhRma believes it's
9 important to utilize an evidence-based approach when
10 addressing all of these issues, and it's nice to see
11 that there was so much evidence in the last two days
12 presented to FDA.

13 Such an approach should rely on adequate
14 consumer research to determine the best way to
15 communicate benefit and risk information to
16 consumers.

17 PhRMA firmly believe that when patients
18 have access to accurate and understandable
19 information about their medical conditions and
20 treatment options, they can partner more effectively
21 with their health care providers to obtain the most
22 appropriate treatment for their individual
23 circumstance.

24 This concludes my oral testimony, and I

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1 would be happy to take any questions.

2 MR. ABRAMS: Thank you, Mr. Lassman, for
3 your presentation.

4 You mentioned the benefits of DTC
5 advertising. We have heard from speakers in the
6 past two days that in addition to DTC being
7 compliant with the regulation, being accurate and
8 balanced, it should go beyond that. It should be
9 educational, it should talk more about the disease
10 state, should focus more on educating people about
11 diseases rather than selling a product.

12 Do you have any response or thoughts
13 about that?

14 MR. LASSMAN: We completely agree, and
15 that's exactly what we have tried to do with our new
16 PhRMA DTC principles, to make the advertisements
17 more informational, more educational, more focused
18 on these things.

19 So we would agree with that, and I think
20 we are doing that.

21 MR. ABRAMS: So you think that there
22 should be less emphasis on the product and more on
23 the disease then?

24 MR. LASSMAN: No, I wouldn't say less

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1 emphasis on the product. Obviously the ads, most of
2 the ads involve products, and we feel that that
3 ought to continue to be the case, that that ought to
4 be available to companies.

5 I think there was testimony yesterday
6 indicating that the product ads may be the most
7 effective in actually getting patients to see their
8 doctors.

9 One of the points that we have made,
10 though, in the new DTC principles is, we do
11 encourage companies to do more of the disease state
12 ads, the more help seeking type of ads as well.

13 MR. ABRAMS: Thank you. Dr. Behrman.

14 MS. BEHRMAN: Two questions. One, do
15 you agree with Mr. Tosh's comment that the presence
16 of the draft help seeking guidance in fact increased
17 the numbers of those ads? Do you believe that your
18 member companies are actually doing more of those
19 because of the guidance?

20 MR. LASSMAN: I have no information
21 about the levels of how much of those help seeking
22 ads are out there, so I can't really comment about
23 that. I think any encouragement by FDA would be
24 helpful.

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1 As I said, we tried to provide
2 encouragement in our DTC principles, and we hope
3 that that will be helpful in spurring more of those
4 types of ads as well.

5 MS. BEHRMAN: I was interested in
6 whether a guidance on compliance, I was trying to by
7 analogy, I'm wondering if guidance on compliance
8 might have a similar effect on such an increase.

9 The other question I had: Does PhRMA
10 have a position on two issues that came up a lot in
11 the last two days: the language in the ads, and the
12 if you will incentives? Particularly cleaning up
13 the ads to the children, the acne ad?

14 MR. LASSMAN: As far as the language,
15 whether it ought to be understandable to consumers,
16 yes we definitely support that. That is a position
17 which we've stated in our comments to FDA's guidance
18 document on the brief summary in print ads.

19 We fully support that. We think it's
20 critical that patients actually understand the
21 health care information, safety information, the
22 effectiveness information.

23 A lot of times it may be difficult to
24 get there. These types of issues are, some of them

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1 unfortunately do have to be presented in medical
2 language which may be difficult to understand.

3 But to the extent we can get there, we
4 think that that is appropriate.

5 MS. BEHRMAN: And incentives, does PhRMA
6 have a position on incentives, coupons, or iTunes,
7 or things like that?

8 MR. LASSMAN: At this point I don't
9 think we have a position on that.

10 MR. ABRAMS: Dr. Aikin?

11 DR. AIKIN: You mentioned that 26
12 companies have signed on, or I guess agreed to
13 follow the PhRMA guidelines.

14 MR. LASSMAN: That's right.

15 DR. AIKIN: What percentage of your
16 total membership is that? And do you anticipate
17 more companies signing on later?

18 MR. LASSMAN: We hope more companies
19 will sign on. I think it's a very substantial
20 percentage of our membership. I don't have the
21 exact figures, but I believe we have somewhere in
22 the low thirties as far as membership; so it's a
23 very substantial proportion.

24 MR. ABRAMS: Dr. Ostrove.

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1 MS. OSTROVE: Just a quick point of
2 clarification. Do the principles with regard to the
3 reminder ads apply to both broadcast and print?

4 MR. LASSMAN: They apply only to
5 broadcast ads.

6 MS. OSTROVE: Then can I follow up and
7 ask why that would only apply to broadcast ads?

8 MR. LASSMAN: Well, that's a very good
9 question. I think the reason is, what we were
10 trying to do with the principles is really address
11 criticisms that we've been hearing.

12 Most of the criticisms around reminder
13 ads had pertained to the broadcast ads, so that's
14 why the principles focused on the broadcast ads.

15 That may be something we look at as we
16 get more experience with this, whether that ought to
17 be extended to print ads. But as it stands right
18 now, it's just limited to the broadcast ads.

19 MR. ABRAMS: A final question: Could
20 you describe PhRMA's position, a brief summary, of
21 exactly what you would like to see with the brief
22 summary happen?

23 MR. LASSMAN: Well, as we stated in our
24 comments, we support the overall thrust of what FDA

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1 is trying to do, which is to make the brief summary
2 more of a summary and more brief, and provide that
3 information in patient-friendly language.

4 The problem that we had with the draft
5 guidance was that it's framed as an exercise of
6 FDA's enforcement discretion, essentially saying -
7 if you look at FDA's regs, stepping back for a
8 second, if the requirement is that every single
9 safety issue has to be presented in the brief
10 summary. What you were saying in your guidance
11 document is, we won't object if you present the most
12 significant and not every single one, but just the
13 most significant.

14 But the issue for us, if that is an
15 exercise of enforcement discretion, I think that's
16 probably a good exercise of enforcement discretion.

17 We unfortunate have product liability issues with
18 that, because if there is an argument that we are
19 not complying with the letter of FDA's regulations
20 in providing risk information to the patients,
21 again, that opens up our membership to product
22 liability concerns.

23 So what we were suggesting is, we
24 support the overall thrust of it. We don't think it

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1 ought to be done as a guidance document or as an
2 exercise in enforcement discretion.

3 If you are really going to do it, we had
4 suggested doing it by changing the regulations.

5 MR. ABRAMS: Thank you, Mr. Lassman.

6 Okay, our next speaker is Peter Pitts
7 from the Pacific Research Institute.

8 MR. PITTS: Thank you, Mr. Abrams.

9 Thank you for the opportunity of
10 addressing this important meeting at a very timely
11 moment.

12 Winston Churchill said that Americans
13 always strive to do the right thing after they have
14 tried everything else.

15 Today we have the opportunity to devise
16 a system, we must devise a system, wherein DTC
17 advertising is designed in equal parts as savvy
18 marketing strategy and powerful public health tool,
19 because these are not mutually exclusive concepts.

20 We must learn from our mistakes. While
21 industry's errors have been in many instances sins
22 of commission, mistakes literally aired in public,
23 so too has the FDA erred, mostly through sins of
24 omission, specifically using personal judgment

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1 rather than social science to decide what in
2 compliance means.

3 This lack of predictability has led to
4 an absence of direction that some harsh critics on
5 Capitol Hill see as an abdication of leadership, and
6 the result is advertising that isn't as potent a
7 public health tool as it might otherwise be.

8 With that as my point of departure, let
9 me ask a question: What do we want pharmaceutical
10 direct to consumer advertising to be when it grows
11 up?

12 The recent consumer survey in Europe
13 asked people in Great Britain, the Czech Republic,
14 France, Germany, Italy, the Netherlands, Spain and
15 Sweden what reforms would most likely increase their
16 quality of care?

17 In every nation, by a large margin, the
18 answer was, quote, giving patients more information
19 about their illness, close quote.

20 Here at home 96.7 million consumers go
21 online, and 65 percent of them seek information
22 about their health.

23 Health care information is the
24 consumer's Rosetta Stone, and public policy

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1 institutes, pharmaceutical firms, communications
2 professionals, health care providers, disease
3 organizations, patient advocates, and academics
4 along with the FDA must be allied and aligned
5 conduits.

6 That being said, how can the FDA help
7 calibrate the proper balance without overstepping
8 its regulatory authority? Is the answer to ramp up
9 the volume of NOVs? I don't think so.

10 More letters do not result in better,
11 more public health driven, communications. Industry
12 by and large strives to be in compliance. But when
13 the rules are vague and fluid, an ad or promotional
14 brochure that is okayed by DDMAC one day can be
15 ruled out of compliance the next, sends ominous
16 signals to both industry and consumers alike, and
17 it's like red meat for some members of Congress.

18 We need better DTC advertising, and the
19 way to get there is to apply sound social science to
20 better communicating medical science.

21 Claude Debussy said that music is
22 between the notes, and this is as true as it is for
23 NDAs as it is for communications oversight. The
24 same techniques used to judge clinical trials cannot

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1 be applied to communications.

2 Current DTC policy is not based on a
3 scientific analysis of the target subject: the
4 consumer. And this raises a crucial question:
5 Where are the social science metrics driving the
6 expert review of pharmaceutical advertising?

7 Specifically, how could marketers more
8 clearly and meaningfully communicate the risk-
9 benefit equation of advertised drugs by following
10 more useful directions from the Food & Drug
11 Administration?

12 FDA needs a solid benchmark study to
13 serve as a foundation for the agency's regulatory
14 oversight of direct to consumer advertising, a
15 social scientific protocol, a quantitative research
16 project composed of structured closed-ended
17 questions, and a sample size representative of the
18 U.S. population with regard to geography, race,
19 gender, age and the treatment of disease of
20 interest.

21 A study armed with questions that would
22 provide insight into the most effective ways to
23 communicate in ways that are understandable by the
24 average consumer; a study that would provide a

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1 social science-based regulatory framework, potential
2 templates, metrics, and most importantly, something
3 that would add predictability to the DDMAC review
4 process.

5 I do not believe that the status quo is
6 a viable option, because as FDA's own research
7 shows, the current brief summary for example is a
8 poor public health tool.

9 "In compliance" and "user friendly"
10 should not be mutually exclusive.

11 In our post-Vioxx world, we can no
12 longer afford to risk - we can no longer afford to
13 allow risk information to remain hidden in plain
14 view. As far as the public health is concerned,
15 that is not an adequate provision.

16 The status quo is a nonstarter, because
17 it is antithetical to the public health.

18 If an educated consumer is our best
19 customer, then industry needs an evidence-based
20 regulatory framework that provides predictable
21 standards for the communications efforts to
22 consumers.

23 Perhaps it's time for a standing
24 advisory committee on health care communications.

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1 FDA cannot continue to regulate vague concepts such
2 as fair and balanced and adequate provision on a
3 case-by-case basis.

4 Instead, the FDA, with input from
5 pharmaceutical, industry, consumers, communications
6 professionals and academia, must develop an
7 evidence-based predictable framework for DTC
8 marketing, and there must be options. Because the
9 same rules cannot apply equally to an allergy
10 medicine on the one hand and an antidepressant on
11 the other.

12 FDA must take the next steps required to
13 put the science back in social science. As Jerry
14 McGuire might say, show me the metrics.

15 Thank you very much.

16 MR. ABRAMS: Any questions from FDA
17 panel?

18 Thank you, Mr. Pitts.

19 MR. PITTS: Thank you.

20 MR. ABRAMS: Okay, our last speaker for
21 the hearing, and I thank you for your patience, is
22 William Vaughn from the Consumers Union.

23 MR. VAUGHAN: Thank you very much, and
24 thank you for your endurance.

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1 I'm here on behalf of Consumer Union,
2 the independent nonprofit publisher of Consumer
3 Reports. We have no conflicts of interest.

4 We don't just test toasters and flat-
5 screen TVs. We try to help people get the best,
6 most effective, safest drugs.

7 We have a best buy drugs campaign on our
8 free website, that uses the Oregon Health and
9 Science's university drug effectiveness review
10 project to try to help people get not just what is
11 advertised on TV, but what the best drugs are, the
12 safest drugs, for the most reasonable price.

13 I'm sorry I'm not bringing any original
14 research to this meeting. But having sat through
15 every presentation, I am going to file a paper
16 tomorrow with a journal, because I have been very
17 surprised that there is a very high correlation,
18 almost 100 percent positive correlation.

19 Those who make money selling medicine
20 and from advertising tend to like DTC; those of us
21 who don't have a financial interest have some
22 problems. And when I get that peer reviewed, if I
23 could submit it to the docket, I'd appreciate it,
24 sir.

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1 We urge the FDA to support major reforms
2 in the advertising of pharmaceuticals. We believe
3 this is a major consumer issue. And as AARP said
4 yesterday, it is a good way to save money in the
5 health sector.

6 You think of direct to consumer
7 advertising on TV, that'd be about two million
8 adults covered under Medicaid. All of this stuff,
9 it' s about 15 million people, maybe more if you're
10 just doing kids, covered under Medicaid. So it's a
11 hunk of money you sometimes wonder could be better
12 spent.

13 We agree with a lot of what has already
14 been said, particularly with AARP. Gary Stein of
15 the Health Systems Pharmacists, the National
16 Consumers League, the Public Citizen, the PAL group
17 today, points made by Kaiser Permanente's presenter
18 about doctors being induced to perhaps misprescribe,
19 Diane Zuckerman of the National Research Center's
20 evocation of emotional ads, and the excellent
21 description of advertising's psychological
22 manipulations, fluttering bumble bee wings,
23 described by Professor Day, all reinforce our
24 beliefs.

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1 And we are not persuaded by testimony
2 that companies have a constitutional right to cause
3 injury or death to their fellow citizens. Therefore
4 Consumers Union urges requiring a two or three year
5 moratorium on advertising of new drugs, because to
6 be frank, we really do not know how safe new drugs
7 are, given the often accelerated approval procedures
8 now in place.

9 We support preapproval of all DTC, and
10 direct to provider, ads, before they are presented
11 to the public and providers, so as to end the long,
12 long, long history of misleading advertising and
13 marketing that overstates benefits and understate
14 risks.

15 And if preapproval is not possible, then
16 there should be substantial penalties for
17 misrepresentation of the safety risks, so strong
18 that companies will want to have preclearance.

19 Washington Legal Foundation this morning
20 was complaining about you all pushing back on some
21 ads. Congratulations. Congratulations for standing
22 up for the public interest.

23 We endorse, we hope the administration
24 in its new budget might endorse S. 930 by Senators

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1 Grassley and Dodd, requiring that ads for those
2 drugs approved on condition of further studies
3 publicly state those safety concerns that are
4 identified and are being investigated.

5 Hopefully that would speed up the day
6 that companies actually do those studies.

7 We support legislation giving FDA civil
8 monetary penalty authority to effectively endorse
9 truth in advertising and penalize repeat offenders.

10 You should require, we think, an
11 addition to all DTC ads, a note that all adverse
12 reactions should be reported to your physician and
13 the FDA at MedWatch, and give the toll free
14 telephone number and website. As you know we're
15 getting about one to 10 percent of probable
16 reactions out there. We should encourage more
17 awareness of this tool.

18 And we believe that if and when Paducah
19 is reauthorized in 2007, enough resources should be
20 dedicated to review of ads so as to make the program
21 truly effective.

22 We would support the device makers'
23 testimony: You need resources to look at device
24 ads. Resources to look at Internet ads. As Dr. Day

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1 noted, the adverse effects are often several clicks
2 further away.

3 And once that legal authority is
4 clarified, the genetic testing kit testimony of
5 yesterday would be a good thing to take a look at.

6 We think we should develop a system
7 where - which drug manufacturers might support, a
8 public service announcements' fund, perhaps run
9 through a foundation or a group that would give
10 completely objective advice. The material might be
11 reviewed by AARP or NIH or even FDA for objectivity,
12 and raise the awareness on these under-diagnosed
13 illnesses, depression, hypertension, cholesterol.

14 But when the companies try to do it
15 themselves, as we've heard from several others, as I
16 think Professor Day pointed out, it sometimes
17 quickly gets less than objective, and less than
18 useful.

19 These are Consumer Union's positions.
20 Listening the last two days, I'd like to add a
21 personal one, and perhaps I could find some money at
22 Consumer Reports to help pay for it.

23 But the next time anybody does a poll of
24 how much Americans like drug ads, could the question

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1 also be asked, would you rather have drug ads, or
2 would you rather have the companies save the
3 advertising money and lower prices or save that
4 money and put it to research on new life-saving
5 drugs? You might get some interesting answers.

6 A moment more or two on the moratorium
7 idea. Here is an ad from a patient database company
8 that appeared about two months ago in a newsletter
9 read by many in the drug world. And it reads, how
10 many prescriptions, how many weeks in market, until
11 you are confident that your drug is safe.

12 If you showed that ad to the average
13 consumer on the street, they'd be pretty shocked.
14 They assume and expect that FDA-approved drugs are
15 safe. Vioxx, almost weekly headlines for the past
16 two years, have shaken that confidence. But the
17 average consumer doesn't think that they are the
18 guinea pigs of this ad, the sort of Emperor has no
19 clothes ad, correctly describes.

20 And the only way to mitigate the damage
21 of quick approval of drugs, tested on a thin
22 population base, is to ban mass advertising for the
23 first two or three years after they have been
24 approved.

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1 Therefore, we support Senator Dr.
2 Frist's call for a two-year moratorium. Congressman
3 Sherrod Brown (phonetic) has a two-year moratorium
4 bill. Representatives Joann Emerson, Rosa Delara,
5 have a three-year bill.

6 We support any and all of those, and
7 hope that you would encourage that.

8 On the issue of preapproval of ads,
9 Consumer Union has been working on the issue of drug
10 ads for a long time. Our 2003 magazine report on it
11 details our analysis of FDA regulatory letters for a
12 five-year period. We are about to update that, and
13 will have a new issue out in a couple of months.

14 But we found a broad and disconcerting
15 range of misleading messages, ads that minimized the
16 product's risk, exaggerated its efficacy, made false
17 claims of superiority over competing products,
18 promoted unapproved uses for an approved drug, or
19 promoted use of a drug still in the experimental
20 stage.

21 A reading of recent regulatory letters
22 seems to indicate a welcome upturn in strong warning
23 letters, for which we congratulate the FDA. We
24 particularly appreciate the emphasis on ensuring

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1 that the risks of a drug are given more prominence.

2 But it appears the overall level of
3 policing and promotions may be still down from
4 previous decade, and that nothing in particular has
5 changed in the type of abuses detected.

6 Companies are repeatedly warned about
7 similar violations, and all too often after the ad
8 campaign has ended, and public damage done.

9 In our 2003 report, we noted that the
10 maker of Claritin had received a total of 11
11 regulatory letters about problems with their ads.
12 How can people smart enough to make such a good pill
13 do such a bad job on ads? I guess their scientists
14 are better than their lawyers, but it's absurd on
15 its face, and it gets the strong impression that the
16 industry is just scoffing at the requirements.

17 As somebody has said, I think it was an
18 FDA person, that the FDA is just playing a game of
19 whack-a-mole, and we need to do better.

20 This disregard for the rules and
21 regulations is why the law should be changed to
22 permit imposition of major civil monetary penalties,
23 particularly on repeat violations.

24 And if you decide not to proceed with

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1 requiring preclearance, again, I hope the
2 disciplinary action could be stronger.

3 The rest of our written statements, the
4 statement for the record, makes some other points.
5 Mostly, you are going to need some more resources.
6 I hope all friends of FDA would be lobbying this
7 fall not to have an across-the-board one or two
8 percent budget cut. That's not helpful.

9 But in the long run, I think you do need
10 more resources, and Paducah would be perhaps the way
11 to do it, we hope not tied to specific timeframes of
12 specific actions, but give you resources to flexibly
13 do your job.

14 And in conclusion, there was one press
15 report this August about this whole meeting, that
16 this is the beginning of a process that might take
17 four years.

18 Ladies and gentlemen, we fought World
19 War II in less than four years, and hope that there
20 is a greater sense of urgency, and that you will
21 make regulatory changes and support legislative
22 changes on a much faster timetable.

23 We believe that faster action will help
24 prevent or minimize further Vioxx-type incidents,

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1 with their attendant deaths and injuries. We thank
2 you for your consideration of these recommendations
3 that we believe will help improve the quality and
4 safety of health care here in the United States, and
5 moderate the rate of health care inflation.

6 Thank you.

7 MR. ABRAMS: Any questions from our FDA
8 panel?

9 Okay, Mr. Vaughn, thank you very much
10 for your presentation.

11 That concludes panel eight. I want to
12 thank all the speakers.

13 (Applause)

14 MR. ABRAMS: At this point we will open
15 up the floor for comments.

16 We will start off with the sign-up
17 sheet. We have one person signed up so far, Gregory
18 Abell from Dana Farber Cancer Institute. If you
19 would come up to a mike.

20 MR. ABELL: So my name is Gregory Abell,
21 and I am a fellow in hematology and oncology at the
22 Dana Farber Cancer Institute.

23 I have three comments, and I want to
24 just stress that these are my personal thoughts and

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1 in now way represent an official position of my
2 institution.

3 The first comment is that as a policy
4 trainee, it's been amazing to see this conference
5 take place. I think that the FDA and DDMAC should
6 be applauded for soliciting commentary and input
7 from the very constituencies that will be affected
8 by the regulations that will come from the
9 organization.

10 And we have made a lot of comments.
11 However, we are one of the only countries that has
12 direct to consumer advertising. And while we are
13 unique among nations, I also think that we are
14 unique among nations in having a commitment to this
15 kind of openness with our federal agencies. So that
16 is my first point.

17 The second point is that I would argue
18 that oncology patients are a special population in
19 terms of direct to consumer advertising. There are
20 two reasons for this.

21 The first is that despite advances in
22 cancer medicine, there doesn't seem to be in
23 medicine a diagnosis that inspires more dread or
24 fear or desperation than a cancer diagnosis.

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1 And I think that cancer patients are
2 especially vulnerable to advertisements that are
3 aimed at them. And for this reason we need to be
4 very careful in scrutinizing advertisements for
5 cancer-related products and make sure that they do
6 not manipulate this sense of dread for marketing
7 purposes.

8 The second reason for that is that
9 chemotherapy - I know this having been a clinical
10 fellow - is very complex to give and to explain to
11 patients in terms of benefits and risks. Many
12 hospitals, most in fact in this country, don't allow
13 the majority of their physicians to administer it,
14 only physicians that have become board certified in
15 oncology.

16 Analogously, advertisements for
17 chemotherapy that are in the general media I believe
18 should have a higher level of scrutiny to make sure
19 that they are in fact providing fair balance.

20 And my third point relates to Dr.
21 Frist's suggestion that there be a two-year
22 moratorium on direct to consumer advertising for
23 products once they are approved.

24 I am not sure that that is appropriate

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1 in terms of cancer medicine. Two years is longer
2 than the natural history of many different types of
3 cancers, such as stage four lung cancer, or
4 pancreatic cancer, and may in fact be too long for
5 patients to gain the possible benefits of direct to
6 consumer advertising in terms of education.

7 I think in lieu of this, again,
8 heightened scrutiny by DDMAC of advertisement for
9 chemotherapeutics is in order, and perhaps the
10 creation of a special division of DDMAC with
11 expertise about chemotherapeutics, cancer biology
12 and also cancer psychology of cancer patients.

13 Thank you very much.

14 MR. ABRAMS: Thank you, Dr. Abell, for
15 your comments. Any other individuals wish to speak
16 to public comment from the floor?

17 Okay. Well, this has been a very full
18 meeting, and one I think that has been most
19 productive. We heard from interested parties about
20 many aspects of DTC including presentation of risk
21 information - much discussion about risk and how it
22 should be presented and what should be presented;
23 various ways of presenting benefit information;
24 impact of diagnosis and treatment; under-treated

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1 medical conditions; how does DTC impact that; data
2 from research conducted related to DTC.

3 There was discussion about new
4 regulations possibly being generated for DTC. Use
5 of celebrities in this type of promotion. A lot of
6 discussion about consideration of consumer friendly
7 language being used for DTC.

8 Use of disease awareness by companies,
9 some discussion of how image and different graphics
10 and their impact on promotions, and reminder
11 advertisements.

12 These are just a few of the discussion
13 items that we had in the past two days. So I think
14 it's been a very full meeting with much information
15 and many discussion items.

16 FDA wishes to thank all the speakers for
17 the time that they took in preparing their
18 presentations, and the time that they took
19 presenting, and replying, to all the questions from
20 the FDA panel.

21 So we thank you.

22 FDA wishes also to thank the attendees,
23 the audience, for your participation and your
24 interest in this very important topic.

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1 The docket will be open for any comments
2 that you may have, any additional comments, and any
3 data from research that has been conducted.

4 We encourage submission of this
5 information.

6 FDA will now carefully evaluate the
7 presentations and the comments made in this meeting;
8 will go over the transcripts when they become
9 available; will go over all the information that is
10 submitted to the docket; to determine the next steps
11 for activities in this area.

12 I don't know if anybody from FDA panel
13 has anything to add to these closing remarks, but I
14 invite anybody to add to my remarks.

15 MS. BEHRMAN: I'd just like to echo what
16 Mr. Abrams said about putting information in the
17 docket. Dr. Abell, you mentioned a topic that we
18 had brought up in the notice, but you were the only
19 one who picked up on it. So comments into the
20 docket are very helpful for us to be able to follow
21 up on the sorts of concerns.

22 Thank you.

23 MR. ABRAMS: That is a good question.
24 Rose? February 28th will be when the docket closes.

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1 Okay, we also wish to thank the folks
2 who put this together, the folks behind the scene,
3 particularly Rose Cunningham of Cedar, and thank you
4 to Bob Grisham (phonetic). Thank you.

5 (Applause)

6 MR. ABRAMS: And Rose, you have some
7 folks with you.

8 MS. CUNNINGHAM: Yes, I'd like to thank
9 Kathleen Quinn and Michelle Lackner for their
10 assistance. They helped answer any questions you
11 had out at the front, and helped get things moving
12 while I was in here. Thank you.

13 (Applause)

14 MR. ABRAMS: Okay, this hearing is now
15 adjourned. Thank you.

16 (Off the record.)

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