AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 107–986

DIRECT TO CONSUMER ADVERTISING (DTC)

HEARING

BEFORE THE

SUBCOMMITTEE ON CONSUMER AFFAIRS, FOREIGN COMMERCE AND TOURISM

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

JULY 24, 2001

Printed for the use of the Committee on Commerce, Science, and Transportation

U.S. GOVERNMENT PRINTING OFFICE

89–956 PDF WASHINGTON : 2004

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ERNEST F. HOLLINGS, South Carolina, *Chairman*

DANIEL K. INOUYE, Hawaii	JOHN McCAIN, Arizona
JOHN D. ROCKEFELLER IV, West Virginia	TED STEVENS, Alaska
JOHN F. KERRY, Massachusetts	CONRAD BURNS, Montana
JOHN B. BREAUX, Louisiana	TRENT LOTT, Mississippi
BYRON L. DORGAN, North Dakota	KAY BAILEY HUTCHISON, Texas
RON WYDEN, Oregon	OLYMPIA J. SNOWE, Maine
MAX CLELAND, Georgia	SAM BROWNBACK, Kansas
BARBARA BOXER, California	GORDON SMITH, Oregon
JOHN EDWARDS, North Carolina	PETER G. FITZGERALD, Illinois
JEAN CARNAHAN, Missouri	JOHN ENSIGN, Nevada
BILL NELSON, Florida	GEORGE ALLEN, Virginia

KEVIN D. KAYES, *Democratic Staff Director*
MOSES BOYD, *Democratic Chief Counsel*
MARK BUSE, *Republican Staff Director*
JEANNE BUMPUS, *Republican General Counsel*

SUBCOMMITTEE ON CONSUMER AFFAIRS, FOREIGN COMMERCE AND TOURISM

BYRON L. DORGAN, North Dakota, *Chairman*

JOHN D. ROCKEFELLER IV, West Virginia	PETER G. FITZGERALD, Illinois
RON WYDEN, Oregon	CONRAD BURNS, Montana
BARBARA BOXER, California	SAM BROWNBACK, Kansas
JOHN EDWARDS, North Carolina	GORDON SMITH, Oregon
JEAN CARNAHAN, Missouri	JOHN ENSIGN, Nevada
BILL NELSON, Florida	GEORGE ALLEN, Virginia

CONTENTS

	Page
Hearing held on July 24, 2001	1
Statement of Senator Dorgan	1
Statement of Senator Fitzgerald	48
Statement of Senator Wyden	2

WITNESSES

Calfee, John E., Ph.D., Resident Scholar, American Enterprise Institute	20
Prepared statement	22
Chockley, Nancy, President, National Institute for Health Care Management Foundation	16
Prepared statement	18
Cloutier, Mark, Policy Director, RxHealth Value	49
Prepared statement	51
Dolinar, Richard, M.D., Endocrinologist, Endocrinologist Associates	59
Prepared statement	61
Glover, Gregory J., M.D., J.D., on behalf of The Pharmaceutical Research and Manufacturers of America	34
Prepared statement	36
Ostrove, Nancy, Ph.D., Deputy Director, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration	3
Prepared statement	5
Shaw, Michael S., M.D., Executive Director, EthicAd®	52
Prepared statement	54
Wolfe, Sidney M., M.D., Director, Public Citizen's Health Research Group	29
Prepared statement	32

DIRECT TO CONSUMER ADVERTISING (DTC)

TUESDAY, JULY 24, 2001

U.S. SENATE,
SUBCOMMITTEE ON CONSUMER AFFAIRS, FOREIGN COMMERCE AND TOURISM,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:33 p.m. in room SR–253, Russell Senate Office Building, Hon. Byron Dorgan, Chairman of the Subcommittee, presiding.

STATEMENT OF HON. BYRON L. DORGAN, U.S. SENATOR FROM NORTH DAKOTA

Senator DORGAN. The hearing will come to order.

My name is Senator Dorgan. I am Chairman of the Subcommittee, and I will be joined by Senator Fitzgerald and I believe Senator Wyden and some others on the Subcommittee. They are delayed with other Senate business on the floor and in other committees. So we are going to begin without them and they will join us later.

The hearing today is to discuss the issue of prescription drugs advertising directed to consumers, what is it about, what is its purpose, what does it do to the cost of prescription drugs in this country. We want to talk about that from a range of different perspectives.

It is hard to turn on the television or open a newspaper or a magazine these days without seeing an advertisement for a prescription drug. I have a few of them here. You have the opportunity with this to vote no on your favorite all-star for the all-star game, the 2001 all-star game in Seattle. You get to vote for your favorite all-star and also are able to see that you ought to be considering taking Claritin. It is an advertisement for Claritin on the all-star ballot.

This is a full-page ad from the *Washington Post* a month or so ago. It says "What is a better way to lower my blood sugar?" Then it advertises a medicine to do so, with a free 30-day supply coupon, despite the fact that, of course, you must go to a doctor and get a prescription. This actually offers a free 30-day supply coupon for this medicine.

This is a Ladies Home Journal, a rather popular magazine. I just pulled out a few of the ads in this magazine. It is full of direct advertising to consumers. "Are you someone who is forgetful? Are you repeating questions? Are you having trouble finding words?" It might apply to all of us, Senator Wyden. If so, here is a prescrip-

tion medicine you need to have. Go see your doctor, tell him what you want prescribed for you.

What about estrogen loss? Here is what you ought to do, go tell your doctor about those symptoms. Rheumatoid arthritis, here is a way to solve it: go tell your doctor.

Dan Reeves, who I saw last night on television in fact, is also here in this magazine. Dan Reeves says: "Lowering my high cholesterol became even more important than football." So this Atlanta Falcons coach says to me last night on television, and to you and to the world in this ad, that we ought to be considering Zocor and we should talk the with our doctor about Zocor.

Direct-to-consumer advertising for medicines that are prescribed by a doctor and available to those the advertising is directed toward only with the prescription of a doctor, what is its purpose, is the impact, good, bad? Does it increase the cost of prescription drugs? In the last couple of years we have had increases in the cost of prescription drugs, both because of utilization and also price inflation, of 18, 19 percent a year. Is some of that caused by direct-to-consumer advertising? Are there benefits to it? If so, what are they?

We want to talk about all of these issues today, and we have invited a number of witnesses what I think will be able to give us some information about it from a number of different perspectives.

I could go through a whole series of data that talks about increased prices for prescription drugs. I want to just make a point about this hearing. I happen to think that there are wonderful, life-saving, breath-taking new prescription drugs in this country, good for those who develop them, good for those who market them. Part of it comes from public funding and investment in public-funded research. Part of it comes from privacy research.

But life-saving drugs only save lives if you can afford them. Those who cannot afford a life-saving drug are not going to have their lives saved by that particular drug. So we want to talk about all of these issues today, focusing especially on the questions that have been raised increasingly by people: why am I the target of a substantial amount of advertising for prescription drugs that can only be achieved by me with a prescription by a doctor. Doctors increasingly tell us that they have patients coming to their office telling them what kind of medicine they want. That is a result of prescription drug direct advertising to consumers.

This is a rather recent and new approach. Only in recent years have we had direct advertising to consumers of prescription drugs. So this hearing will explore the impact of that.

Let me call on my colleague Senator Wyden from Oregon for a comment.

STATEMENT OF HON. RON WYDEN, U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you, Mr. Chairman, and thank you particularly for your leadership. You have been extremely involved in a whole host of prescription drug issues. You and I have been tackling these issues now for 20 years and it is a pleasure to be able to team up with you. This is exactly what the Consumer Affairs

Subcommittee ought to be doing, is tackling these kinds of issues, and I commend you for your effort.

I have been interested in these questions since my days as director of the Oregon Gray Panthers, and I think you are right, Mr. Chairman, there is no question that these ads have had an extraordinary impact on the Nation's senior citizens in particular. I think it is important to look now at the ramifications of what these ads mean.

Suffice it to say there are a whole host of issues that have to be addressed and a variety of competing interests that need to be balanced. I do not think that the American people want us in the United States Senate to be the arbiter of what information they get as long as that information is accurate. But at the same time, they do think that we ought to look at the health implications, for example, of massive amounts of advertising, as you have touched on. That is an area that really has not been examined.

There are First Amendment rights in this country to communicate and the government's policy has been that accurate information ought to be made available. But at the same time, one ought to take a longer view, a view that gets out beyond just looking at an individual prescription and look at the health consequences of massive amounts of advertising, and that has not been done.

The other aspect of all of this is that even without the kind of advertising that has gotten most of the attention today in the magazines and television and other sources that have been touched on well by you, by the time many older people and consumers come to their doctor's office they come today armed with an enormous amount of information from the Internet. So clearly as we look at the ways in which consumers get information, we are going to have to look at all of the various sources, and the Internet—we saw that yesterday in our e-health hearing at one of our other subcommittees—has had revolutionary impact in terms of people's access to information and its consequences, both for their pocketbook and for their health.

So I look forward to working with you and again appreciate your leadership.

Senator DORGAN. Senator Wyden, thank you very much.

Let me call our first witness. The first witness today will be Dr. Nancy Ostrove, Deputy Director of the FDA's Division of Drug Marketing, Advertising, and Communication. If Nancy Ostrove would come forward I would appreciate it. We would ask those in the audience to please turn off cell phones.

Dr. Ostrove, thank you very much. You are, I understand, going to discuss with us the rationale behind the FDA's 1997 advertising guidelines. We appreciate your being here and hope that you will address in your testimony some of the issues that we raised.

STATEMENT OF NANCY OSTROVE, PH.D., DEPUTY DIRECTOR, DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS, FOOD AND DRUG ADMINISTRATION

Dr. OSTROVE. I hope to. Good afternoon. I am Nancy Ostrove, Deputy Director of the Division of Drug Marketing, Advertising, and Communications at the FDA. We are the group that regulates prescription drug promotion. Thank you very much for inviting us

to discuss our oversight of what we call DTC, the promotion of prescription drugs directly to consumers.

FDA looks at DTC as kind of a double-edged sword. There is real potential value in getting patients to recognize the symptoms or the non-symptoms of undertreated conditions and getting them treated. Ads can help in this respect. There is also the potential for increasing the inappropriate use of medications for patients who do not need them or should be on other medications.

The available research in this area is equivocal. You can find support for just about any position you want. My written testimony touches on some of the research we have conducted or examined. What it adds up to is that FDA is not aware of any evidence that DTC promotion is increasing inappropriate prescribing. On the other hand, there is evidence that DTC promotion may be encouraging patients to obtain additional information about their conditions and products and to talk to their health care providers about health issues that they have not raised before.

There are three important things to understand about our authority. One is that the act and the regulations focus on the content, not the existence, of prescription drug promotion. Two is that the law does not make a distinction between targeted audiences. The law has never banned prescription drug advertisement to consumers. Up until the early 1980's it just was not done. Three, the act specifically prohibits us from requiring pre-clearance of advertisements except under extraordinary circumstances.

My written testimony also contains some details of the history of DTC promotion, but for today let us start in 1985 with FDA's announcement that the regulations for overseeing promotion directed toward health care professionals also provide sufficient safeguards to protect consumers. After we made this announcement, we started seeing more and more print advertisements.

But the current debate over DTC did not really heat up until we issued a draft guidance that specifically addressed broadcast. You see, the regulations had always allowed TV and radio ads. Any ad, print or broadcast, that makes a claim about a product also has to include the product's most important risk information. Broadcast ads also have to do one of two other things. They either have to give every single risk from a product's approved labeling or have a mechanism for ensuring that the audience can get the labeling.

In the late 1980's product sponsors felt they could not include every single risk in a TV ad and get the networks to air the ad—they still believe that—and FDA was not sure that it was feasible to have a mechanism that would ensure that patients could get the product information required as an alternative to presenting every single risk.

But by the mid-1990's many changes had occurred in the marketplace, and in technology, and that included increasing acceptance of the Internet, increased availability of print ads, and common use of toll-free telephone numbers to get information. Given these changes, we came to believe that sponsors could in fact ensure that consumers could get the additional product information conveniently.

So in 1997 we issued a draft that we finalized in 1999 of guidance that gave advice on how sponsors could meet the regulatory

requirement for product information disclosure for broadcast ads by giving references to multiple sources of information; not just one source but many. At the time we issued the guidance we said that we would assess the impact on the public of it and of DTC promotion in general.

We closely monitor DTC promotion and especially broadcast ads to ensure that the information that consumers need to understand any claims and the product's risks is understandably presented. Even though the sponsors do not have to submit their promotional materials until the time they appear in public, most sponsors voluntarily submit the broadcast ads to us for review and comment.

Because of this voluntary cooperation, we believe that we review most product claim broadcast ads before they appear, although we do not know in truth whether we review most reminder and help-seeking ads.

To sum up, at this time we are not aware of any evidence that DTC promotion is harming the public health. However, we continue to examine the issue. We intend to continue closely scrutinizing DTC promotion, working with industry to ensure that broadcast ads comply with regulatory requirements, and taking timely enforcement action when it is appropriate.

Thank you for your patience. I will be happy to answer any questions.

[The prepared statement of Dr. Ostrove follows:]

PREPARED STATEMENT OF NANCY M. OSTROVE, PH.D., DEPUTY DIRECTOR, DIVISION OF DRUG MARKETING, ADVERTISING AND COMMUNICATIONS, FOOD AND DRUG ADMINISTRATION

Introduction

Mr. Chairman and Members of the Subcommittee, I am Nancy Ostrove, Deputy Director of the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA or the Agency). DDMAC regulates prescription drug promotion and helps ensure that FDA-regulated industry complies with the applicable provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act and implementing regulations.

I am here today to talk about promotion that manufacturers of prescription drugs (product sponsors) direct toward consumers and patients. This is referred to as "direct-to-consumer" promotion or DTC. Such promotion uses multiple avenues for reaching lay audiences, including, but not limited to: television and radio advertisements, print advertisements, telephone advertisements, direct mail, videotapes and brochures.

It is important to understand the scope of FDA's authority in this area. It is also important to understand the different types of advertisements that are directed toward consumer audiences.

Statutory and Regulatory Authority

The FD&C Act and regulations do not distinguish between professional and consumer audiences. Section 502(n) of the FD&C Act specifies that prescription drug advertisements must contain "a true statement of . . . information in brief summary relating to side effects, contraindications, and effectiveness" of the advertised product. The implementing regulations (Title 21, *Code of Federal Regulations* [CFR] Section 202.1), originally issued in the 1960s, specify, among other things, that prescription drug advertisements cannot be false or misleading, cannot omit material facts, and must present a fair balance between effectiveness and risk information. Further, for print advertisements, the regulations specify that every risk addressed in the product's approved labeling must also be disclosed in the advertisements.

For broadcast advertisements, however, the regulations require ads to disclose the most significant risks that appear in the labeling. The regulations further require that the advertisement either contain a summary of "all necessary information re-

lated to side effects and contraindications" or provide convenient access to the product's FDA-approved labeling and the risk information it contains.

Finally, the FD&C Act specifically prohibits FDA from requiring prior approval of prescription drug advertisements, except under extraordinary circumstances. Also, the advertising provisions of the FD&C Act do not address the issue of drug product cost.

Types of Advertisements

There are three different types of ads that product sponsors use to communicate with consumers: "product-claim" advertisements, "help-seeking" advertisements, and "reminder" advertisements. Advertisements that include both a product's name and its use, or that make any claims or representations about a prescription drug, are known as "product-claim" advertisements. These ads must include a "fair balance" of risks and benefits. In addition, they must provide all risk information included in the product's FDA-approved labeling or, for broadcast advertisements, provide convenient access to this information. In our regulations, the phrase "adequate provision" is used to identify the convenient access option. Unlike the "product claim" ads, "help-seeking" advertisements and "reminder" ads need not include any risk information.

A "help-seeking" advertisement discusses a disease or condition and advises the audience to "see your doctor" for possible treatments. Because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad and FDA does not regulate it.

The second type of advertisement that does not need to include risk information is called a "reminder" advertisement. The regulations specifically exempt this type of ad from the risk disclosure requirements. Like "help-seeking" ads, the "reminder" ad is limited, although in a different way from "help-seeking" ads. "Reminder" ads are allowed to disclose the name of the product and certain specific descriptive (e.g., dosage form) or cost information, but they are not allowed to give the product's indication or dosage recommendation, or to make any claims or representations about the product. The exemption for "reminder" ads was included in FDA's regulations for promotions directed toward health care professionals, who presumably knew both the name of a product and its use. "Reminder" ads serve to remind health care professionals of a product's availability. They specifically are not allowed for products with serious warnings (called "black box" warnings) in their labeling.

Evolution of DTC Promotion

Prior to the early 1980's, prescription products were not promoted directly to consumers and patients. Instead, product sponsors often produced materials that were given to health care professionals to pass on to patients if they thought this would be appropriate for particular patients. In the early 1980's, a few companies started advertising products directly to patient audiences (specifically, older people concerned about pneumonia and people taking prescription ibuprofen to treat arthritis pain). As a result of questions and concerns about promotion directed toward non-health care professionals, in 1983 FDA requested that sponsors suspend DTC ads to give the Agency time to study the issue.

The industry complied with this request, and during the ensuing moratorium FDA conducted research and sponsored a series of public meetings. In 1984, the University of Illinois and Stanford Research Institute jointly sponsored a symposium to discuss consumer-directed prescription drug advertising from a broad research and policy perspective. On September 9, 1985, FDA withdrew the moratorium in a *Federal Register* (FR) Notice (50 FR 36677), which stated that the "current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers."

During the early 1990's, product sponsors increasingly used consumer magazines to advertise their products. These ads typically included a promotional message together with the "brief summary" of adverse effects, similar to that used in physician directed ads. The "brief summary" statement, which frequently appears in small print, is not very consumer friendly. In the 1990's, product sponsors also started using television advertisements in a limited fashion. Television advertisements were limited because FDA and industry did not believe that it was feasible to disseminate the product's approved labeling in connection with the ad. The extensive disclosure needed to fulfill this requirement essentially precluded the airing of such ads. For example, one way to satisfy this requirement would be to scroll the "brief summary," which would take a minute or more even at a barely readable scrolling rate. The industry, therefore, resorted to television ads that did not require risk disclosure.

By the mid-1990's, product sponsors started placing "reminder" ads on television. Because these ads only mentioned the name of the drug, however, they were ex-

tremely confusing to consumers, who, unlike health care professionals, were not knowledgeable about the name and the use for these products.

In response to increasing consumer demand for information, FDA began to consider whether broadcast advertisements could be constructed to ensure access to product labeling, the only alternative to including all of an advertised product's risk information. FDA considered suggestions about providing access to multiple sources of product labeling as a means of satisfying the requirement that consumers have convenient access to FDA-approved labeling when manufacturers broadcast a "product-claim" advertisement.

In August 1997, FDA issued a draft guidance entitled: "Guidance for Industry: Consumer-Directed Broadcast Advertisements" that clarified the Agency's interpretation of the existing regulations. The Guidance described an approach for ensuring that audiences exposed to prescription drug advertisements on television and radio have convenient access to the advertised product's approved labeling. The proposed mechanism consisted of reference in the broadcast advertisement to four sources of labeling information: a toll-free telephone number, a website address, a concurrently running print advertisement, and health care professionals. Following a comment period, and detailed review and consideration of the comments, FDA made only minor changes to the draft guidance, and issued it in final form in August 1999 (64 FR 43197, also found at *www.fda.gov/cder/guidance/1804fnl.htm*). In announcing the final guidance, FDA advised that the Agency intended to evaluate the impact of the guidance, and of DTC promotion in general, on the public health, within two years of finalizing the guidance.

Stakeholder Perspectives

A number of stakeholder groups have expressed strong interest in DTC promotion. Those that are positive about DTC promotion assert that this practice will:

- Improve consumers' knowledge of drugs and drug availability.
- Encourage consumers to talk with their health care providers about their health problems.
- Allow consumers and patients to have a greater role in decisions about their own health care that they say they desire.
- Improve communication between patients and their physicians.
- Improve appropriate prescribing by allowing physicians to get more information about their patients from their patients.
- Lower the cost of prescription drugs.

Not all stakeholders are positive about DTC promotion. Opponents assert that DTC advertising will:

- Confuse consumers about drugs.
- Make it appear that prescription drugs are safer than they are.
- Interfere with the patient-physician relationship because patients will insist that their physicians prescribe the advertised products.
- Increase inappropriate prescribing.
- Raise the cost of prescription drugs.

Finally, there is a group of stakeholders with a less polarized view of DTC promotion. They believe that such promotion has both benefits and risks, but that it should be strictly regulated, and that, preferably, all DTC materials should be "pre-approved" by FDA. They often assert that there are potential public health benefits associated with patients visiting health care providers about untreated diseases or conditions, particularly those that appear to be under treated in the population and that are responsible for long-term harm (for example, high cholesterol, high blood pressure, diabetes and osteoporosis).

Current Situation

FDA recognizes that drug promotion raises certain issues for health care professionals and different issues for consumers, in light of differences in medical and pharmaceutical expertise. For this reason, FDA has monitored DTC promotion, and especially broadcast promotion, very closely to help ensure that adequate contextual and risk information, presented in understandable language, is included to fulfill the requirement for fair balance and to help the consumer accurately assess promotional claims and presentations.

Product sponsors of prescription advertisements are required to submit their promotional materials to FDA around the time these materials are initially put into public use. FDA receives approximately 32,000 of these submissions per year, for

all types of promotion, including promotion to health care professionals. Product sponsors also can submit draft materials to FDA for review and comment prior to using them. DDMAC has made it a high priority to provide comments to product sponsors on voluntarily submitted draft broadcast advertisements within a reasonable time. In fact, although it is not required, a majority of product sponsors voluntarily submit their broadcast advertisements to DDMAC for prior review and comment at some point as advertising materials are being produced. Product sponsors may ask for review and comment at the very initial stages of production (by supplying the words they intend to use along with rough drawings of their proposed graphics), or at the later stages of final videotape production. DDMAC only gives final comments on final videotapes because inappropriate presentations can turn an otherwise acceptable advertisement into an unacceptable one (for example, by pacing the risk disclosure too rapidly, including multiple distracting visual images during the risk disclosure, or including images that overstate the efficacy of the product beyond what is supported by substantial clinical evidence).

Since January 1997, sponsors of about 65 prescription drugs have aired "product-claim" advertisements on television or radio. A small number of prescription biological products also have been advertised. Nine products fall into the allergy category (nasal and ocular anti-histamines, and nasally administered corticosteroids), while another eight products treat skin or hair-related problems (acne, cold sores, rosacea, baldness, unwanted facial hair, nail fungus). More importantly, ten products are designed to treat diseases that are believed to be under treated, including high cholesterol and heart disease, and mental health problems like depression. Five products to treat or prevent osteoporosis or menopausal symptoms have been advertised. Other advertised products are approved to treat such conditions or diseases as asthma, Alzheimer's Disease, arthritis, chronic obstructive pulmonary disease, diabetes, insomnia, migraine, obesity, overactive bladder, serious heartburn, smoking cessation, and sexually transmitted diseases. Most of these are serious problems where patients are in the best position to recognize symptoms.

It is important to note that DDMAC does not know how many different advertisements have aired in broadcast media for these 65 drugs. There have been multiple campaigns for a number of the products, including the allergy and high cholesterol products. In addition, many campaigns include different length "product-claim" commercials, as well as multiple short "reminder" commercials. DDMAC does not track the number of different broadcast advertisements that are submitted. Further, because "help-seeking" advertisements, if done properly, are not considered to be drug ads, most product sponsors do not send them to DDMAC under the submission requirements for prescription drug promotional materials. Therefore, we have no measure of how many of these have been in the public domain.

Enforcement Related to DTC Promotion

Since 1997 FDA has issued:

- 30 "untitled" (or "Notice of Violation") letters on "product-claim" broadcast advertisements. Such letters request that the violative promotion be stopped immediately. Product sponsors virtually always comply immediately with this request.
- 3 "warning letters" on broadcast advertisements. This is a higher-level enforcement action, and requests that a remedial campaign be conducted by the company to correct the impressions left by the ad.
- 12 "untitled" letters on purported "reminder" broadcast advertisements.
- 3 "untitled" letters on purported "help-seeking" broadcast advertisements.

Most of the violations cited were because the ad overstated or guaranteed the product's efficacy, expanded the indication or the patient population approved for treatment, or minimized the risks of the product, through either inadequate presentation or omission of information.

Since January 1997, the Agency has issued:

- 44 "untitled" letters that addressed DTC print advertisements or other promotional materials, including purported "reminder" and "help-seeking" materials.
- 1 "warning letter" for a specific DTC print advertisement, and 1 "warning letter" that included a DTC print advertisement as part of an overall misleading campaign.

Generally, the violations involving print ads making "product-claim" ads were similar to those cited above. Nearly all "reminder" ad violations were the result of representations about the product that triggered the need for full disclosure of bene-

fits and risks. "Help-seeking" ad violations were due to a particular product being implied in the message. As noted above, however, FDA cannot determine how many specific advertisements serve as the denominator for assessing how many have resulted in enforcement action compared with those that have not.

Research on DTC Promotion

A number of groups have been conducting research on DTC promotion. Much publicly available research consists of surveys utilizing samples of consumers or patients to examine attitudes about DTC promotion and self-reported behaviors related to DTC promotion in the context of patient-physician visits and use of prescription drugs. The groups sponsoring this research include: Prevention magazine, TIME Inc., the National Consumers League, and American Association of Retired Persons. Partial results of a few surveys of physicians have been made publicly available. FDA remains concerned, however, about the representativeness of the physician survey sample.

In 1999, FDA sponsored a telephone survey that focused on a national probability sample of patients who had seen a physician for a problem of their own within the three months prior to the survey. The results of this patient survey suggested that patients are seeking additional information as a result of DTC promotions that they have seen. This information was sought primarily from health care professionals, and secondarily from reference texts and family. Generally, between 10 and 20 percent of respondents said that they sought additional information from the sources referenced in broadcast advertisements—toll-free telephone numbers, websites, and print advertisements. A major result, and one that is consistent with results of Prevention's national surveys, is that a significant minority of respondents said that a DTC ad has caused them to ask a doctor about a medical condition or illness they had not previously discussed. This could represent a significant and positive public health benefit, particularly if these patients are talking about undiagnosed heart disease or other serious disorders.

The survey results also suggest that DTC advertisements are not significantly increasing visits to a physician's office. For the most part, patients said that they had recently visited their doctors for the traditional reasons: because it was time for a check-up (53 percent), because they were feeling ill (42 percent), or because they had a sudden symptom or illness (41 percent). Only two percent said that they had visited their doctor because of something they had seen or heard. Of those patients who had a conversation with their doctor about a prescription drug: 81 percent said that their doctor had welcomed the question, 79 percent said that their doctor discussed the drug with them, and 71 percent said that their doctor had reacted as though the conversation was an ordinary part of the visit. Only four percent said that their doctor seemed upset or angry when the patient asked about a prescription drug. According to the patients, therefore, physicians seem to be reacting well to questions about prescription drugs. Finally, only 50 percent of these patients said that their doctor gave them the medication discussed. Thirty-two percent said that the doctor recommended a different drug. Twenty-nine percent of the respondents indicated that behavioral or lifestyle changes were suggested by the doctor. It therefore appears, from FDA's patient survey, that physicians are comfortable denying prescriptions when the prescription would not be right for the patient.

A small number of patients who were denied prescriptions said that their doctors told them why. Reasons included: the drug was not right for the patient; the doctor wanted the patient to take a different drug; the drug had side effects of which the patient was unaware; the patient did not have the condition treated by the drug; the patient did not need a prescription drug; the patient could use a non-prescription drug; and there was a less expensive drug available.

Patients also were asked about their attitudes concerning prescription drug advertisements. Their answers indicated somewhat mixed feelings. Eighty-six percent agreed that these ads help make them aware of new drugs, 70 percent agreed that the ads give enough information to help the patient decide if they should discuss the product with a doctor, and 62 percent agreed that ads help the patients have better discussions with their doctors about their health. Only 24 percent agreed that DTC ads make it seem like a doctor is not needed to decide whether a drug is right for someone. In contrast, 58 percent agreed that DTC ads make drugs seem better than they really are, 59 percent agreed that ads do not give enough information about the advertised product's risks and negative effects, and 49 percent agreed that these ads do not give enough information about the benefits and positive effects of the advertised product.

Next Steps

In issuing both the draft and the final broadcast advertisement guidance, FDA stated its intent to assess the impact of the guidance, and of DTC promotion in general, on the public health. FDA is also aware that privately funded research is being planned to examine the effects of DTC promotion. At present, FDA is not aware of any evidence that the risks of DTC promotion outweigh its benefits. FDA intends to carefully examine all available data, to determine whether the public health is adequately protected.

This concludes my prepared remarks. I will be glad to answer any questions you may have on this topic.

Senator DORGAN. Dr. Ostrove, thank you very much.

You indicated near the start of your testimony that the FDA is not aware of any information that would suggest inappropriate prescribing as a result of direct-to-consumer advertising. The fact that you are not aware of information, does that suggest no information exists or no studies have been done, or is it just that you are not aware of them?

Dr. OSTROVE. Well, it does not suggest that no information exists. Certainly there might be some. We have tried to make it clear to the public and we have asked in many circumstances and in many venues for any information that would be useful to our assessment of the impact of DTC promotion. People have come forward. There have been studies that have been done looking at patients. There have been some studies of physicians. The representativeness of the samples is a little questionable. We recently participated in a design conference that HHS sponsored to try to encourage research into this area.

So it is not that it necessarily is not out there, but it certainly has not been brought to our awareness.

Senator DORGAN. One of the next witnesses, Nancy Chockley, President of the National Institute for Health Care Management Research and Educational Foundation, says in her testimony: "In an analysis we will be releasing soon, we have found that the 50 drugs most heavily advertised to consumers in 2000 had aggregate sales increases last year of 32 percent compared to 14 percent for all other drugs."

Can you give me an analysis of that? That follows a comment she makes in her testimony: "Direct-to-consumer advertising appears to be inducing significant new demand for prescription drugs and thus contributing to the recent sharp rise in pharmaceutical spending." Do you agree or disagree with that conclusion?

Dr. OSTROVE. I think it is extremely difficult to tease out the impact of direct-to-consumer advertising, given the other factors that are involved. In addition to DTC advertising, the manufacturers are out there advertising to health care professionals, and in many cases when they have a DTC campaign, and if they are smart, the first thing that they do is they let the health care professional know about that campaign, because they do not want the prescriber to be blind-sided.

So at the same time you are having a campaign to consumers, which by the way is also seen by health care professionals, there is also a separate campaign that is going to the health care professionals. In addition to that, of course the manufacturers put their money where they think the market is. So they are going to spend more where they think that there is a market for something.

So this is one of the issues that was raised in the design conference, how do you tease out the impact of DTC without doing a controlled study, which we are not aware that anyone has done and would be a fairly significant undertaking.

The other piece of that is that even if there is an influence of DTC on utilization, our concern is, our question is, is that appropriate? Are people going in and appropriately talking to their doctors about conditions that are important for them and that in fact they have, and are they getting the appropriate treatment, or is it increasing inappropriate treatment? That is what we have no data on. I do not think that the data that are going to be a part of this report are likely to address that.

Senator DORGAN. That is an important question, I think, and if we have no data on it should we aspire to get data and, if so, how? Does the FDA propose that we aspire to get such data?

Dr. OSTROVE. Well, the FDA has in fact requested a number of times to the industry and to other interested stakeholders that research be done to look at this. The agency itself, of course, has—the agency itself is doing what research it feels it can do. We recently in 1999, we did a survey of patients, people who had seen their doctors in the last 3 months, and we are hoping to do another one. We are also hoping to do a survey of physicians and looking at their experiences with DTC and how it has influenced their practices.

So we are doing what we can in this area, and we have encouraged the private sector to do the same. We have not seen anything as yet. We are aware that at least some manufacturers are interested in doing this, but we really do not know where that is.

Senator DORGAN. But I am wondering whether it should be the manufacturers that would do such a study. They obviously have an interest in the outcome of the study. Should there not be some independent party doing a study? Should the FDA be recommending some mechanism in government to have a study completed?

Dr. OSTROVE. Well, certainly HHS is interested in this whole area, in the cost issues as well as in FDA concerns, which is the public health issues and the protection of the public health. It is difficult for me to answer whether this should be done. Certainly I think on a theoretical basis, yes, it should be done. Then it is a matter of who is going to do it, how is it going to get done.

As I said, one of the reasons for kind of hoping that the manufacturers would do it is the relative—the resources that they have.

Senator DORGAN. But you would agree that manufacturers have a vested interest in the outcome?

Dr. OSTROVE. Yes.

Senator DORGAN. It seems to me not logical that you would have someone do a study who has an interest in the outcome of the study.

Dr. OSTROVE. It would be best for an uninterested party, a party that does not have a vested interest, to do this.

Senator DORGAN. Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman.

Let me start, if I could, Dr. Ostrove. Chris Castle, who I met when I was teaching gerontology in Oregon, recently said—she is

now chairman of geriatrics at Mount Sinai in New York. She said recently: "Direct to consumer advertising has made a huge impact on sales of medications which are not always the best medications for people to take."

Would you by and large agree with that statement of Dr. Castle's?

Dr. OSTROVE. That is a very general statement, a huge impact on medications that are not always the best. I am not sure exactly what data she is basing that statement on, so it would be difficult.

Senator WYDEN. In your opinion, are there any ramifications for the use of generic drugs in this whole focus on direct-to-consumer advertising? As we know, in many instances, not always but in many instances, the generic drug is cheaper. It sure looks like the bulk of the advertising direct-to-consumer is of the more expensive brand names. I would be interested in your knowing whether you think there are any ramifications in this trend for the use of generics?

Dr. OSTROVE. I think certainly there are potential ramifications for the use of generics. The innovator manufacturers clearly have greater resources, monetary resources to advertise their products than the generic manufacturers do.

What is kind of interesting is, at least from some of the data that we have from our study, is that when patients went in to see a doctor and talked to the doctor about a particular prescription product, in only 50 percent of the cases did they actually get the product that they had discussed. In a number of cases what ended up happening is that they got another product.

My suspicion is that—and we do not have the actual details of this, but in many of those cases it may have been case where the gatekeeper prescriber said: You know, I am glad you came in to talk to me about this condition; you do have this condition, but you do not need that drug, it is more expensive, or it is not what you need; here is one that has been out on the market a long time, it has got a better safety profile; why do you not take it.

So certainly in some cases that is what I believe happened. We also know that in that certain percentage of the cases the doctor told the patient that what they needed was behavioral and lifestyle changes.

So the gatekeeper—the physician or the prescriber, excuse me, is acting as a gatekeeper in these particular situations. So it is hard again to kind of tease out how much of that is going to be influencing the use of generics. Hopefully, physicians will be using this, prescribers will be using this opportunity as kind of a learning opportunity, a point to communicate with the patient.

Senator WYDEN. This is an area I am going to follow up with you and others in government, because I think Senator Dorgan is absolutely right. What we hear about from our constituents, older people and others, is the affordability question. I am very concerned about the ramifications of direct-to-consumer advertising for access to generics. If you just look at the ads that Senator Dorgan held up, these are blockbuster brand name drugs, they are exciting products. You do not seem to see the same kind of focus on marketing this way on generics. I think we need to do follow-up work in this area.

Dr. OSTROVE. If I can add one more thing, we have also looked at the products that are being advertised most heavily to consumers and in many cases for those products they are breakthroughs and there are no generics. I am not saying that is true in all the cases, but in many of the cases there are not generics available.

Senator WYDEN. It is a fair comment, and one of the things I think we ought to look at is the evolution of how this drug comes into market and what happens when it goes off to a patent.

Dr. OSTROVE. Absolutely.

Senator WYDEN. Let me ask you just a couple of other questions. I appreciate Senator Dorgan's indulgence. A number of physician groups across the country have been urging resolutions through their state societies to in effect block this whole trend. What their argument largely appears to be is that they feel the this trend in advertising is interfering with the doctor-patient relationship, that the pharmaceutical industry in some way is intruding into the doctor-patient relationship.

Do you think there is any validity to that argument?

Dr. OSTROVE. We have heard a lot of anecdotal reports from physicians that they feel that DTC advertising is interfering with the doctor-patient relationship. We have also heard anecdotal reports from other physicians that it is improving the relationship they have with their patients, because the patients are coming in, they are more informed, they are more willing to take their medication, in other words their adherence is better.

Our data—in our survey we asked patients how their doctor reacted to the discussion of the prescription drug when they had these discussions. The majority of them, in the high 70's, low 80's, said that the doctor was very good about it. Very few of them, only 4 percent I think of the patients, said that the doctor seemed to be disturbed by their interaction.

So it would appear that the physicians are doing a pretty good job on the whole of dealing with patients. The patients do not perceive any problems. But this is an area that we feel needs more research and it is one of the reasons why we would like to do a survey of a representative sample of physicians, to get it from their perspective.

Senator WYDEN. That would be helpful as well.

The last question I wanted to ask: Do you see any relationship between direct-to-consumer advertising and this trend toward coupons and guarantee programs? The concern is I think you all have had discussed with you is that they use these coupon programs and these discount programs to sort of bring people in, but they bring them in on the most expensive drugs again, and that this has been tied in some way to the direct-to-consumer advertising trend.

What, if anything, has the agency picked up on that?

Dr. OSTROVE. Well, it is a marketing technique.

Senator WYDEN. Are you troubled by this? Are you concerned about what I have described?

Dr. OSTROVE. We have looked at the whole area and we are troubled by some—more troubled by some things than others.

Senator WYDEN. Tell me what part of this troubles you, then?

Dr. OSTROVE. Anything that gets into the cost issue, where apparently a product is being touted for its cost benefits as opposed to its clinical benefits, is troubling. But in terms of our authority, these coupons, these offers, unless they are false or misleading, lacking in fair balance in some way, or involving an omission of material fact, there is not a good argument for us to object to them on the basis of the regulations.

Senator WYDEN. I understand that. My time is up, but I think it goes again to the point that I was making, that if they are accurate so be it, but I am troubled by the fact that you give people, you give senior citizens discounts on something, so in effect you get them tied, you get them bonded to a certain kind of pharmaceutical at a very expensive price. Then the coupon program is over and they have developed an affinity for that product and it is sort of cemented by direct-to-consumer advertising.

I just want us to start looking at what is really going on in the marketplace, and that is why I think what Senator Dorgan is doing is important and I appreciate it.

Senator DORGAN. Thank you, Senator Wyden.

Dr. OSTROVE. One other piece with regard to that. I hope I am not interrupting.

Senator DORGAN. That is fine.

Dr. OSTROVE. But there is a value or at least there appears to be some data that indicate that direct-to-consumer advertising actually makes it more likely that people will take their medications, will continue on their regimen, will fill their prescriptions. Given that noncompliance is such a big problem in taking medications, there is that other side of it, that if people in fact do become committed to their medications perhaps they will use them more appropriately and not stop taking them, or at least go to their doctors if they do.

Senator DORGAN. Will you submit that information for the record that you just cited? Is there a source for that?

Dr. OSTROVE. A survey that Prevention magazine has done. I believe that they asked those kinds of questions about compliance in their 1998 and 1999 surveys.

Senator DORGAN. Dr. Ostrove, how large is the Division of Drug Marketing, Advertising, and Communication?

Dr. OSTROVE. We have 32.

Senator DORGAN. You seem to, based on the questions I have asked and Senator Wyden has asked, seem to come down on the side of suggesting this is really a good thing. You have used a little cautionary language, but by and large as I interpret what you are saying, on balance you think direct-to-consumer advertising is probably fine, probably helps. Is that a good way to summarize what you just told us?

Dr. OSTROVE. Well, I am not sure—it is the double-edged sword metaphor. I guess we believe that there are good aspects to it, but we believe that there are potentially not so good aspects to it as well. So we are hoping for a balance.

Senator DORGAN. When I started today I held up this, which is a Washington Post full page ad, "What is the better way to lower my blood sugar," and then it provides a medicine, name of a medicine, and a free 30-day supply coupon. If you read this in all the

smaller type, you understand that you have got to get a prescription from a doctor.

But someone who is not a careful reader would just see, I have got a high blood sugar level, I get a free 30-day supply. Is this the sort of thing you look at in terms of advertising? You have how many people looking at that at your agency?

Dr. OSTROVE. We have 14 reviewers who do primary reviews and one of them is devoted full-time to direct-to-consumer advertising. Yes, we look at the overall presentation.

Senator DORGAN. 14. The consumer advertising has increased very substantially, as you know, in recent years, the rampup since 1997. Have the resources that you employ to respond to these increased at all?

Dr. OSTROVE. Well, the person who is devoted to direct-to-consumer is a relatively new—yes, we have kind of moved resources around. We prioritize our workload as a function of what we think is important out in the marketplace, so we respond to changes in the marketplace.

Senator DORGAN. When you said a person, there is more than just one person?

Dr. OSTROVE. Oh, absolutely. All the primary reviewers—the primary reviewers work on different classes of drugs, and depending on the class they will work more or less on DTC advertisement. Some classes have very little DTC, other classes have a lot.

Senator DORGAN. My understanding is in 1998 the FDA issued 158 warnings and untitled letters regarding promotional materials, drug promotional materials, both for direct-to-consumer ads and detailing. In 1999 it went from 158 down to 107, in 2000 it went down to 79. What is this decrease attributed to? Is there less enforcement or is there better compliance?

Dr. OSTROVE. I think there are probably a lot of factors that go into that. We are in the process of looking at how best to structure things so that we can use our resources most effectively. I am not really sure how to attribute that decrease. We have had some turnover. That may be part of it. We are spending a lot of time on kind of advisory activities, and the hope of that is to get the information, to get the promotional materials, before they reach the public. So again on a voluntary basis, manufacturers can submit their promotional materials and we give advice and comment.

So some of the change may be due to that. Some of it may be due to more people working on educational——

Senator DORGAN. Would you submit for the record an analysis of that after you have had a chance to visit with your agency?

Dr. OSTROVE. Happy to do that.

Senator DORGAN. Again, one would expect as direct-to-consumer advertising dramatically increases, and it really has—I think all of us understand that—one would expect FDA warnings not to drop by 50 percent, but would expect them to probably keep pace with the increase in promotional advertising, because there is a lot of money at stake. This is a large industry with a very substantial bankroll that is advertising very, very aggressively.

What I see is a decrease by 50 percent of the warnings and untitled letters that you are sending out. Somehow that seems to sug-

gest to me a less aggressive enforcement attitude with respect to this.

Dr. OSTROVE. Well, actually let me clarify that, please. You were talking about all of the untitled and warning letters, and that deals with—actually, most of those are toward professionally directed materials. I do not have the numbers with me, but I can get the numbers back to you that would demonstrate that in fact our enforcement of direct-to-consumer promotion has not decreased in the last 5 years.

Senator DORGAN. We will just ask you to submit that for the record.

Dr. OSTROVE. I will definitely do that.*

Senator DORGAN. Dr. Ostrove, thank you very much for being with us. We appreciate your testimony.

We would like to ask the next panel to come forward: Dr. Stephen Findley, Director of Research and Policy, the National Institute for Health Care Management; Dr. Sidney Wolfe, Director, Public Citizen, Health Research Group; Dr. Gregory Glover, attorney-physician, representing the Pharmaceutical Research and Manufacturers of America, PhRMA; Dr. John Calfee, a Resident Scholar at the American Enterprise Institute.

We welcome all four of you. We have asked that you submit your statements for the record and ask that you summarize your statements in 5 minutes. Let me begin—we have Nancy Chockley here in place of Stephen Findley. Let me begin with Ms. Chockley, President of the National Institute for Health Care Management. Would you proceed.

STATEMENT OF NANCY CHOCKLEY, PRESIDENT, NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT FOUNDATION

Ms. CHOCKLEY. Yes. Good afternoon, Mr. Chairman and Senator. Thank you very much for this opportunity to testify. I am Nancy Chockley, President of the National Institute for Health Care Management Foundation. We are a research and policy group based here in Washington. We get our funding from health plans, from the government, and from private foundations. We have been doing a lot of work looking at the pharmaceutical industry and what is driving expenditure growth. I would like to make just a couple of points, four points really, here today on what we have been finding.

One is that, as you already stated, direct-to-consumer advertising appears to be inducing new demand for prescription drugs and thus contributing to the recent sharp rise in pharmaceutical spending. Specifically, the data show that the drugs driving the growth in utilization and sales are also the drugs that are most heavily advertised. Simply put, we have found what Madison Avenue has known all along: advertising works.

In an analysis, as you mentioned before, that we will be releasing probably in the next month, we found that the 50 drugs most heavily advertised to consumers in 2000 had an aggregate sales increase last year of 32 percent compared to about 14 percent for all other drugs, which by the way number over 9,800 drugs. So we are looking at 50 versus about 9,800 drugs.

---

*The information referred to was not available at the time this hearing went to press.

A large portion of the increase in sales for the 50 most heavily advertised drugs comes from a sharp increase in the number of prescriptions filled for them. As the chart over here illustrates, the combined number of prescriptions for these 50 drugs was up almost 25 percent last year. You compare that to the other 9,800 drugs, they were up less than 2 percent. So it does appear that it is having an impact.

I would like to note, though, that these numbers are preliminary and we are still working on them. But let me give you a specific example with Vioxx. We found that the growth in sales for the new arthritis drug Vioxx contributed more than any other single drug to the 19 percent increase in retail prescription drug spending in 2000. Sales of Vioxx shot up from $330 million in 1999 to $1.5 billion. So that is an over a billion dollar increase in sales in just 1 year.

Perhaps not surprisingly, Vioxx was the most heavily advertised prescription drug in the Nation in 2000. Its maker, Merck, spent over $160 million promoting the drug to consumers.

With the success of direct-to-consumer advertising and the new avenues open to reaching the consumers, we would predict that the pharmaceutical industry will be spending more to reach out and market directly to consumers. This expansion will follow the trend that you have alluded to. Over the last 3 years 1998 to 2000, spending on direct-to-consumer advertising has almost doubled.

It is important to note, though, that the $2.5 billion spent on direct-to-consumer advertising really is only a small part of what the industry spends in total in promoting their drugs. They spend about $15.7 billion in total, $2.5 billion on DTC ads.

As was referred to earlier by Nancy, we do not know how direct-to-consumer ads are affecting the physician-patient relationship or how they are changing health outcomes for patients. We need more studies on this and some of the work they are doing—there was a meeting with the Department of Health and Human Services on this. But we really need more information. Prevention magazine is really kind of out there in front and that is a little scary when you are talking about such a big industry.

But they have found some interesting things, including that when a consumer comes in and asks for a specific drug 70 percent of the time they walk out with that drug. So it clearly is having an impact.

While some contend that direct-to-consumer ads are a valuable source of information for consumers, we must recognize that the information in such ads is not packaged for the benefit of the public's health, it is really meant to sell a specific drug. In this unique consumer market, direct-to-consumer ads prompt consumer behavior without providing substantive and complete information about the advertised product, treatment alternatives, or the disease.

In conclusion, I would like to say that for consumers to make really informed decisions they need better, more balanced information on prescription drugs and we should facilitate that in two ways. One is I think we should raise the standards for direct-to-consumer ads and what is in them. I guess we will be hearing from some other groups on that point.

But also, I think that we need to organize the different stakeholders in this industry with government leadership to try to provide an independent source of information. What we are spending on prescription drugs is going up, as you said, 19 percent a year. You are debating about adding Medicare prescription drug benefit. It really behooves us all to come up with an independent source of information so we can actually make some good comparisons between treatment options.

[The prepared statement of Ms. Chockley follows:]

PREPARED STATEMENT OF NANCY CHOCKLEY, PRESIDENT, NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT FOUNDATION

Good afternoon, Mr. Chairman and Members of the Subcommittee. Thank you for the opportunity to testify today on this important issue.

I am Nancy Chockley, president of the National Institute for Health Care Management Foundation. The NIHCM Foundation is a non-partisan, non-profit group. We conduct research on health care policy issues and manage health projects with funding from health plans, the government and private foundations. One of our research priorities has been and continues to be analysis of the pharmaceutical marketplace. Two of our recent studies are included in the supporting materials, and the others are available on our web site.

I will focus my remarks today on four key points:

1. Direct-to-consumer advertising appears to be inducing significant new demand for prescription drugs, and thus contributing to the recent sharp rise in pharmaceutical spending. Specifically, our data show that the drugs driving the growth in utilization and sales are also the drugs that are being most heavily advertised to the public. Simply put: DTC advertising works.

In an analysis we will be releasing soon, we have found that the 50 drugs most heavily advertised to consumers in 2000 had an aggregate sales increase last year of 32%, compared to 14% for all other drugs (which number about 9,850).

As the chart behind me illustrates, most of the increase in sales for the 50 most heavily advertised drugs came from a sharp increase in the number of prescriptions filled for them. Combined, the number of prescriptions for these 50 drugs was up almost 25% from 1999 to 2000. In contrast, the number of prescriptions for all other prescription drugs increased less than 2%. I would like to note these numbers are preliminary.

To give you an example, we found that growth in the sales of the new arthritis drug Vioxx contributed more than any other single drug to the 19% increase in retail prescription drug spending in 2000. Sales of Vioxx shot up from $330 million in 1999 to $1.5 billion in 2000. Perhaps not suprisingly, Vioxx was the most heavily advertised prescription drug in the nation in 2000. Its maker, Merck, spent $160.8 million promoting the drug to consumers.

2. The success of DTC advertising, combined with computer technology which is opening up new ways to reach consumers directly, lead us to predict that drug companies will continue to expand their efforts to market their products directly to consumers. This expansion will follow the trend seen over the last three years: from 1998 to 2000, spending on direct-to-consumer advertising has almost doubled. In 2000, the pharmaceutical industry spent $2.5 billion on DTC ads. It is important to note this accounts for only a portion of the $15.7 billion total expenditure on promotional spending for prescription drugs.

3. We don't know how DTC ads are affecting the physician-patient relationship or how they are changing health outcomes for patients. We need more studies to better understand the role marketing is playing. The Department of Health and Human Services held an important conference on this issue in May, and the FDA is also currently studying this question. We strongly encourage more federal funding of research that helps explain the impact of marketing on health and health care.

4. While some contend that DTC ads are a valuable source of information for consumers, we must recognize that the information in such ads is not packaged for the benefit of the public's health. It is meant to sell prescription drugs. In this unique consumer market, DTC ads prompt consumer behavior without pro-

viding substantive and complete information about the advertised product, treatment alternatives, or the disease.

For consumer decisions to be truly informed, consumers must be provided with better, more balanced information on their prescription drugs. We should facilitate this by: one, raising the standards for the content of DTC ads; and two, organizing collaboration among key stakeholders in the health care industry and the government to develop objective sources of information that compare treatment options. Currently, consumers and physicians rely on the pharmaceutical companies as their primary source of information on pharmaceutical products. With prescription drug expenditures increasing by almost 19% a year and Congress looking at adding a prescription drug benefit for Medicare beneficiaries, the timing is right to address the scarcity of unbiased pharmaceutical information that exists. It is essential for physicians and consumers to have access to a source of information which may help them to discern and compare the benefits and costs of pharmaceutical products. The government could play a key role in facilitating such a vital information source.

Elaborating on the preceding points

In September 2000, we released our first research brief on DTC prescription drug ads. In May 2001, we released a study on pharmaceutical spending in the retail marketplace in the year 2000. Although we will not be releasing our next study of DTC ads until September, we have included in this testimony data on ad spending in 2000 which will be published in that study.

Pharmaceutical companies spent $2.5 billion on all forms of DTC prescription drug ads in 2000; 85% of that total was spent on the 50 most heavily promoted drugs.

Like the Vioxx example given earlier, we found that growth in the sales of the heavily-promoted antiulcer drug Prilosec was responsible for a substantial portion of the rise in overall pharmaceutical spending in 2000. Retail sales of the drug rose from $3.6 billion in 1999 to $4.1 billion in 2000. It's now the best selling drug in the country. Prilosec's maker, AstraZeneca, spent $107.7 million promoting the drug to consumers in 2000. It was the second most heavily promoted drug.

It is important to note that DTC ads are only one factor among many factors that drive the sales growth of a product. While it is feasible that DTC ads are playing a comparatively small role relative to these other factors, our data and recent surveys indicate otherwise.

Recent studies by the FDA and *Prevention* magazine have found, for example, that consumers are quite receptive to the ads. They are not only aware of them; they appear to be acting on them. In a recent survey by *Prevention* magazine, conducted in June 2000, 32% of respondents who had seen or heard a drug ad—and 90% had—talked to their doctor about an advertised medicine or the disease it targets. Of this group, one in four asked their doctors for a specific medicine they had seen advertised. And 70% of those who made such a request walked out of the office with a prescription for that specific drug.

Let me translate those percentages into numbers of people. If 150 million adults saw the ads, 48 million will have talked to their doctor as a result, 12 million will have asked for a specific drug, and 8.4 million will have gotten it that same day.

This brings me to another central point I want to make today: we don't yet know whether DTC advertising is, on balance, beneficial or detrimental.

Are the ads leading to the inappropriate use of some drugs? Are they compromising the safe use of some drugs, leading consumers to believe the drugs are safer or more efficacious than they may actually be? Are they inducing demand for drugs that would not otherwise be first-line treatments?

I am sure we will all agree today that we will soon need to know the answers to these questions. Opinions about the effects of DTC ads will not suffice in the long run. We strongly support research that probes these issues.

Research is needed to better understand the positive role that DTC ads could be playing. If studies find that DTC ads are inducing millions of Americans to go to the doctor for *needed* visits and that they are then getting *appropriate* care they would not otherwise get, then DTC advertising may be a powerful new tool to help create a healthier population. If, on the other hand, studies find that prescription drug mass media ads are inducing millions of *inappropriate* prescriptions, then we may have to conclude we have a problem.

Until studies can determine the impact of DTC advertising, we will have to weigh carefully what we already know about the benefits against the social and health costs of DTC ads.

Furthermore, we must recognize that DTC drug ads are not primarily designed—and probably never could be—as public health tools. They are designed to successfully market specific products. Quite simply, consumers need other sources of infor-

mation on prescription drugs to make truly informed choices. We would recommend that the Department of Health and Human Services initiate a process to examine how that might come about. All health care stakeholders should be involved.

My final point today is one that often gets overlooked in this debate. Spending on DTC ads is growing at a time when pharmaceutical companies appear to be increasingly reliant upon the earnings of their blockbuster drugs. The power of DTC ads could be an incentive for drug companies to invest resources in extending the exclusivity of their blockbuster drugs, instead of investing in the development of innovative new products. To the extent that DTC ads give companies further inducement to protect their aging blockbusters, DTC ads may ill serve public health.

The health of the population is best served by an industry that is putting the maximum amount of money into developing truly innovative new drugs for the most serious life-threatening and debilitating diseases. The public's health will not be advanced as much if drug companies focus disproportionately on inducing potentially inappropriate consumer demand for repackaged or slightly improved drugs to treat a range of non-threatening conditions.

Prescription drugs help millions of Americans live normal, productive lives, yet they are unique consumer products. They have the potential for serious harm as well as great benefit. They are part of a complex system of medical care that must be ruled first and foremost by science and careful human judgement. Congress has long recognized the complexity and uniqueness of the pharmaceutical marketplace in their regulation of this industry. The growth of DTC advertising poses new questions about how consumers perceive prescription drugs and use them. DTC ads—just as the products they promote—appear to have the potential for benefit but also for harm.

Thank you.

Senator DORGAN. Ms. Chockley, thank you very much.

Mr. Calfee, I understand that you are to catch a plane to leave the country.

Mr. CALFEE. That is right.

Senator DORGAN. So we will call on you so that you can testify and leave the country, and I hope it is not a reflection on your testimony here.

[Laughter.]

Senator DORGAN. But why do you not, so that we can accommodate your time issue, why do we not let you proceed, Mr. Calfee.

STATEMENT OF JOHN E. CALFEE, PH.D., RESIDENT SCHOLAR, AMERICAN ENTERPRISE INSTITUTE

Mr. CALFEE. I appreciate it. I want the record to reflect that I planned to leave the country, I made plans to leave the country before I made plans to testify.

I have submitted written testimony and I have some briefer remarks to read into the record right now. Mr. Chairman, I would like to thank you for inviting me to testify today on the effects of direct-to-consumer advertising of prescription drugs.

Economic research has shown that advertising makes markets work better. For example, advertising increases the incentives for manufacturers to create new or improved products. Especially important is the ability of advertising to provide information. Society has yet to discover another mechanism that is the equal of advertising in its power to provide crucial information in a concise, usable, and memorable format, and to provide that information to those who need it most.

The question today is whether the prescription drug market provides yet another example of the benefits of advertising or, on the contrary, is an exception to the rule. There are good reasons, I believe, to expect direct-to-consumer advertising of prescription drugs

to be a valuable tool for consumers and patients. The medical literature documents that millions of consumers remain undiagnosed or untreated for serious medical conditions for which useful drug therapies exist. A prime reason appears to be that consumers are not aware of therapies that could help them, especially therapies that are relatively new or are improvements over older treatments.

Examples of such undertreated conditions include depression, diabetes, obesity, high blood pressure, and elevated cholesterol. In most cases, it is consumers themselves who must take the initiative to see their physician and discuss their symptoms and possible treatments.

A striking example of this situation was provided this past May in a Federal report on the treatment of elevated cholesterol. That report came from the National Cholesterol Education Program at the National Institutes of Health. It said that millions of middle aged and elderly people could reduce their risk of a heart attack by one-third or more if they begin taking one of the powerful statin-class drugs for reducing serum cholesterol.

But again, consumers must take the initiative in order to realize these benefits. What is needed is to get essential information about cholesterol and heart disease to the consumers who need it. Now that the flurry of publicity about the NIH report has passed, it is up to advertising to do the real work of alerting consumers.

I believe it is fair to say that direct-to-consumer advertising is likely to provide consumers with essential information about cholesterol and heart disease faster and better than any information program mounted by governments, public health organizations, or health care providers.

The proposition that advertising can help consumers in dealing with prescription drugs is not merely theoretical. We now have ample evidence of the benefits of direct-to-consumer advertising. Much of this evidence can be found in the consumer surveys conducted by the Food and Drug Administration, Prevention magazine, and other organizations. These surveys show that consumers like DTC advertising and they think it helps them talk to their doctors about medical conditions. DTC advertising inspires consumers to learn more about illnesses and drug therapies. It tends to make consumers more aware of both the benefits and risks of pharmaceuticals as many consumers read and pay attention to the risk information in advertising.

Twenty-seven percent of respondents in the FDA survey were prompted by ads to talk to their doctors about medical conditions they had never previously discussed with their doctors. DTC ads also remind patients to refill their prescriptions and to have confidence in the value of continuing their therapies, as was pointed out by the FDA spokesman just earlier.

Fortunately, there is little convincing evidence of adverse effects from DTC advertising. Expenditures on DTC ads are only about 2 percent of total spending on prescription drugs. There is little reason to think that DTC ads raise prices. Average prices in the heavily advertised statin drug market, for example, have been stable for the past 6 years despite escalating demand.

DTC advertising is also unlikely to contribute to overall expenditures on prescription drugs except to the extent that ads encourage

patients to obtain needed therapies that they would otherwise do without. There is little, if any, evidence that DTC ads have caused systematic inappropriate prescribing. Risk-benefit information in ads tends to be reasonably balanced. Indeed, the FDA would hardly tolerate anything else.

Only about 4 percent of respondents to the FDA's 1999 survey on DTC advertising said that they had encountered adverse reactions from their doctors when they talked about advertised drugs. In fact, overwhelming proportions of survey respondents in the FDA survey reported that when they asked their physicians about advertised drugs their questions were met with tolerance and respect and were treated as ordinary parts of physician-patient interactions.

In conclusion, DTC ads appear to be providing consumers with a useful, even essential, tool in today's rapidly changing health care market.

That concludes my remarks. I would be glad to answer questions.

[The prepared statement of Mr. Calfee follows:]

PREPARED STATEMENT OF JOHN E. CALFEE, PH.D., RESIDENT SCHOLAR, AMERICAN ENTERPRISE INSTITUTE

Mr. Chairman, I wish to thank you for inviting me to testify today on the effects of direct-to-consumer (DTC) advertising of prescription drugs. I am an economist who has devoted considerable attention to advertising, health care markets, and the pharmaceutical industry. During 1980–1986, I served in the Bureau of Economics at the Federal Trade Commission, where I specialized on consumer protection, including advertising regulation. Some of what I say today is drawn from my recently published book, *Prices, Markets and the Pharmaceutical Revolution* (AEI Press, 2000). That book is available from the publisher, AEI Press, and is also downloadable from the American Enterprise Institute website (www.aei.org). Earlier, I wrote a book on advertising, *Fear of Persuasion: A New Perspective on Advertising and Regulation* (London: Agora; North American distribution by the American Enterprise Institute). I have also written numerous articles and book chapters on pharmaceutical advertising and related topics, and recently presented the results of a new empirical study of the effects DTC advertising for the statin class of cholesterol-reducing drugs (Calfee, Winston, and Stempski 2001). Much of this testimony is based on a recently released paper on what we can learn from consumer surveys on DTC advertising (Calfee 2001).

This statement addresses four topics: (1) the relationship between DTC advertising and prescription drug prices; (2) the relationship between DTC advertising and prescription utilization and costs; (3) why DTC advertising is likely to help consumers and patients; and (4) what consumer research can tell us about the impact of DTC advertising.

DTC Advertising and Prescription Drug Prices

Expenditures for out-patient prescription drugs have been increasing at about 15% annually (Berndt 2000; NIHCM 2001). Several studies have found that about three-fourths of these increases have been caused by expanded usage and switching to newer and more effective drugs, while price increases have accounted for only about one-fourth (Berndt 2000; Dubois et al. 2000; RxHealth Value 2001). Even this modest role for price increases is overstated, because standard measures of pharmaceutical prices fail to take into account improvements in the quality and value of new drugs or drugs that have found expanded uses (Triplett 1999).

These facts suggest that even if DTC advertising increases prices, such an effect has been quite limited simply because overall price increases have been small. But there is little reason to expect DTC advertising to significantly increase prices at all. Research has generally found that advertising tends to reduce prices, rather than increase them, primarily because advertising makes markets more competitive (Calfee 1997, p. 10–11, and citations therein).

A current example of the separation between DTC advertising and prescription drug prices can be found in the market for the statin class of cholesterol-reducing drugs such as Pravachol, Zocor, and Lipitor. Total expenditures for statin drugs

have increased rapidly, making this one of the largest therapeutic categories in terms of total sales (NIHCM 2001). Statin drugs have also been among the leaders in DTC advertising (NIHCM 2001). Yet average statin drug prices have been stable or even slightly declining, according to data from the widely respected market research firm, IMS Health (proprietary data supplied to author, summarized in Calfee, Winston, and Stempski 2001). Moreover, the oldest statin drug, Mevacor, is about to go off patent. Hence average statin drug prices may substantially decline in the future.

DTC Advertising and Prescription Drug Expenditures and Utilization

DTC advertising totaled approximately $2.6 billion in 2000 (Adams 2001). This is about 2% of total prescription drug expenditures, which were recently estimated at $132 billion (NIHCM 2001). Clearly, even the total elimination of DTC advertising would have a negligible direct effect on total pharmaceutical costs.

The real question, however, is whether DTC advertising pushes expenditures upward and if so, whether it increases expenditures inappropriately. There is little evidence that recent increases in drug expenditures have been caused by inappropriate prescriptions. For example, a recent unpublished study of the rapidly growing statin drug market found no tendency toward less appropriate prescribing in this rapidly growing market (Dubois, et al., 2001). On the whole, increases in drug utilization seem to be driven primarily by the fact that health care organizations, physicians, and patients find many of the newer drugs to be extremely valuable. In fact, there is strong evidence that many of the most effective drugs are underused, rather than overused (see citations in the next section). Hence public debate has focussed on how to pay for more extensive drug therapy, rather than on how to curtail it.

Whether DTC advertising is actually increasing usage has apparently been the subject of very little systematic research. In an attempt to fill this gap, I and two co-authors undertook a study of the statin drug market (Calfee, Winston, and Stempski 2001). Using proprietary data on DTC advertising, other forms of promotion, statin prescriptions, statin sales, and cholesterol-related office visits, plus other data, were found no detectable influence from DTC advertising or other forms of promotion on the volume of statin prescriptions, which simply increased steadily throughout the study period regardless of large fluctuations in DTC advertising. One reason for the apparent lack of a short-term connection between advertising and prescriptions is the fact that several steps must take place between the time when a consumer reacts to an ad and when that consumer receives a prescription (initial physician visit, cholesterol check, advice for life-style changes, etc.)—if a prescription is written at all.

This is not to say that DTC advertising does not increase sales for advertised brands. But the evidence suggests that prescribing decisions are dominated by the physician's advice, which may involve non-drug therapy, a generic prescription, or an over-the-counter drug recommendation, as alternatives to prescribing the advertised brand.

Why DTC Advertising Is Likely to Help Consumers and Patients

Decades of research have established that advertising makes markets work better by providing information and enhancing competition (Calfee 1997). Advertising is especially useful for providing consumers with essential information that they would otherwise ignore, fail to receive, or receive too late. The Federal Trade Commission, which regulates most advertising, has emphasized that advertising plays an essential role in improving consumer information and otherwise improving markets (FTC 1996).

There are compelling reasons to expect DTC advertising to improve the prescription drug market. Some of the most important medical information—especially relatively new information—often fails to reach physicians or patients in a timely manner. This situation is reflected in the proliferation of practice guidelines for physicians, and also in published findings that medical practice often falls well short of what can be achieved by following even the least controversial aspects of consensus guidelines (Calfee 2000, p. 24–26). Consumers and patients, of course, tend to be even less well informed than their doctors.

Many of the most valuable new drugs involve conditions or illnesses that require consumers to take the initiative in seeking medical advice for dealing with depression, for example, or to learn whether one is at risk for heart disease and if so, what can be done to reduce that risk. A number of studies and consensus statements from the medical community have documented the existence of large numbers of underdiagnosed and undertreated consumers who suffer from serious, yet treatable medical conditions such as elevated cholesterol, depression, obesity, diabetes, and hypertension (Calfee 2000, p. 24–26).

A new report from the National Cholesterol Education Program at the National Institutes of Health illustrates these trends. That report concluded that elevated cholesterol should be treated much more aggressively than in the past, even as earlier studies have found that most persons who should have been treated under the previous guidelines were in fact not treated and often, not even identified (NIH 2001).

These circumstances dictate that patients and consumers must play an active role in their own health care. In particular, consumers need to acquire information about medical therapies, talk to their physicians about medical symptoms and conditions, and decide with their doctors how to deal with illnesses and conditions.

Both the FTC (1996) and the FDA have noted the potential value of DTC advertising in addressing these problems. The Food and Drug Administration, in particular, has stated, "It [DTC advertising] is consistent with the whole trend toward consumer empowerment. We believe there is a certain public health benefit associated with letting people know what's available." (Stolberg 2000). Even the American Medical Association, whose constituency has traditionally opposed prescription drug advertising to consumers, recently issued a statement that concluded, "If used appropriately, direct-to-consumer (DTC) advertising has the potential to increase patient awareness about treatment options and enhance patient-physician communication. Advertising directly to the public educates patients, enabling them to better understand and participate in medical care." (AMA 2000). In 1998, *Lancet*, a leading British medical journal, ran an editorial arguing that DTC advertising would benefit European consumers.

What Consumer Research Can Tell Us about the Impact of DTC Advertising

In August 1997, the FDA relaxed its regulatory requirements for DTC advertising on broadcast media including television (Calfee 2001, FDA 1997). This decision triggered large increases in the volume of television DTC advertising while also prompting a shift from print to broadcast media. In August 1999, after a two-year review, the FDA reaffirmed its new policy, while also announcing its intention to review DTC advertising again in 2001 (FDA 1999a). This past March, the FDA announced the beginning of its latest review, which will include commissioning surveys of both consumers and physicians (FDA 2001).

In the meantime, several studies have appeared on the impact of DTC advertising. These consist primarily of a number of nationally representative surveys of consumers. The most notable examples include a 1999 survey commissioned by the FDA itself (FDA 1999b, 1999c), and a series of surveys commissioned by *Prevention Magazine* (1999, 2000). Other more limited, but nonetheless useful research includes national consumer surveys by AARP, the National Consumers League, and NewsHour with Jim Lehrer (with the Kaiser Family Foundation and the Harvard School of Public Health); a survey of California consumers (Bell, et al. 2000), and content analyses of individual DTC ads (Wilkes 2000). I focus here on the findings from national surveys, especially those by the FDA and *Prevention Magazine*.

DTC Advertising and Consumer Information

The national consumer surveys have provided a number of useful findings on the relationship between DTC advertising and consumer knowledge about prescription drugs. One finding is that DTC ads provide a reasonable balance of information about both benefits and risks. In the FDA survey, for example, there was little difference in the prominence of benefits vs risks or warnings, and 70% disagreed with the statement that DTC ads "make it seem like a doctor is not needed to decide whether a drug is right for me." In a response to a 1999 *Prevention* survey question about whether advertising made respondents feel more or less confident about drug safety, 70% said "no difference" or "less confident."

The surveys also supply direct and indirect evidence that DTC advertising provides valuable information to consumers. Responses revealed very high levels of awareness and attention to DTC ads, as the proportion of respondents recalling DTC ads ranged between 72% (FDA survey) and 95% (aided recall in the 1999 *Prevention* survey). Such high awareness levels strongly suggest that consumers gained information about the core topics of DTC ads: details on a variety of medical conditions, potential therapies, alternative dosages, and other important topics, in addition to risk information. The potential value of making so much information available through advertising is clear from the AARP survey results, in which 27% of respondents said their doctors seldom or never discussed pharmaceutical risks, and another 18% said physicians did so only sometimes, while 27% said their doctors rarely or never discussed alternative drug therapies.

The bulk of respondents (on the order of 80% in the FDA survey) noticed information on benefits, risks, and warnings. Substantial proportions read some or all of

the fine-print risk information in print ads, and readership was much higher for those who had a special interest in the advertised drug. In particular, the FDA survey found remarkably high levels of readership of the fine-print risk information in print ads: 40% said they read half or more of that information, another 26% said they read a little of it, and 85% said they would read all or almost all of the information if they were especially interested in the drug. The *Prevention* survey obtained roughly similar results, also finding high levels of attention to detailed risk information.

The surveys also suggest that DTC ads motivated consumers to seek additional information from numerous sources, including, of course, their own doctors. Of special importance is the finding that DTC ads opened up new topics for consumers to investigate. Twenty-seven percent of respondents in the FDA survey were prompted by ads to talk to their doctors about medical conditions they had never previously discussed. These results are consistent with the fact that many of the most heavily advertised drugs treat conditions that are widely believed by the medical community to be undertreated, such as elevated cholesterol, depression, obesity, diabetes, and hypertension.

Of special interest in the FDA survey was the balance of information on risks and benefits in DTC ads. A series of detailed questions revealed a remarkably balanced assessment. Asked what kinds of information they saw in ads, 87% of respondents said, "the benefits of the drug," while 82% said, "risks or side effects," and 81%, "who should not take the drug." The proportion of respondents who thought ads lacked information on benefits (49%) was nearly as large as the proportion who though ads lack information on risks (59%). The *Prevention* surveys provided similar results.

DTC Advertising and Patient-Doctor Relationships

Both the FDA and *Prevention* surveys document that large majorities of consumers agree that DTC ads provided sufficient information to prepare to talk to their doctors—70% in the FDA survey. But advertising was far from a dominant influence. In the FDA survey, respondents said the main reasons for expecting a new prescription were: past prescription history, information from friends or relatives, and previous discussions with physicians.

Large majorities of respondents to the FDA survey reported favorable assessments of their talks with their doctors, and encountered no resentment or other unfavorable reaction. This is apparent from the numbers in Table 1. Most respondents said their doctor welcomed their questions (81%), reacted as if those questions were an ordinary part of a visit (71%), and proceeded to discuss the drugs with the patient (79%). Only 4% said their physician "seemed angry or upset." Equally important, of those who had not asked such questions of their physicians, only 3% expected to encounter an adverse reaction if they were to ask such a question in the future. Eighty-five percent of respondents were satisfied or very satisfied with their discussions with physicians about advertised drugs, with only 7% unsatisfied or very unsatisfied. Finally, 62% agreed or strongly agreed that DTC ads helped them have better discussions with their physicians.

Table 1. Physician Reactions When Asked About an Advertised Drug

	Question 28: "Which, if any, of these possible reactions did your doctor have when you asked about the [advertised] drug?"	Question 33: "Which, if any, of these possible reactions do you think your doctor would have if you asked about a prescription drug you had seen advertised?" (May say "Yes" to more than one.)
Welcomed question	81%	69%
Discussed drug	79%	82%
Reacted as if the question were ordinary part of visit	71%	56%

Table 1. Physician Reactions When Asked About an Advertised Drug—Continued

	Question 28: "Which, if any, of these possible reactions did your doctor have when you asked about the [advertised] drug?"	Question 33: "Which, if any, of these possible reactions do you think your doctor would have if you asked about a prescription drug you had seen advertised?" (May say "Yes" to more than one.)
Got angry or upset	4%	3%
None of the above	2%	1%
Don't know/refused	1%	2%
Sample size	220	607

Adapted from: Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications. Attitudes and behaviors associated with direct-to-consumer (DTC) promotion of prescription drugs: main survey results. Available at: http://www.fda.gov/cder/ddmac/dtcindex.htm. Accessed May 1, 2001.

In 26% of the discussions motivated by advertising, according to the *Prevention* survey, patients said they requested prescriptions for specific brands, and they usually got one. We do not know, however, the extent to which these requests arose from discussions in which physicians had already made clear that the decision was up to the patient, perhaps because the choice was obvious or because any of several alternatives was acceptable. In the FDA survey only about half of physicians wrote a prescription when asked about a specific drug. These surveys provide no reason to suggest that these requests and questions about specific advertised drugs tended to yield inappropriate prescriptions.

Overall Consumer Attitudes Toward DTC Advertising

Consumers generally like DTC ads and find them useful. In the FDA survey, those who liked DTC ads outnumbered those who did not by nearly two to one. Eighty-six percent said the ads "help make me aware of new drugs," and 62% said DTC ads help them have better discussions with their physician about their health. In the 1999 *Prevention* survey, 76% thought that ads "allow people to be more involved with their health care," 72% said that DTC ads "educate people about the risks and benefits of prescription medicines," and 63% said that DTC ads "help people make their own decisions about prescription medicines." Finally, 76% of respondents to the National Consumers League survey agreed that prescription drug ads "increase consumer knowledge about medicines," and 78% agreed that prescription drug ads "increase consumer knowledge about disease."

Positive Spillovers from DTC advertising

Survey research also provides something that may be surprising to most observers: evidence that DTC advertising provides spillover benefits to consumers, beyond any gains realized by the manufacturers who pay for the ads. One spillover benefit, for example, is increased consumer awareness of the simple fact that virtually all prescription drugs are risky and have side effects. This must be clear to anyone who has perused a few of the "brief summaries" in print ads or noticed the staccato list of warnings in TV ad voice-overs. In addition, the 1999 *Prevention* survey found that physicians tend to provide more risk information to those patients who ask about advertised drugs.

A second category of spillover benefits is the dissemination of information about new, previously undiscussed conditions. Advertising about elevated cholesterol, obesity treatments, and the like do not invariably lead to prescriptions for the advertised drugs. On the contrary, when ads induce patients to talk to their doctor, most patients do not actually ask for or about the brand whose advertising sparked the discussion, and when they do, the result is a mixture of prescriptions for the advertised drug, prescriptions for a competing drug, recommendations for OTC drugs, and advice to change life-styles or behavior. Ads can raise awareness of the need for a particular type of drug to treat a particular condition, but the benefits of that consciousness-raising may go to the patient and to competitors rather than to the advertiser.

A third spillover benefit is to call consumers' attention to nondrug approaches to improved health. Many ads start out by mentioning the value of dietary changes and exercise. When DTC ads succeed in getting consumers to talk to their doctors about obesity, diabetes, depression, and cholesterol levels, those consumers probably learn that behavioral and life-style changes are the first line of treatment. In response to a 2000 *Prevention* survey question asked of respondents who said that ads had caused them to talk to their physician, 53% said their doctor had mentioned a nondrug therapy for their condition. The proportions were much higher for certain conditions: diabetes (77%), high cholesterol (92%), and obesity (84%).

Finally, a fourth example of spillover benefits is inducing compliance with drug therapies. Research has shown that inadequate compliance with physician instructions when taking prescription drugs is an extremely common and dangerous problem (Calfee 2000, p. 19). Advertising is an excellent vehicle for inducing better compliance because consumers tend to pay attention to advertising for brands they use. It is no surprise, therefore, that the FDA survey found that consumers pay special attention to ads for drugs they are taking or in which they have a special interest.

In 2000 *Prevention* survey, about half of those respondents taking a prescription drug recalled seeing an ad for a drug they were using. Thirty-six percent said the ads made them feel better about the safety of their prescriptions, while only 3% said the ads made them feel worse. In response to a crucial question—"Do ads make you more or less likely to take your medicine regularly?"—"more likely" outscored "less likely" by 22% to 3%. In addition, 33% in the 1999 survey said that prescription drug ads reminded them to have their prescriptions refilled.

There is no reason to expect the reminder powers of DTC advertising to be restricted to the advertised brand. Although no research appears to have been done on the topic, these survey results strongly suggest that by reminding patients to take their medicine and refill their prescriptions, DTC ads tend to encourage patients to persist in their drug therapy.

Conclusions

There are good reasons to expect DTC advertising to provide valuable information to consumers and otherwise improve the health care market. The emerging evidence on DTC advertising effects, particularly the results of consumer surveys by the FDA, *Prevention Magazine*, and others, indicates that DTC ads are in fact providing substantial benefits while avoiding most or all of the problems that some analysts have suggested DTC ads could bring.

This evidence goes far toward explaining why the FDA reaffirmed its policy of permitting DTC advertising in August 1999. Indeed, the agency noted at the time that "FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising" (FDA 1999b). The FDA is to be congratulated for persisting in its policy toward DTC advertising in the face of criticism and opposition from diverse segments of the health care community. Equally worthy of praise is the fact that the FDA commissioned a well-designed consumer survey that could easily have uncovered severe problems with its new policy, rather than providing support for the policy (which it did, of course).

We have learned at least six things from the leading consumer surveys and other evidence on DTC advertising. First, we can largely rule out the possibility that DTC advertising is causing systematic consumer deception, including the inappropriate downplaying of risks and side effects. The FDA and *Prevention* surveys, in particular, addressed this topic in so many ways that it is very unlikely that widespread consumer deception has escaped detection by the FDA regulators.

Second, DTC advertising provides valuable information, and not just on obvious topics such as potential treatments and dosages, but also on risks and side effects. On the whole, DTC advertising appears to increase the salience of both risks and benefits from drug therapy. Third, the information in DTC advertising motivates consumers to seek additional information from many sources, but especially from physicians and pharmacists. Many of these consumers ask about conditions they had not previously discussed with their doctors.

A fourth finding is that from the patient's perspective at least, DTC advertising is causing almost no tension in the doctor's office. Very few respondents—usually well under 5%—encountered resentment or resistance when they brought up what they had seen in advertising, or asked about specific drugs. Fifth, consumers like DTC advertising. They think it helps them in making decisions and in talking to their doctors.

Sixth, DTC advertising yields significant spillover benefits that go to consumers rather than to advertisers. Such benefits range from heightened awareness of the inherently risky nature of prescription drugs to better compliance with drug thera-

pies and even motivation to pursue life-style and behavioral changes that may obviate the need to use pharmaceuticals. In particular, ads reminded consumers to take their medications and to refill their prescriptions. Overall, DTC ads appear to make patients more comfortable with the risks and benefits of the medicines they take.

Overall, these survey results are strongly supportive of a situation in which consumers are motivated by advertising first to seek additional information—specially from physicians, and particularly for previously untreated or inadequately treated conditions—and then to work with their doctor to reach a decision about what if any prescription drug to use.

References

Adams, C. (2001) "FDA plans to review policy allowing direct-to-consumer drug ads for TV," *Wall Street Journal*. March 28, 2001, p. B1.

American Medical Association (2000) Council on Ethical and Judicial Affairs of the American Medical Association, "Direct-to-Consumer Advertisements of Prescription Drugs," 55/1 *Food and Drug Law Journal* 119–124.

Bell, Robert A., Michael S. Wilkes, and Richard Kravitz (2000) "The Educational Value of Consumer-targeted Prescription Drug Print Advertising," 49/12 *Journal of Family Practice* (December).

Calfee, John E. (1997) *Fear of Persuasion: A New Perspective on Advertising and Regulation*, London: Agora; North American distribution by the American Enterprise Institute.

Calfee, John E. (2000) *Prices, Markets, and the Pharmaceutical Revolution*. American Enterprise Institute, Washington, D.C.

Calfee, John E. (2001) "What Consumer Surveys Show About Direct-to-Consumer Advertising of Prescription Drugs," available from author and from the Coalition for Health Care Communication (www.cohealthcom.org).

Calfee, John E., Clifford Winston, and Randolph Stempski (2001) "The Effects of Direct-to-Consumer Advertising for Cholesterol-reducing Drugs," presented at the University of Chicago Conference on The Regulation of Medical Innovation and Pharmaceutical Markets, April 20–21, 2001.

Dubois, Robert W., Charles M. Alexander, Sally Wade, Andrew Mosso, Leona Markson, J.D. Lu, Soma Nag, and Marc L. Berger (2001) "Growth in Use of Lipid Lowering Therapies: Bad News? Good News? Or the Wrong Question?" Draft available from Robert W. Dubois, Protocare Sciences, Inc., 2400 Broadway, Suite 100, Santa Monica, CA 90404.

Federal Trade Commission, Bureau of Consumer Protection and Bureau of Economics (1996), "Comments to the Food and Drug Administration on Direct-to-Consumer Promotion of Prescription Drugs," January 11, 1996.

Food and Drug Administration, Center for Drug Evaluation and Research (1997) "Draft Guidance for Industry on Consumer-Directed Broadcast Advertisements," July 1997; announced in *Federal Register*, v. 62, n. 155, p. 43171–43173 (Aug. 12, 1997, Docket 97D–0302).

Food and Drug Administration, Center for Drug Evaluation and Research (1999a) "Guidance for Industry: Consumer-directed Broadcast Advertisements," August 1999; announced in *Federal Register*, v. 64, n. 152, p. 43197–43198 (Aug. 9, 1999, Docket 97D–0302).

Food and Drug Administration, Center for Drug Evaluation and Research (1999b) "Questions and Answers on Guidance for Industry: Consumer-Directed Broadcast Advertisements," August 1999; announced in *Federal Register*, v. 64, n. 152, p. 43197–43198 (Aug. 9, 1999, Docket 97D–0302).

Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications (1999c) "Attitudes and Behaviors Associated with Direct-to-Consumer (DTC) Promotion of Prescription Drugs: Main Survey Results," available at www.fda.gov/cder/ddmac/dtcindex.htm.

Food and Drug Administration (2001) "Agency Information Collection Activities; Proposed Collections; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs," Docket No. 01N–0078, *Federal Register*: March 19, 2001 (Volume 66, Number 53).

Lancet (1998) Editorial, "Pushing Ethical Pharmaceuticals Direct to the Public," v. 351, March 28.

National Consumers League (1998) "Health Care Information and the Consumer: A Public Opinion Survey." Washington, D.C.: National Consumers League (1701 K Street, NW, Suite 1200, Washington, DC 20006).

National Institute for Health Care Management (NIHCM) (2001) "Prescription Drug Expenditures in 2000: the Upward Trend Continues." Washington, D.C.: NIHCM Foundation.

NewsHour with Jim Lehrer, Kaiser Family Foundation, Harvard School of Public Health (2000a) "National Survey on Prescription Drugs: Toplines." Available at www.kff.org.

NewsHour with Jim Lehrer, Kaiser Family Foundation, Harvard School of Public Health (2000b) "National Survey on Prescription Drugs: Highlights and Chartpack." Available at www.kff.org.

National Institutes of Health, National Cholesterol Education Program (2001) "Recommendations on Lipoprotein Measurement," from the Working Group on Lipoprotein Measurement.

Prevention Magazine (1999) "A National Survey of Consumer Reactions to Direct-to-Consumer Advertising."

Prevention Magazine (2000) "International Survey on Wellness and Consumer Reactions to DTC Advertising of Rx Drugs."

RxHealth Value, "Prescription Drug Expenditures Increase More Than 24%," downloaded May 17, 2001 from www.rxhealthvalue.com, summarizing a May 2001 report from the Schneider Institute for Health Policy at Brandeis University.

Stolberg, Sheryl Gay (2000) "Ads that Circumvent Doctors: Want a New Drug? Plenty to Choose From on TV," *New York Times*, January 23, 2000.

Wilkes, Michael S., Robert A. Bell, and Richard L. Kravitz (2000) "Direct-To-Consumer Prescription Drug Advertising; Trends, Impact, And Implications," *Health Affairs*, March/April.

Senator DORGAN. Mr. Calfee, thank you very much.

You must leave soon, is that correct?

Mr. CALFEE. That is correct.

Senator DORGAN. Senator Wyden.

Mr. CALFEE. But not immediately, please.

Senator DORGAN. Let me do this, if you do not mind, with your permission. Let me hear from Dr. Wolfe and Dr. Glover. It will take about 10 minutes, then we will have some questions. We will ask the questions of you first so that you may leave.

STATEMENT OF SIDNEY M. WOLFE, M.D., DIRECTOR, PUBLIC CITIZEN'S HEALTH RESEARCH GROUP

Dr. WOLFE. Thank you.

There is little doubt that false and misleading advertising to patients and physicians can result in prescriptions being written for drugs that are more dangerous and/or less effective than perceived by either the doctor or the patient. It is counterintuitive not to believe that misleading advertising, of which there is quite a bit, and I will go through some of the numbers, does not convince people as much or more than non-misleading advertising, and therefore Dr. David Kessler's statement, which I agreed with when he made it, that advertising can cause death and injury if it results in inappropriate prescribing, has got to be true.

The fact that there are not any studies of it, your point Mr. Chairman, it is not that there are careful studies which have shown no evidence of inappropriate prescribing. There are not any good studies that have been done. As I said, the evidence that the industry has is that when they do direct-to-consumer advertising, as pointed out, in conjunction with prescription advertising to doctors, the prescribing goes way up. It is a combination of the both. An often misled prescriber and a misled patient can combine to get a prescription written that might otherwise not have been written.

This can then lead to a subsequent toll of deaths and injuries that would not have occurred had safer, more effective drugs been prescribed. Senator Wyden's question is also very legitimate in the sense that inappropriate prescribing may be prescribing a more ex-

pensive drug instead of a less expensive drug, ultimately leading the patient not to have enough money to take care of themselves. So from the standpoint of cost, inappropriate prescribing can also be dangerous.

The more than 500 prescription drug advertisements that have been found by the FDA to violate Federal laws and regulations from 1997 to the present include approximately 90 direct-to-consumer ads. These numbers would be significantly larger if FDA's Division of Drug Marketing, Advertising, and Communication had more staff to investigate the rapidly expanding area of DTC drug promotion.

As seen in the table included in my testimony—these are taken from FDA's own data—there has been a sharp and steady decrease during the last 3 years in the number of FDA warning letters and notices of violation of FDA laws and regulations to drug companies concerning prescription drug advertising. For the last full year, mid-2000 through mid-2001, the total number of advertising enforcement actions, 74, was less than one-half, 47 percent, of the 158 enforcement actions taken 3 years ago, mid-1997 through mid-1998.

There is no evidence of an advertising/pharmaceutical industry epiphany resulting in fewer illegal advertisements for prescription drugs. Therefore the only plausible explanation for this dangerous decrease is that the police force, DDMAC, has not been strong enough in numbers of investigators, along with the lack of adequate pro-enforcement leadership, meaning from the Commissioner and the head of the drugs division, from the top officials.

That this latter explanation, inadequate enforcement, is correct will be seen—and my optimism comes out here—when the FDA, with the urging and support of your committee and the Appropriations Committee, begins to increase the number of actions taken against these violative acts. Until then, Americans, both physicians and patients, will be harmed by prescribing decisions about which drugs to use based on all too frequently false and misleading information from advertisements which are much less likely now to be stopped because of poor enforcement.

In addition to more staff, there is a dire need for direct-to-consumer specific regulation since, other than the late 1990's guidance concerning TV advertising which Dr. Ostrove spoke of, which is a guidance, not a regulation, there are no regulations specifically written for direct-to-consumer advertising. The FDA has been using regulations promulgated after the 1962 Kefauver–Harris amendments that were clearly intended for prescription drug advertising directed to health professionals, such as doctors and pharmacists.

We have been urging the agency since the mid-1980's to propose and finalize such consumer-specific DTC regulations that would make it easier to evaluate the ads in the context of patient, not health professional, comprehension.

Beyond more staff and direct-to-consumer specific regulations, there is a need for much more enforcement power. At present the FDA is limited to a notice of violation or warning letter to companies found to violate the law or regulations. Theoretically, in the face of multiple warnings to the same company, criminal prosecu-

tion is a possible tool. This latter power has only been used a handful of times in the past 30 years. To our knowledge, never has it been used for direct-to-consumer advertising.

Despite a series of 11 illegal ads for Claritin, 8 of which were direct-to-consumer, 14 illegal ads for Flonase and Flovent, two drugs, one used for nasal problems and the other for pulmonary problems—8 of these 14 illegal ads are DTC—and 5 illegal ads for Celebrex, one DTC, no criminal prosecution of these companies. What is more, the ability to assess drug companies large civil monetary penalties for advertising violations could serve as a deterrent, but the FDA has no authority at all to impose civil monetary penalties on any drug company for anything, whether it is advertising violations or anything else.

Senator Kennedy attempted to get such authority included in the 1997 Food and Drug Modernization Act. It was fought hard and successfully by the industry. If the FDA does not have the ability to impose massive fines, if not criminally prosecute these companies, the companies will just laugh and continue violating the law with another violative ad.

Just briefly, a few articles that certainly do raise some serious questions about some of the optimistic things that Dr. Ostrove talked about and that Mr. Calfee talked about. In one study researchers found that consumers rated the safety and appeal of drugs described with an incomplete risk statement more positively than those drugs for which risks were described more completely. It has obvious implications since many direct-to-consumer ads understate the safety of drugs.

Another study found that consumer beliefs that there was prior scrutiny of ads, DTC ads, by the FDA and that they were held to higher standards than other ads were generally wrong. Another study on the educational content—we hear from the industry these are for education; they are really not to sell drugs; we just want to educate the public—found that, while may ads provided information about the name and symptoms of the disease for which the drug was being promoted, few educated the patients about the success rate of the drug, how long you had to use the drug, alternative treatments, including behavioral change, which could improve their health, or misconceptions about the disease. The authors concluded the ads provide only a minimum amount of educational information.

Finally, one study asked patients what they would do if a doctor refused to prescribe a drug that the patient wanted as a result of a DTC ad. One-fourth of the patients said they would seek a prescription elsewhere and 15 percent said they would consider terminating the relationship with the physician. To the extent that this obviously impairs the doctor-patient relationship, this goes counter to what was said before.

Patients with these attitudes were ones who had a more favorable evaluation of DTC advertising and who possessed more faith in the current government regulation of DTC ads.

In closing, FDA resources and specific regulatory authority to monitor the accuracy of drug safety and effectiveness portrayed in DTC ads are dangerously inadequate and many patients' perceptions of these ads and their subsequent response to the "informa-

tion" therein is similarly dangerous. The present situation concerning DTC advertising is unacceptable and it is our hope that your committee will participate in initiating actions to remedy these serious problems.

I would also request that a study put out by another part of our organization, Public Citizen Congress Watch, related very much to the issues that Senator Wyden raised about drug costs and that you raise, be put in the record. It is called "Prescription Research and Development Myths: The Case Against the Drug Industry's R and D Scare Card."

Senator DORGAN. Without objection, it will be put in the record.*

Dr. WOLFE. Thank you.

[The prepared statement of Dr. Wolfe follows:]

PREPARED STATEMENT OF SIDNEY M. WOLFE, M.D., DIRECTOR, PUBLIC CITIZEN'S HEALTH RESEARCH GROUP

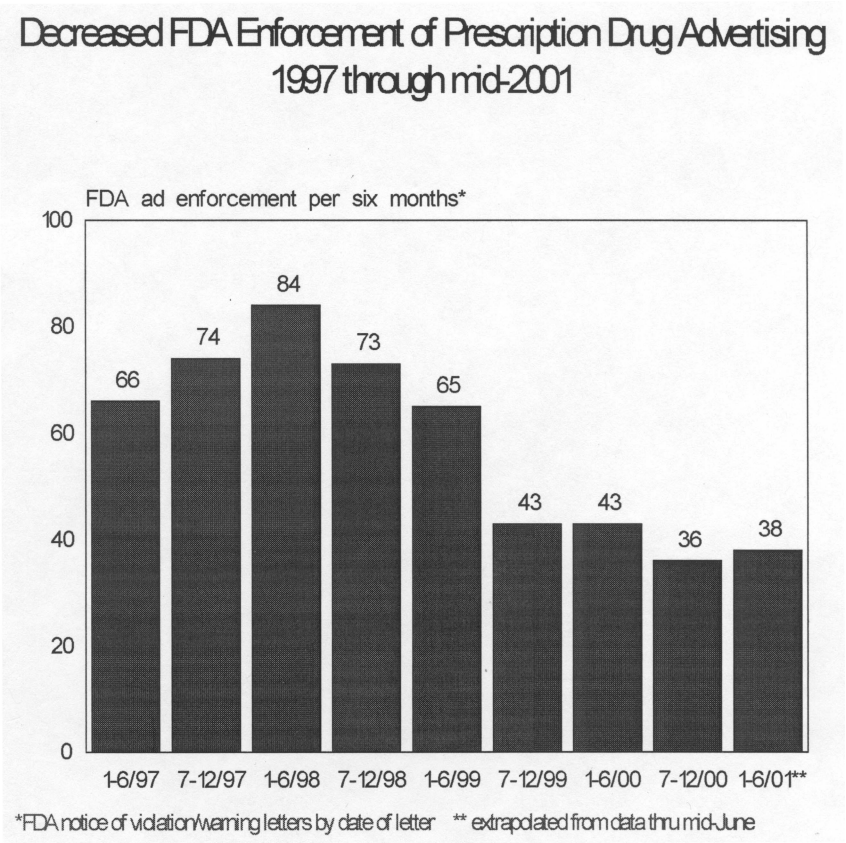
Because of the strong First Amendment in the U.S constitution, there is no way that DTC prescription drug advertising could ever be banned in this country. Having said that, however, there is an urgent need for more fine-tuned, better-staffed and much tougher government regulation of its content. There is little doubt that false and misleading advertising to patients and physicians can result in prescriptions being written for drugs that are more dangerous and/or less effective than perceived by either the doctor or the patient. This can then lead to a subsequent toll of deaths and injuries that would not have occurred had safer, more effective drugs been prescribed.

The more than 500 prescription drug advertisements that have been found by the FDA to violate federal laws and regulations from 1997 through the present include approximately 90 DTC ads. These numbers would be significantly larger if FDA's DDMAC (Division of Drug Marketing Advertising and Communication) had more staff to investigate the rapidly expanding area of DTC drug promotion. Such advertising has more than tripled in dollar volume from $791 million in 1996 to $2.5 billion in 2000. But the number of FDA staff assigned to reviewing and investigating all of prescription drug advertising, during the same interval, has only increased from 11 in 1996 to 14 at present. I have been informed that there is, or will shortly be, an increase in DDMAC staff to monitor such advertising and it comes none too soon. Even this may well not be adequate.

As seen in the table on the next page, there has been a sharp and steady decrease during the last three years in the number of FDA warning letters and notices of violation of FDA laws and regulations to drug companies concerning prescription drug advertising. From a peak of 84 such enforcement actions during the first six months of 1998, the number has fallen steadily to 36 FDA actions during the last six months of 2000 and an estimated 38 actions during the first six months of 2001.

For the last year (mid-2000 through mid-2001) the total number of DDMAC advertising enforcement actions—74—was less than one-half (47%) of the 158 enforcement actions taken three years ago (mid-1997 through mid-1998). There is no evidence of an advertising/pharmaceutical industry epiphany, resulting in fewer illegal advertisements for prescription drugs. Therefore, the only plausible explanation for this dangerous decrease is that the police force—DDMAC—has not been strong enough in numbers of investigators along with a lack of adequate pro-enforcement leadership from the top officials in FDA. That this latter explanation, inadequate enforcement, is correct will be seen when the FDA, with the urging and support of your committee, begins to increase the number of actions taken against these violative ads. Until then, Americans—both physicians and patients—will be harmed by prescribing decisions about which drugs to use based on all-too-frequently false and misleading information from advertisements which are much less likely to be stopped because of poorer enforcement by the FDA.

* The information referred to has been retained in Committee files.



In addition to more staff, there is a dire need for DTC-specific regulations since, other than the late 1990's guidance concerning TV advertising—which is a guidance not a regulation—*there are no regulations specifically written for DTC advertising*. The FDA has been using the regulations promulgated after the 1962 Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act that were clearly intended for prescription drug advertising directed at health professionals such as doctors and pharmacists. We have been urging the agency since the mid-1980's to propose and finalize such consumer specific DTC regulations that would make it easier to evaluate the ads in the context of patient, not health professional, comprehension. Beyond more staff and DTC-specific regulations there is a need for much more enforcement power. At present, the FDA is limited to a Notice of Violation or Warning Letter to companies found to violate the law or regulations. Theoretically, in the face of multiple warnings to the same company, criminal prosecution is a possible tool. This latter power has only been used a handful of times in the past 35 years. To our knowledge, criminal prosecution has never been used in the context of DTC advertising, despite, for example, a series of 11 illegal ads for Claritin (8 DTC), 14 illegal ads for Flonase/Flovent (8 DTC). (Flonase and Flovent are the same drug in two versions, one used for allergy, the other for asthma). There have also been five illegal ads for Celebrex (1 DTC).

The ability to assess drug companies large civil monetary penalties for advertising violations might actually serve as a deterrent for companies who now just stop the violative ad, when requested by the FDA, then create and massively disseminate a new one shortly thereafter. The FDA currently lacks the authority to impose any civil penalties for drug advertising or, in fact, for any other illegal drug industry activity concerning prescription drugs. It is long overdue that the Congress give the FDA this authority.

A search of the peer-reviewed, published medical studies concerning DTC advertising yields findings that, for the most part, are also quite worrisome:

- In one study, researchers found that consumers rated the safety and appeal of drugs described with an incomplete risk statement significantly more positively than those whose risks were described more completely.[1] (This has significant implications since so many DTC ads understate the safety of drugs.)
- Another study found that consumer beliefs that there was prior scrutiny of DTC ads by the FDA and that they were held to higher standards than other ads were generally wrong. A substantial proportion believed that only the safest and most effective drugs could be advertised DTC and that the FDA required prior review of ads. DTC ads led one-fifth of people to request a prescription.[2]
- A study on the educational content of DTC ads found that while many ads provided information about the name and symptoms of the disease for which the drug was being promoted, few educated the patients about the success rate of the drug, how long you had to use the drug, alternative treatments including behavioral changes which could improve their health, or misconceptions about the disease. The authors concluded that the ads provided only a minimal amount of educational information.[3]
- One study asked patients what they would do if a doctor refused to prescribe a drug that the patient wanted as a result of a DTC ad. One-fourth of patients said they would seek a prescription elsewhere and 15% said they would consider terminating their relationship with their physician. The patients with these attitudes were ones who had a more favorable evaluation of DTC advertising and who possessed more faith in the current government regulation of DTC drug ads.[4]

In summary, FDA resources and specific regulatory authority to monitor the accuracy of drug safety and effectiveness portrayed in DTC ads are dangerously inadequate and many patients' perceptions of the ads and their subsequent response to the "information" therein is similarly dangerous. The present situation concerning DTC advertising is unacceptable and it is our hope that your committee will initiate actions to remedy these serious problems.

Senator DORGAN. Dr. Wolfe, thank you.

Next on this panel we will hear from Dr. Glover. Dr. Glover, and you are an attorney-physician representing PhRMA, is that correct?

Mr. GLOVER. That is correct.

Senator DORGAN. Thank you. Welcome.

STATEMENT OF GREGORY J. GLOVER, M.D., J.D., ON BEHALF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. GLOVER. Mr. Chairman and Members of the Subcommittee: On behalf of the Pharmaceutical Research and Manufacturers of America, I thank you for inviting me today to testify on direct-to-consumer advertising of prescription drugs. I am a licensed physician and a practicing attorney with the law firm of Ropes and Gray and I specialize in FDA regulatory issues and intellectual property law.

PhRMA represents the country's major research-based pharmaceutical and biotechnology companies, which are the source of virtually all new drugs in the United States. PhRMA strongly supports direct-to-consumer advertising of prescription medicines as currently regulated by FDA and opposes any further restrictions on this pro-patient, pro-health activity.

---

[1] J Health Communic 2000 Oct-Dec;5:349–69.
[2] J Gen Int Med 1999;14:651–7.
[3] J Fam Pract 2000;49:1092–8.
[4] J Fam Pract 1999;48:446–52.

Under current practices, patients are now more actively involved in their own health care than ever before. Rather than remaining uninformed and relying entirely on an increasingly complex health care system, patients are asking questions, evaluating information, and making choices. Direct-to-consumer advertising provides a valuable resource for patients to obtain information about specific diseases, conditions, and treatments.

Patients suffering from chronic conditions may be dissatisfied with current treatment, but may be unaware that different options are available with fewer side effects and easier dosing regimens. Similarly, pharmaceutical advertisements improve the public health by raising awareness of conditions and diseases that often go undiagnosed and untreated.

There are encouraging signs that direct-to-consumer advertising is helping to address these issues. A survey by Prevention magazine found that, as a result of direct-to-consumer advertising, an estimated 24.7 million Americans talked to their physicians about a medical condition they had never previously discussed with a doctor. In other words, millions of people who had suffered in silence were encouraged to seek help.

A 1999 survey by Prevention magazine found that 27 percent of respondents asked their physicians about conditions they had not discussed before. These conditions ranged from arthritis and heart disease to depression. In the 2 years that ads for a medicine for erectile dysfunction have appeared, millions of men have visited their doctors to request a prescription for the drug. For every million men who asked for the medicine, it was discovered that an estimated 30,000 had untreated diabetes, 140,000 had untreated high blood pressure, and 50,000 had untreated heart disease. These numbers are striking and they are just for one drug.

A growing body of evidence suggests that consumers like direct-to-consumer advertising. A 1999 survey by FDA found that those who liked these ads outnumbered those who did not by nearly two to one. 86 percent said, the ads helped make me aware of new drugs and 62 percent said the ads helped them have better discussions with their physicians about their health.

A survey by Prevention magazine found that 76 percent of respondents thought ads help people be more involved in their health care and 72 percent felt the ads educate people about the risks and benefits of prescription medicines.

There is also growing acceptance of this type of advertising by doctors. A survey last year found the 64 percent of doctors believe that such advertisements had helped educate and inform their patients and 40 percent of the doctors surveyed believed that ads have increased patient compliance.

Critics contend that direct-to-consumer advertising drives up the price of drugs. In fact, while total pharmaceutical expenditures are rising, price increases have been in line with inflation. Most of the increase in drug expenditures has come from the increased use of prescription medicines, including the use of newer, more effective therapies.

The increased use of prescription drugs is a healthy trend. Drugs not only save lives, they save by reducing the need for alternative, more expensive care. Still, only 8.2 percent of every health care dol-

lar is spent on prescription medicine, compared to 32 percent on hospital care and 22 percent on physician and clinical services.

In summary, direct-to-consumer advertising helps address consumers' need for information about diseases and treatments. More important, direct-to-consumer advertising can improve public health by starting a dialogue between patients and doctors that may lead to a better understanding and treatment of a patient's condition.

I hope you will support patients and oppose those advocating adoption of a do not tell, do not ask policy, do not tell people about new medicines and hope they will not ask. That policy would be bad for the public health.

I will be pleased to answer any questions you may have. Thank you very much.

[The prepared statement of Dr. Glover follows:]

PREPARED STATEMENT OF GREGORY J. GLOVER , M.D., J.D., ON BEHALF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. Chairman and Members of the Subcommittee:

On behalf of the Pharmaceutical Research and Manufacturers of America, I am pleased to appear at this hearing this afternoon on direct-to-consumer (DTC) advertising of prescription medicines. I am a licensed physician and a practicing attorney with the law firm of Ropes & Gray, specializing in FDA regulatory issues and intellectual-property law. PhRMA represents the nation's leading researchbased pharmaceutical and biotechnology companies, which are leading the way in the search for new cures and treatments that will enable patients to live longer, healthier, and more productive lives.

This year, PhRMA member companies will invest more than $30 billion to discover and develop new medicines. The mapping of the human genome has opened new frontiers, new paths to better health, pointing the way to treatments never dreamed possible. The industry is most encouraged about the prospects for exponentially better treatments—and, possibly, cures—for Alzheimer's, AIDS, arthritis, cancer, diabetes, heart disease, stroke, and many other diseases.

Just a few weeks ago, for example, a breakthrough drug for leukemia was approved. This medicine, which blocks the biochemical switch that causes normal cells to turn cancerous, heralds a whole new era of very promising cancer research. The FDA is reviewing an application for a new, life-saving drug that reduced the risk of death from sepsis by a dramatic 20 percent in a study published in *The New England Journal of Medicine.* Sepsis kills more than 1,400 people every day and is the leading cause of death in non-coronary intensive-care units with an estimated treatment cost of $17 billion annually in the United States.

Left sitting on the pharmacy shelf, medicines don't do anyone any good. Unless they are prescribed for patients, medicines cannot prolong life, ease pain, reduce disability, or make life better. And unless medicines are prescribed and used, they will not generate the funds needed for private industry to continue to research and develop future cures and treatments.

That is why PhRMA enthusiastically supports DTC advertising of prescription medicines, which is regulated by the FDA, and opposes any further restrictions on this pro-patient, pro-health activity.

Patients are seeking more information as they navigate the increasingly complex maze that is our health-care system. We believe more information is good. Medicines have been proven to be the most cost-effective form of health care and can often keep patients out of hospitals and nursing homes and help them avoid surgery and other, more expensive forms of care. For example, a 1998 study sponsored by the National Institutes of Health (NIH) found that treating stroke patients promptly with a clot-busting drug nets an average savings of $4,400 a year per patient by reducing the need for hospitalization, rehabilitation, and nursing-home care. According to NIH, use of this medicine could save the health-care system more than $100 million a year.

Background

Over the course of history, the medical community has resisted DTC advertising of prescription medicines. Physicians wanted tight control over what information

was conveyed to patients. In 1555, for example, the Royal College of Physicians in London decreed that "no physician teach people about medicines or even tell them the names of medicines." The fear was that people would use medicines improperly and be harmed.

That attitude persisted for more than 400 years. As recently as the mid-1980's, the FDA imposed a voluntary moratorium on DTC ads. After the moratorium was discontinued, many pharmaceutical companies began advertising their medicines directly to consumers, following FDA rules.

In 1997, the FDA issued guidelines that clarified the agency's broadcast advertising requirements. No longer would the FDA require ads to contain voluminous and often confusing information about a drug's side effects in radio and television ads. Under the FDA's draft guidance, ads must list major health risks as well as side effects, and must set forth four ways for consumers to receive additional information: through an 800 number, an Internet site, reference to a print ad in a major national publication, and through their physician or pharmacist.

The FDA's 1997 decision stemmed from a policy that had led to ineffective and confusing advertisements. Prior to the 1997 guidance, the FDA required that a brief summary of the prescribing information for a drug had to be included in all advertisements that both name a prescription drug and state its purpose, including broadcast ads. The brief summary is an FDA-approved document that advises physicians, in very technical language, how to properly use a drug. Because of technical, scientific wording in the brief summary, it is very difficult for patients and consumers without a medical background to understand.

Prior to the 1997 guidance, pharmaceutical companies that wanted to include both the name of a drug and the condition it was intended to treat were forced to include the small print that constituted this complicated prescribing information. While feasible in newspapers and magazines, such ads were not possible for radio and television. This prompted companies to advertise on television in more oblique ways that, while meeting legal requirements, may not have been very helpful to patients. In such ads, *either* the name of a medicine *or* the name of the illness could be mentioned—but not both. Consumers were often left to guess what disease a medicine was intended to treat.

This system was clearly unsatisfactory. As Dr. William Jacott, a trustee of the American Medical Association (AMA), said at the time: "The problem with the way the FDA currently regulates ads is that they discourage companies from providing information that may educate the consumer. The merest mention of symptoms and a drug requires that a company also include reams of information that most people won't read and many wouldn't understand anyway."

In announcing the clarifying guidance in August 1997, Michael Friedman, M.D., then FDA Lead Deputy Commissioner, said: "Today's action can help promote greater consumer awareness of prescription drugs." And Robert Temple M.D., Associate Director for Medical Policy at the FDA's Drug Division, said that, under the new guidance, ads could inform consumers about new products about which they might not otherwise learn. As an example, he cited a new generation of antihistamines that don't cause drowsiness. "You need to be told by someone that those products are out there or you'll never know," he said.

The Information Revolution in Health Care

Under current practices, patients now are more actively involved in their own health destinies than ever before. The consumer movement and the information explosion have empowered patients to participate in decisions concerning their health care. Armed with information, patients have become active partners with health-care professionals in managing their own health care. And they are savvy consumers.

Rather than remaining uninformed and relying entirely on an increasingly complex health-care system, patients are asking questions, evaluating information, and making choices. Direct-to-consumer advertising provides a valuable resource for patients to obtain information about specific diseases, conditions, and treatments, particularly in rural areas of the country where access to providers and health-care information may be difficult.

Too often, many common yet serious conditions go untreated even though effective treatments are available. Affected individuals may not realize that they need treatment. Others who are aware of their symptoms may not know that treatment is available. Patients suffering from chronic conditions may be dissatisfied with their current treatment, but may be unaware that different options are available with fewer side effects or an easier dosing regimen.

Advertising, however, is only one source of user-friendly information that consumers have at their disposal. Some 50 consumer magazines focusing on health care

reach the news stands every month. Just about every television station in the country has an on-screen physician.

The *Physician's Desk Reference*, or *PDR*, once confined to doctors' offices, is now available in a consumer edition at pharmacy counters. Internet users can surf tens of thousands of sites dedicated to health-care topics. In fact, according to health-care consultant Lyn Siegel, about 25 percent of online information is related to health care and more than half of the adults who go on the web use it for health information. So, while DTC advertising is an important source of information for consumers, it is clearly not their only source. But DTC advertising is the most accurate because it is regulated by the FDA.

DTC advertising helps to meet the increased demands of consumers for information about diseases and treatments. Most important, DTC advertising can improve public health. It is intended to start a dialogue between patients and doctors. Often, this dialogue will not result in a doctor prescribing the drug mentioned by a patient. But it will prompt a discussion that may lead to better understanding and treatment of a patient's condition. It should be emphasized, however, that physicians ultimately decide whether therapy is needed, and, if so, which therapy is most appropriate for a particular patient.

Underdiagnosis and Undertreatment

Pharmaceutical advertisements raise awareness of conditions and diseases that often go undiagnosed and untreated. For example, the American Diabetes Association estimates that six million Americans have diabetes but don't know it. One third of the people with major depression seek no treatment and millions of Americans are unaware that they have high blood pressure. By informing people about the symptoms of such diseases and the availability of effective, noninvasive treatments, DTC advertising can improve public health.

There are encouraging signs that this is happening. Following are just a few examples:

- A survey by *Prevention Magazine* found that, as a result of DTC advertising, an estimated 24.7 million Americans talked to their doctors about a medical condition they had never discussed with a physician before. In other words, millions of people who had previously suffered in silence were encouraged to seek help.
- A 1999 survey by the FDA found that 27 percent of respondents asked their doctors about a condition they had not discussed before. Conditions ranged from diabetes and heart disease to arthritis, depression, and other undertreated conditions.
- In the two years that ads for a medicine for erectile dysfunction have appeared, millions of men have visited their doctors to request a prescription for the drug. For every million men who asked for the medicine, it was discovered that an estimated 30,000 had untreated diabetes; 140,000 had untreated high blood pressure, and 50,000 had untreated heart disease. These numbers are striking—and they're just for one drug.
- A study by IMS Health, a health-care information company, found that, in the one year after an advertising campaign for an osteoporosis drug began, physician visits by women concerned about this disease doubled.
- According to a survey by Scott-Levin, a consulting firm, the number of patients visiting their physicians for treatment of depression has increased from about 17 million in 1996, before treatments for depression were widely advertised to consumers, to more than 20 million last year.
- Some 19 million Americans have moderate to severe disability from migraines, and 11 million of them are untreated or are treated sub-optimally. Migraine sufferers miss more than 157 million workdays a year and cost U.S. employers as much as $17 billion annually in decreased productivity. The good news is that, since migraine medicines began to be advertised to consumers, the number of people who visited their physicians for treatment rose from about 6,200,000 in 1996 to about 7,100,000 last year, according to a study by Scott-Levin.
- Many health-care organizations reported an increase in requests for information since DTC advertising restrictions were eased in 1997. For example, the American Foundation for Urological Disease experienced a 30–40 percent increase in requests for information.

Spillover Benefits

According to a recent analysis of consumer surveys by John E. Calfee, Ph.D., of the American Enterprise Institute, DTC advertising also provides important "spill-

over" benefits to patients, which have nothing to do with the specific products advertised.

One such benefit is an increased awareness that virtually all prescription medicines have risks and side effects. In addition, physicians, when discussing conditions highlighted in advertising such as obesity and high cholesterol, are able to suggest lifestyle changes to their patients. And DTC advertising also improves compliance—it prompts patients actually to take their prescribed medicines. In response to a *Prevention* survey question, 31 percent of the respondents said that ads made them "more likely" to take their medicines regularly, compared to only 2 percent who said they were "less likely" to do so.

According to Express Scripts Senior Director of Outcomes Research, Brenda Motheral, Ph.D., who was quoted in the *Pink Sheet* on March 5, 2001: "People are sticking with their chronic medications in higher proportions than what we've seen in the past . . . Probably a big driver of that, based on some work that our group has done, is direct-to-consumer advertising."

The Views of Consumers, Physicians, and Regulators

A growing body of evidence suggests that consumers like DTC advertising. A 1999 survey by the FDA found that those who liked these ads outnumbered those who did not by nearly 2 to 1. Eighty-six percent said the ads "help make me aware of new drugs," and 62 percent said the ads helped them have better discussions with their physician about their health. A survey by *Prevention Magazine* found that 76 percent of respondents thought the ads "help people be more involved in their health care" and 72 percent felt the ads "educate people about the risks and benefits of prescription medicines."

The best way to understand how patients feel about DTC advertising is simply to listen to them. Following are comments from patients written to PhRMA companies:

A patient with herpes wrote: "For many years people have suffered in silence and shame. Making it known that this product is available helps those in need. Putting advertisements in magazines and television was a wonderful idea."

A patient with chronic obstructive pulmonary disease (COPD) stated: "You have a commercial on TV that mentions COPD and educates the public—in about 30 seconds—as to the prevalence of the disease. I firmly believe more public education is not just useful but necessary as the number of people with COPD increases. So I want to thank you for raising public awareness of this dreadful disease, and also I want to say thanks for helping to keep me alive these past ten wonderful years."

Finally, a patient with asthma wrote: "My concern is the fact that this product is not being advertised enough. I have cut back my asthma episodes by 80–90 percent. I have had asthma since I was 3 years old and am now 51. Please get the word out about how well this product works."

There also is growing acceptance of DTC advertising by doctors. Historically, physician organizations, as well as individual physicians, have expressed concerns about DTC advertising. However, a 2000 survey by Louis Harris Interactives and the Harvard University School of Public Health found that 64 percent of doctors believe that DTC advertising of prescription drugs helped "educate and inform" their patients, and 40 percent of the doctors surveyed believe the ads increased patient compliance.

A 1999 survey by the FDA showed that, when patients asked physicians about an advertised medicine, 81 percent of patients said the doctor welcomed the question. Only 4 percent said their physicians appeared angry or upset when asked about a medicine. According to *Prevention,* only 26 percent of patients who talked to their physicians about an advertised medicine actually asked for a prescription, while 72 percent asked for more information.

The AMA continues its support of accurate pharmaceutical advertising as "appropriate and legal," according to a letter by Dr. Richard Johnson in the July 6 issue of the *Bergen Record.* Writing to clarify recent reports about AMA's policy on DTC advertising, Dr. Johnson, who heads the Association's relevant Reference Committee, stated that the Committee provided language to the AMA House of Delegates "from numerous physicians who testified that DTC ads are valuable because they sometimes educate consumers about health conditions and possible treatments that inform consumers better. Testimony also indicated that drug ads may encourage some patients to seek out their physicians and have more knowledgeable discussions about their health conditions and, if applicable, treatment options."

The FDA, reaffirming in August 1999 its policy of permitting DTC advertising, stated: "FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising."

Increased Drug Utilization: a Positive Development

Critics of DTC advertising claim that it drives up pharmaceutical expenditures. While total pharmaceutical expenditures are rising because there is a growing realization of the value of prescription medicines, drug expenditures still make up less than 10 cents of every health-care dollar.

The fact that more patients are getting more and better medicines is good news—for patients, for the health-care system, and for society. Just a few weeks ago, the federal government published new cholesterol standards in an urgent attempt to encourage people to reduce their risk of heart attacks. The National Institutes of Health recommended that millions more Americans should take cholesterol-lowering drugs, which would nearly triple the number of adults using these drugs. Dr. Claude Lenfant, director of the Heart Institute, said that adherence to these guidelines could mean that heart disease would no longer be the top killer of Americans.

Following are a few more examples of the cost-effectiveness of medicines, using drugs that have been the subject of DTC advertising:

- A cholesterol-lowering drug was found to reduce hospital admissions by a third during five years of treatment, according to a study by University of Pennsylvania researchers. In addition, patients who were admitted to hospitals had shorter stays and were less likely to need bypass surgery or angioplasty. Said Dr. Sanford Schwartz, a physician and economist at the University of Pennsylvania: "This is both good medicine and good economics."
- A study published in *The Journal of the American Medical Association* showed that treating Type 2 diabetes with a medicine to improve glycemic control improved the quality of life for patients and helped keep them out of the hospital and on the job.
- A study published in *Health Economics* found that medical costs declined by $822 per employee per year and absenteeism dropped by nine days when depressed workers were treated with prescription medicines. Savings from improved productivity and the reduction in work loss and medical costs far outweighed the cost of the treatment.

Advertising Promotes Competition

People often confuse total drug expenditures, which are going up for the public-health reasons just outlined, and drug-price increases, which have been in line with inflation in recent years. According to IMS Health, total drug expenditures rose 14.7 percent in 2000. Of that figure, only 3.9 percent represented price increases. The remaining 10.8 percent reflects utilization—the fact that more patients are using newer and more effective medicines.

The increased use of prescription drugs is a healthy trend. Drugs not only save lives—they save money in many cases by reducing the need for alternative, more expensive care such as hospitalization, confinement in a nursing home, and surgery. Still, only 8.2 percent of every health-care dollar is spent on prescription medicines, compared to 32 percent on hospital care and 22 percent on physician and clinical services.

Historically, advertising has promoted competition and increased volume of sales. If anything, this tends to lead to lower—not higher—prices.

Conclusion

In summary, DTC advertising helps to meet the increased demands of consumers for information about diseases and treatments. More important, however, DTC advertising can improve public health. It is intended to start a dialogue between patients and doctors that may lead to a better understanding and treatment of a patient's condition.

Mr. Chairman and Members of the Subcommittee, I hope that you will support patients and oppose those who advocate adoption of a "don't tell, don't ask" public-health policy: don't tell people about new medicines—and hope they won't ask. That policy would be detrimental to public health.

Instead, I hope you will stand behind the patients' right to know about new medicines, to seek information from a variety of sources, including DTC advertising, and to work with their physicians to help themselves to better health. Ultimately, a physician determines the appropriate medical treatment and may or may not prescribe a medication that may or may not have been advertised and mentioned by a patient.

Thank you very much. I would be happy to answer any questions.

Senator DORGAN. Dr. Glover, thank you very much.

Let me ask a question or so of Mr. Calfee, and if Senator Wyden has a question for Mr. Calfee, and then we will allow him to catch his airplane.

Mr. Calfee, you indicated that advertising makes markets work better, something that I agree with. Are there peculiar or unusual different circumstances with respect to advertising of prescription drugs? Others on the panel have talked about the need for regulation in this area of advertising. Do you believe that in this area of advertising regulation is necessary? We obviously now have some regulation. Some are calling for more.

Mr. CALFEE. We have a lot of regulation. I would say the prescription drug advertising is regulated more stringently than advertising for any other products available in this country. The FDA is unique, I think, among agencies in the stringency with which it regulates advertising. Maybe the SEC is somewhat equivalent with securities ads, but for ordinary products, for products that people buy, FDA advertising is far stricter than it is for any other products.

But in addition, the big difference, of course, is that you need a prescription. Two colleagues of mine and I recently did a study of advertising for the statin drugs, Lipitor, Zocor, et cetera, and we gathered proprietary data to look and see what happens in this market when DTC advertising goes up and down, and it does go up and down very rapidly. We could not find any connection between the gyrations in the advertising and changes in the prescriptions of these drugs.

As far as we can tell, the reason for that is that an ad may get you to talk to your doctor about a drug, but once the drug comes up, once you are talking to your doctor, the doctor's influence appears to be overwhelming over other considerations. In the case of statin drugs, if you talk to your doctor about a drug, the doctor probably will tell you: Well, how much do you weigh, what is your diet, and things like that, do you ever exercise, check your cholesterol, and then probably put you through to some advice for some lifestyle changes, and it is pretty far down the road before you may or may not get a prescription, and then the prescription will be whatever the doctor thinks you need, if anything.

Senator DORGAN. Mr. Calfee, that conclusion seems to be at odds with the conclusion that Ms. Chockley talked about, saying that the most heavily advertised drugs in 2000 had an aggregate sales increase of 32 percent compared to 14 percent increase for all other drugs. One would expect that, A, advertising works and, if it works, those drugs that are the most heavily advertised would have the highest increase in growth in sales. That is exactly what Ms. Chockley was testifying to.

You seem to suggest that is not the case.

Mr. CALFEE. Yes. I have looked at a lot of advertising research over the years and it turns out that if you look at a market you often see that advertising follows roughly the same pattern as sales, but if you look very closely at the data often what you find is something that Nancy Ostrove of the FDA mentioned, which is that manufacturers tend to advertise products that are doing well. In other words, they have found that if a product is really doing well, then they may get more payoff from the advertising, at least

for their particular brand, because after all what they are really advertising is their brand, not the entire product category.

So often what you find is that advertising tends to follow sales rather than leading the sales, and whether advertising actually increases those sales is often a very iffy question. It is very difficult to determine, and sometimes the advertising does do something for the brands, but does not do it for the whole product category.

Senator DORGAN. Mr. Calfee, you are describing something that is foreign to my experience of study as an MBA student, that advertising follows sales performance. That would rewrite the book on marketing as I knew it.

Mr. CALFEE. You will find some books that you would not be able to rewrite.

Senator DORGAN. Maybe I did not read them.

Senator Wyden.

Senator WYDEN. Just one if I could, Mr. Calfee, on this question of the ramifications for generics, because this is—we all acknowledge that there is virtually no studies at this point, there is no analysis, and clearly more needs to be done. But it seems to me that we do know that direct-to-consumer advertising is increasing the volume of these drugs, these brand name drugs.

You develop the affinity with your physician and the use of that drug, and it just seems to me again conceptually that it is likely that you will be using generics at some point.

Do you disagree with that?

Mr. CALFEE. To the general principle that advertisement on the whole on average tends to increase sales of a product, I do not have any objection to that as a general principle. It turns out that the effect is usually much less than what people think it is.

Now, in the particular case of branded versus generics, I guess the real question is whether or not advertising somehow heads off a switch to generic drugs when generics become available. There may be some effect in that direction. We do not really know for sure. What we do know, of course, is that when generics appear market shares shift very rapidly and prices tend to drop very rapidly. So generics do quite well when they get in the market.

Senator WYDEN. Well, we are going to explore this. I heard Dr. Glover say are we getting into a do not ask, do not tell kind of relationship. I am for asking, I am for telling, but I am also for looking at carefully some of the ramifications here that have not been looked at. I think that is what troubles Senator Dorgan and I.

I will have some more questions in a moment. I know you have to get a plane.

Senator DORGAN. Mr. Calfee, thank you for joining us today and you are excused.

Let me ask a couple of questions of the others. Dr. Wolfe, you in your testimony described part of what I was asking our first witness about, Dr. Ostrove. That is the issue of enforcement and enforcement of regulations specifically. You indicated that you felt the FDA has had a reduced level of enforcement even ad advertising has increased?

Dr. WOLFE. According to their own data, there is almost a 50 percent decrease in the last 3 years in enforcement actions. As Dr. Ostrove said, that is a combination of both direct-to-consumer and

prescription, but I believe, contrary to what she said, that there has been as much of a falloff, particularly in the last year or so, in direct-to-consumer enforcement activities.

I would be interested in seeing the data, but the point is that the people there that she described, the approximately 13 or 14, are not much more than there were before there was no direct-to-consumer advertising or virtually none in the early nineties. It is nowhere near enough. The number of venues—television, radio, print, and so forth—have just outstripped—and whereas we ourselves strongly believe, have published a number of books, some best-selling books on getting accurate information to patients, they do not have drug ads in them and they do not have a biased viewpoint. They have a review of published studies and experts in every field.

When you start getting into the conflict of interest of putting out "information" that is really primarily intended to sell drugs, not primarily intended to educate, it needs serious policing. The FDA is an agency in the public health service. It is not doing an adequate job policing. I am told they are interviewing some people now for some more positions. We have made requests to the FDA commissioners for 10 or 15 years to ask for more than the number of positions they have in this important part of the FDA.

Again to repeat what Dr. Kessler had said long ago and what I agree with, everyone thinks about the drug approval process as one which, if it goes wrong, a drug that is unduly safe will get on the market and someone will die. People do not think as much as they should about the advertising policing process, because if people write a prescription, a doctor writes a prescription based on his or her own advertising input to patients, and it turns out that they could have written a prescription for a safer drug, for a less expensive drug, the patient does not do well.

This has to be policed much more than it has. Whereas the number and amount of money being spent on direct-to-consumer advertising has skyrocketed up, the other kinds of advertising have also increased, not as dramatically, but the overall, as mentioned, is close to $16 billion a year. It is an enormous amount of money and the amount of money in FDA's budget to do surveillance over it is inadequate. We need better policing. Otherwise whatever is being done which is selling drugs is being done on a sort of hucksterism kind of basis to the extent that the ads are misleading.

Senator DORGAN. Dr. Glover, if in the last year there was a 19 percent increase in the cost of prescription drugs, substantially because of increased utilization, some as a result of price inflation, and if one believes that advertising works and therefore, if advertising works, that has in part contributed to that 19 percent increase—you may disagree with that pretext—but if that is the experience, what do you expect will happen on behalf of PhRMA with respect to the cost of prescription drugs next year, the year after, the year after that?

We have seen three very healthy double-digit years of cost increases. Where is this heading?

Dr. GLOVER. Assuming that your facts are correct, first off, we believe this is a difference between the price of pharmaceuticals, which has remained in line with inflation, and the cost of pharmaceuticals. The cost of pharmaceuticals is driven both by price and

by volume. In a society where you are shifting your health care dollars from more expensive forms of care, such as physician services and hospital stays, to the pharmaceutical industry, it is a good thing and it is in the public health and it is pro-consumer to have more of those dollars go to prescription pharmaceuticals that keep people on their jobs, in their communities, and out of hospitals and consuming much more expensive care.

Therefore, while I cannot predict where the number is likely to go in the future, we should applaud the possibility that we will have newer and better medicines that people will want to use, that physicians will want to use, in lieu of putting people in hospitals and sending them to physicians at a much higher cost overall to society.

Dr. WOLFE. I just want to I think correct the record. PhRMA has repeatedly stated that the price increase—now we are talking about price, not the volume, but the price increase—of prescription drugs is in line with the consumer price index. I have heard this over and over again. I looked at the data on the consumer price index. From 1991 to 2000, a 10-year period, the consumer price index for prescription drugs went up 1.7 times more than the consumer price index for all items, and in the last 5 years it sent up almost 3 times more.

So this statement that this overall expenditure is largely due to things other than price and that price is in line, to me a 1.7-fold increase above the consumer price index in 10 years and almost 3 times is not exactly in line. It is out of line. It is not the only reason why we are paying more for drugs, but it is an important reason.

Ms. CHOCKLEY. The 19 percent number is ours. It is from NIHCM, and so I can tell you how it breaks down actually. Between 1999 and 2000 retail prescription drug spending went up by $20.8 billion. What we have found is 42 percent of it was due to, the increase in prescription drug spending, was because of the increase in prescriptions, so 42 percent. 36 percent was due to a shift from less expensive drugs to more expensive drugs, and 22 percent was because of just pure inflation.

Senator DORGAN. Dr. Glover, do you wish to respond, and then I will call on Senator Wyden.

Dr. GLOVER. Certainly, in two respects. First off, the NIHCM number of 19 percent is the percent that includes costs other than the costs that are charged by the pharmaceutical companies. It includes costs that are added on by retail pharmacies to the costs that go to consumers.

Second, with respect to Dr. Wolfe's comments about the inflation rate, it is not clear until we look at the numbers whether 1.7 percent is substantially out of line.

Dr. WOLFE. 1.7 times, not percent. 1.7 times larger than the consumer price index.

Dr. GLOVER. Dr. Wolfe, given that the consumer price index inflation rate has been very small for the last 10 years, 1.7 times does not indicate the severity of any disparity that you want to show.

So at any rate, our position, we maintain what I said as being accurate, that we did not say that it was the same as or lower than

the CPI. We said it was in line with the CPI. It is not twice the CPI, it is not ten times the CPI. We still stand by our position that the majority of the price increase is due to increased utilization, which is something that is good.

Senator DORGAN. Senator Wyden.

Senator WYDEN. I will get us back to the more mundane subject of direct-to-consumer advertising. Dr. Glover, economics 101 suggests to me that the drugs that are going to be advertised are the ones that are going to be money-makers. It is just plain and simple. It is a marketplace economy. Those are going to be the ones that get advertised. So drugs that many people are going to need, but are ones that there is not significant profit in, are not going to get the same kind of attention in direct-to-consumer advertising.

So I wonder if what you are really talking about is an ask and tell policy, but only with respect to drugs where you can make a significant profit. That would concern me as well in terms of the ramifications for our society. How would you respond to that?

Dr. GLOVER. In the scheme of drugs that are patent protected, I do not know what the difference is between the advertising for those products that are more profitable than others. Your earlier question suggested that you were drawing a distinction between patent protected pioneer drugs and generic drugs. Pharmaceutical companies——

Senator WYDEN. I am not asking about that now. I am just talking about economics 101. You advertise where you are going to make money, and there are a lot of drugs folks need where you are not going to make a lot of money. So it seems to me that your asking and telling policy, which I happen to think makes a lot of sense, I think that is in the interest of empowering consumers, really is not one that applies across the board, but it is an ask and tell policy that relates only to drugs where there is a significant profit to be made.

Dr. GLOVER. Well, clearly, Senator, it only makes commercial and economic sense for companies to advertise products that they are most interested in selling. But you cannot suggest that we are advertising profitable products in lieu of advertising unprofitable products that could be equally substituted for the same condition.

As FDA has indicated and as the pharmaceutical industry will tell you, the products that get most of the attention are products that are true innovations, that are having a substantial impact on patient care. Those products are often the same products that patients most need because what was previously available was insufficient.

Senator WYDEN. I am just dying to have somebody in American enterprise show me where they are advertising unprofitable products.

Dr. GLOVER. I do not think any industry intentionally advertises unprofitable products, Senator.

Senator WYDEN. I thought that is what you just said, that there is no evidence of whether you are advertising profitable products or unprofitable.

Dr. GLOVER. No, what I said, Senator, is that it is unlikely to be the case that anyone is advertising a profitable product for which

there is an alternative that is less profitable. These are drugs where there usually is no alternative.

Senator WYDEN. I just think that the policy of asking and telling, which I support, ought to extend across the board, and I do not get the evidence that that is the case. If there is any information that you could supply us for the record that would indicate that it is applying to a variety of these other products where there are not significant profits to be made, I would very much like to see it, and Senator Dorgan has made it clear he is going to hold the record open.

One other question——

Dr. GLOVER. You should not expect that that information exists, Senator.

Senator WYDEN. Right. But you made the claim.

Dr. GLOVER. I made the claim.

Senator WYDEN. That is why I was interested in it.

Dr. GLOVER. I made the claim that in every industry no one intentionally advertises unprofitable products. You should not expect this industry to be any different. I also made the claim that the products that get advertised are the pharmaceutical innovations. For those products there is no unprofitable alternative.

Finally, as with every other industry, we do not force people to advertise things that are not in their commercial best interest.

Senator WYDEN. Ms. Chockley, if I might, you called for an independent source to try to make sure that people got accurate drug information. That operation is going to be a busy one. Suffice it to say they would have to handle information that goes out over the Internet and information that is available from a variety of sources.

Who do you think should be the independent source in this country for monitoring the drug information that gets out?

Ms. CHOCKLEY. I think it has to include all stakeholders, so it should include the pharmaceutical industry, it should include the government, it should include doctors, most importantly. But I think that we are going to continue to see this trend increasing and the growth in pharmaceuticals I think everyone is predicting is going to continue at this high rate.

I think it behooves us all to have an independent source of information, both for consumers and for physicians.

Senator WYDEN. So who sets this up? I am not clear. You want all these various people to sit around——

Ms. CHOCKLEY. And therefore make it unworkable?

Senator WYDEN. I thought it was an interesting concept. I was curious how it would work.

Ms. CHOCKLEY. Well, I think that that is the direction that we should move, then, is that there are a couple of—Rinehart and some other researchers are talking about trying to come up with more of an independent group that brings together the different stakeholders.

What is very interesting and kind of gets to a couple of the comments that you made is in the study where we showed that prescription drug spending went up by 19 percent, if you remember I said there were over 9,800 drugs. Half of the increase was in 23 drugs, half the increase. So we could do a lot by just looking at a

few number of drugs in terms of looking at how effective they are and when it is appropriate, etcetera, to use them.

Senator WYDEN. I will tell you, I think the industry has a valid point when they say there are a lot of reasons why the cost of drugs are going up.

Ms. CHOCKLEY. Sure.

Senator WYDEN. There are a whole host of them, and we do need to study the implications here. There is not anybody on the planet today, if they were redesigning Medicare, would not include a pharmaceutical benefit. I had a physician in Washington County at home who put a senior citizen in the hospital not long ago for 6 weeks because the person could not afford an outpatient benefit. So of course pharmaceutical spending went up in that kind of instance. But that was the government's fault, that was not the fault of anybody in the prescription drug industry.

But what I think Senator Dorgan has raised today are a variety of issues that we ought to be looking at. We ought to be looking at the implications on generic drugs. I have made it clear we ought to be concerned about that. We ought to be looking at the question of the doctor-patient relationship. We ought to be looking at the area Dr. Wolfe has talked about, ramifications for coupons and these programs that draw people in and once they have got them there is an affinity there. I think I made it clear to Dr. Glover that, while I support his ask and tell policy, I want it extended across the board in our society, and I am concerned about the ramifications that it may apply only to these profitable drugs.

So all of you have given excellent testimony and I wish I could spend the day with Senator Dorgan because he is doing important work. But thank you for this time.

Senator DORGAN. Senator Wyden, thank you very much.

Let me just mention—let me ask a brief question, Dr. Glover, and Dr. Wolfe wanted to comment, then I want to go to the next panel. Dr. Glover, in response to questions posed by Senator Wyden, he was asking I think a very specific interesting question, and I think your answer was, understandably, that the drug companies advertise where it is profitable and in their interest to do so.

But then it seems to me what Senator Wyden was getting at is if advertising direct-to-consumer is a public service and if it is done only in circumstances where it is profitable to do so for the industry, then it becomes only a public service to the extent that it profits the industry with respect to those specific drugs. Is that not the case?

Dr. GLOVER. That is clearly going to be—it clearly is going to be the case that we will advertise where it seems to be in our commercial best interest. We believe, however, and I believe that other panelists will confirm this, that there are spillover effects from our advertising for the drugs that we want to, namely that we raise consumer awareness about certain conditions for which there are treatments that were not previously available; and second, what we think is more important is that it stimulates a conversation with the doctor. Where these patients go in, they do not always get the drug that we have been advertising. They are often told they need to change their health care, their lifestyle. Sometimes they are

given an over-the-counter drug and sometimes they are given another prescription drug.

So while clearly we are going to advertise where we think it is in our best interest, we believe there are going to be spilloff effects there.

Senator DORGAN. Let me say that I think there are benefits to direct-to-consumer advertising and I think there are risks. I agree with Dr. Wolfe's opening statement that it is not the case where I think the clock will be turned back on this issue, but the risk questions I think in addition to the benefit issues pose some very interested challenges for us.

Dr. Wolfe, you wanted to make a comment.

Dr. WOLFE. Just a comment on the now absent Senator Wyden's question. One category of drugs where it is quite clear that the drugs with the best record in terms of preventing death from heart attack and stroke are the least advertised and the most advertised are the ones that do not have as much evidence, and that is for hypertension. Calcium channel blockers, which do lower blood pressure but do not have anywhere near the evidence of preventing stroke and heart attack that beta blockers and diuretics do, are much more advertised and have actually surpassed them in the number of prescriptions.

One can say why is it not that the companies that sell beta blockers and diuretics, many of which are generically available, to repeat that point, why do they not advertise? Well, some of them are just small generic companies that mainly cannot keep up with the brand name companies. But even some of them who are brand name companies do not want to advertise because they can make more money off of the much more expensive and, at least as the evidence is right now, less effective calcium channel blockers.

I think that is a good example where the advertising is not limited just to the breakthrough drug that is much better than anything else on the market.

Senator DORGAN. Dr. Wolfe, thank you very much. This panel has been very helpful and I thank you for your testimony.

I am going to call on the next panel, and as I do I want to recognize our ranking member, Senator Fitzgerald from Illinois. Next we are to hear from John Gilensky, Executive Director of RxHealth Value, Dr. Michael Shaw, Executive Director of EthicAd®, and Dr. Richard Dolinar, an endocrinologist from Phoenix, Arizona.

Let me welcome our ranking member, who has been on the floor of the Senate and is just now joining us, Senator Fitzgerald.

STATEMENT OF HON. PETER G. FITZGERALD, U.S. SENATOR FROM ILLINOIS

Senator FITZGERALD. Thank you, Senator Dorgan. I appreciate your holding this hearing and I am sorry that it conflicted with a floor speech I had to give about the problems at the O'Hare Airport in Chicago, which I am sure you have experienced at one time or another.

I think this is an important topic. I come to this debate with a fairly open mind. I have not previously taken a position on this issue. I come from a family where hardly anybody ever used prescription drugs. To this day, I think the only thing that my par-

ents, who are in their seventies, have in their medicine chest is aspirin. My parents were always cautious about taking any kind of prescription medicine, and that is the kind of orientation I have had in my own life with my own family, too.

I do believe that consumers benefit by having as much information available to them as possible. I am concerned, however, that direct-to-consumer advertising has in its initial years stimulated more usage of prescription drugs than perhaps would be optimal. I think that consumers will have to over time develop a healthy skepticism about those kind of ads. They may not have had that same kind of skepticism with respect to prescription drug advertising a few years ago because we did not have those kind of ads before then.

I know my nine-year-old child, when he was a few years younger, every time he saw an ad for a toy or for a cereal he would tell me we had to get it, that that cereal is the best cereal. I would say, how do you know that, and he would parrot a television ad that he had seen. Now as he has gotten older, he has realized that all those advertisements have to be taken with a degree of skepticism.

Just as he has learned that, I think consumers probably have to develop a healthy degree of skepticism with respect to prescription drug advertisements. But I am not sure that I would ever want to go so far as saying that we should prohibit or ban companies from making those advertisements. But really I come to this with a pretty open mind, and I want to compliment Senator Dorgan for his interest in the area and for convening this hearing.

With that, I welcome panel two.

Senator DORGAN. Senator Fitzgerald, thank you very much.

We have Mr. Mark—is it "CLO-tier"?

Mr. CLOUTIER. Correct.

Senator DORGAN. Mark Cloutier—let me amend my earlier announcement—Executive Director of RxHealth Value; Dr. Michael Shaw and Dr. Richard Dolinar. Mr. Cloutier, why do you not proceed.

STATEMENT OF MARK CLOUTIER, POLICY DIRECTOR, RxHEALTH VALUE

Mr. CLOUTIER. Thank you, Mr. Chairman. Senator Dorgan, Members of the Committee: I am Mark Cloutier, Policy Director of RxHealth Value, which is a national coalition of consumer groups, labor unions, provider groups, business groups, and employers, insurers and health plans, pharmacy benefit management organizations, and academic researchers who are committed to improving Americans' access to health-improving prescription drugs.

As you can understand, a deliberative body comprised of nearly 30 organizations will rarely arrive at a full consensus regarding any issue. Remarkably, our membership has achieved consensus regarding the recommendations I am offering regarding direct-to-consumer advertising of prescription drugs to consumers and patients. We believe safety is at stake. I believe the fact of these consensus recommendations indicates the fundamental importance of this issue for the members of RxHealth Value.

It is our belief that this form of advertising affects the health and safety of American patients and consumers. The tremendous

increase in the extent of direct-to-consumer advertising of prescription drugs since the FDA removed the requirement for brief summary of risk information in 1997 is well documented. It is almost impossible to open a general news magazine, view prime time television, or listen to the radio and not see or hear advertising for prescription drugs.

Given that the prescribing physician is the decisionmaker regarding the use of these medications, it is all the more startling that so many resources are expended by drug manufacturers to affect the attitudes of consumers and patients. Although there is little evidence, as we heard from Dr. Ostrove, currently available regarding whether consumer and patient attitudes affect physician choice in prescribing, no stakeholders in the health system and healthy economy have suggested that the impact of such advertising is insubstantial.

Given the FDA's expressed interest in assessing the effects of direct-to-consumer advertising, we expect more direct evidence of impact will be available in the near-term future. While we await the results of planned and pending studies on the effects of advertising on the attitudes, behaviors, and medical outcomes of consumers and patients, RxHealth Value members are concerned that risk information in particular is not adequately or effectively conveyed in direct-to-consumer advertising.

One of our member organizations, AARP, recently conducted a survey of members to assess the impact of direct-to-consumer advertising, finding that the majority of those surveyed could not recall ever seeing risk information in the ads. As you went up in age cohorts, there was even less recall of risk information. This poses a serious safety risk to consumers and patients.

In our first public recommendation to the FDA presented 1 year ago at the National Press Club, RxHealth Value emphasized the fundamental importance of protecting safety of patients and consumers who are confronted by DTC advertising. Thus, RxHealth Value recommends that the Congress direct the FDA to convene a task force of key stakeholders, including the pharmaceutical manufacturers who advertise prescription drugs, as well as consumer groups, patient organizations, provider groups, payers and relevant experts, to develop and test standards for information disclosure in direct-to-consumer advertising, to more carefully define the concrete meaning of fair balance in disclosing benefits and risks of advertised medications, to include disclosure of other appropriate therapies in addition to alternative medications.

As you may know, the AMA approximately a month ago passed a resolution calling on language "Your doctor may recommend other treatment options that may be equally or more effective." We want to support that resolution.

To further define "fair balance" to mean that full disclosure of risks and side effects be given equal print and air time as the description of benefits in the same communication.

RxHealth Value recommends that the appropriate agencies of the Federal Government conduct ongoing research to evaluate the effect of direct-to-consumer advertising on the health of American consumers and patients. It is a given that many Americans appreciate the increased awareness of diseases and conditions and poten-

tial therapies which direct-to-consumer advertising makes possible. It is also true that such advertising can obscure potential hazards of the pharmaceutical advertised and neglect the relative value of other forms of therapy.

Only thorough independent research can demonstrate the differential impact of such advertising upon the health choices of American patients and physicians.

In conclusion, the members of RxHealth Value applaud the Subcommittee for beginning the investigation of the effects of this increasingly pervasive influence on the therapeutic choices of American consumers and patients. We pledge our assistance in implementing any of these recommendations we have offered and thank the Subcommittee for this opportunity to comment.

[The prepared statement of Mr. Cloutier follows:]

PREPARED STATEMENT OF MARK CLOUTIER, POLICY DIRECTOR, RXHEALTH VALUE

Mr. Chairman, Members of the Subcommittee, I am Mark Cloutier, Policy Director of RxHealth Value, a national coalition of consumer groups, labor unions, provider groups, business groups and employers, insurers and health plans, pharmacy benefits management organizations, and academic researchers committed to improving Americans' access to health-improving prescription drugs. (Our membership list is appended below.) As you can understand, a deliberative body comprised of nearly 30 organizations will rarely arrive at full consensus regarding any issue. Remarkably, our membership has achieved consensus regarding the recommendations I am offering regarding Direct-to-Consumer (DTC) advertising of prescription drugs to consumers and patients. Safety is at stake. I believe the fact of these consensus recommendations indicates the fundamental importance of this issue for the members of RxHealthValue. It is our belief that this form of advertising affects the health and safety of American patients and consumers.

The tremendous increase in the extent of DTC advertising of prescription drugs since the FDA removed the requirement for the "brief summary" of risk information in 1997[1] is well documented[2]. It is almost impossible to open a general news magazine, view a prime time television program or listen to the radio and not see or hear advertising for prescription drugs. Given that the prescribing physician is the decision-maker regarding the use of these medications, it is all the more startling that so many resources are expended by drug manufacturers to affect the attitudes of consumers and patients. Although there is little evidence[3] currently available regarding whether consumer and patient attitudes affect physician choice in prescribing, no stakeholders in the health system and health economy have suggested that the impact of such advertising is insubstantial. Given the FDA's expressed interest in assessing the effects of DTC advertising, we expect more direct evidence of impact will be available in the near term future.

While we await the results of planned and pending studies on the effects of DTC advertising on the attitudes, behaviors and medical outcomes of consumers and patients, RxHealthValue members are concerned that risk information in particular is not adequately or effectively conveyed in DTC advertising. One of our member organizations, AARP, recently conducted a survey of members to assess the impact of DTC advertising[4] finding that the majority of those surveyed could not recall ever seeing risk information in the ads. This poses a serious safety risk to consumers and patients. In our first public recommendations to the FDA, presented one year ago at the National Press Club, RxHealth Value emphasized the fundamental impor-

[1] Draft Guidance for Industry: Consumer Directed Broadcast Advertisements: Availability. *Federal Register* 1997; 62:43171.

[2] Findlay, Stephen. Prescription Drugs and Mass Media Advertising. NIHCM, Sept. 2000.

[3] Bero, Lisa A. & Lipton, Shira. Methods for Studying the Effects of Direct-to-Consumer Pharmaceutical Advertising on Health Outcomes and Health Services Utilization. (Paper to be presented at ASPE Conference on Methods to Assess Effects of DTC Advertising, May 30, 2001).

[4] Foley, Lisa A. & Gross, David J. Are Consumers Well Informed About Prescription Drugs? The Impact of Printed Direct-to-Consumer Advertising. AARO: Public Policy Institute, April 2000.

tance of protecting the safety of patients and consumers who are confronted by DTC advertising[5]

Thus, RxHealth Value recommends that the Congress direct the FDA:

- To convene a task force of key stakeholders, including the pharmaceutical manufacturers who advertise prescription drugs, as well as consumer groups, patient organizations, provider groups, payers and relevant experts, to develop and test standards for information disclosure in DTC advertising.
- To more carefully define the concrete meaning of "fair balance" in disclosing benefits and risks of advertised medications to include disclosure of other appropriate therapies in addition to alternative medications.
- To further define "fair balance" to mean that full disclosure of risks and side effects be given equal print and air time as the description of benefits in the same communication.

RxHealthValue recommends that the Congress direct that the appropriate agencies of the Federal Government conduct on-going research to evaluate the effects of DTC advertising on the health of American consumers and patients. It is a given that many Americans appreciate the increased awareness of diseases and conditions and potential therapies which DTC advertising makes possible. It is also true that such advertising can obscure potential hazards of the pharmaceutical advertised and neglect the relative value of other forms of therapy. Only thorough, independent research can demonstrate the differential impact of such advertising upon the health choices of American patients and physicians.

In conclusion, the members of RxHealth Value applaud the Subcommittee for beginning the investigation of the effects of this increasingly pervasive influence on the therapeutic choices of American consumers and patients. We pledge our assistance in implementing any of the recommendations we have offered and thank the Subcommittee for this opportunity to comment.

Senator DORGAN. Mr. Cloutier, thank you very much.

Next we will turn to Dr. Shaw.

STATEMENT OF MICHAEL S. SHAW, M.D., EXECUTIVE DIRECTOR, ETHICAD®

Dr. SHAW. Good afternoon, Mr. Chairman, Senator. On behalf of EthicAd® and the health care community we represent, thank you to the Subcommittee for this opportunity to comment on direct-to-consumer advertising. This is the area to which our organization is dedicated. EthicAd® is an independent and neutral nonprofit organization composed of leaders of the academic health care community. Dr. Michael E. DeBakey is our chairman emeritus.

EthicAd®'s goal is to promote the development of DTC advertising in a manner that maximizes public health benefits. We do not oppose DTC advertising, we are not critics of the pharmaceutical industry. Rather, we support the idea that industry should work with other stakeholders to define voluntary self-regulatory standards for DTC. These standards should be designed to assure the American public that the DTC advertising they see represents reliable, accurate, and trustworthy medical information.

The pharmaceutical industry has a long and honorable tradition of collaboration with the health care community in the development of high quality professional and patient education programs. This traditional relationship is usually a collaborative effort between the health care community and industry. This system provides important checks and balances on the marketer, and I am certain this distinguished body understands the importance of checks and balances.

[5] Policy Recommendations. RxHealth Value May 10, 2000.

DTC represents a dramatic shift in this traditional relationship. DTC removes these important checks and balances. DTC provides an opportunity for industry to act autonomously to develop and disseminate health care information for the consumer without any outside input or review by the medical community.

The issue is not the relatively innocuous television and magazine advertisements. These highly advertised and visible programs are closely monitored by the FDA. They represent only the tip of the iceberg. Industry is investing hundreds of millions of dollars in a wide variety of consumer web sites, patient informational programs and relationship marketing projects.

The overwhelming majority of these arrangements are not reviewed by FDA. Who, then, assures the reliability of this information?

Currently this DTC content is developed by marketing departments and their advertising agencies, subject only to the internal medical review within a given company. Most DTC programs are not pre-approved by the FDA. Does this current system assure consumers of reliable and unbiased health care information? Industry has no uniform standards other than the expectation that they will comply with FDA requirements. But there are an estimated 60 to 70,000 pieces of DTC material developed each year. The FDA has only 13 full-time reviewers. As a practical matter, the FDA can review only a sampling of these materials. Clearly, DTC presents great potential for abuse.

There is a wide disparity in how different companies approach DTC. Many pharmaceutical companies are socially responsible and ethical in preserving consumer trust. Other companies take a narrower view. They focus on DTC merely as a mechanism to drive sales. The consumer is often unable to differentiate between those DTC programs designed the promote their health and welfare and those programs designed merely to promote sales. There are no standards, best practices, or even clear goals for DTC. There should be. We applaud the exceptional work of FDA. The agency has balanced conflicting demands of its stakeholders to review mountains of promotional materials using extremely limited resources. FDA is the American public's best protector in this area. It requires increased resources to manage the increased demands placed upon it by DTC.

But FDA regulations alone will not solve the DTC problem. These regulations represent minimum legal requirements. They do not and cannot and many would argue should not define optimal behavior. Clearly, something additional is needed. We do not believe that additional legislative action is required at this time. Instead, we suggest that there is immediate need for industry collaboration with other stakeholders in the development or support of voluntary self-regulatory goals, standards, and best practices. These standards will assure the American public that the DTC health care information they receive is reliable, understandable, and trustworthy.

Rather than wait for government or industry action, the academic health care community that EthicAd® represents has developed suggested standards and best practices. These specific standards are summarized in my full written testimony. We believe that

reasonable people develop responsible solutions. We welcome and need the active involvement of the pharmaceutical industry and the oversight of Congress and the FDA to implement voluntary DTC standards.

Thank you for the opportunity to share these views and to answer your questions.

[The prepared statement of Dr. Shaw follows:]

PREPARED STATEMENT OF MICHAEL S. SHAW, M.D., EXECUTIVE DIRECTOR, ETHICAD®

EthicAd®

EthicAd® is a non-profit organization representing the neutral and independent views of the academic healthcare community. The EthicAd® Steering Committee and Advisory Board is chaired by, Dr. Michael E. DeBakey, Director of the DeBakey Heart Center of the Baylor College of Medicine, and Donna Hill Howes, R.N., M.S., Director of Health Education for Time, Inc. Health. It is also composed of leaders in medical education. Many of those members have collaborated with the pharmaceutical industry in the development of professional educational programs and materials. EthicAd®'s Executive Director, Dr. Michael Shaw, is a physician, educational filmmaker, former-educational media specialist at the National Institutes of Health National Library of Medicine and President of Shaw Science Partners, Inc. in Atlanta, GA.

Part 1—Executive Summary

Direct-to-Consumer Advertising and Public Health

During the past two years, EthicAd® has studied the legal, ethical and practical issues underlying DTC advertising. In order to better understand the needs and views of the various stakeholders, we obtained advice and input from the pharmaceutical industry, regulatory community, consumer groups, healthcare professionals, managed care providers, insurers and members of the legislative community.

While a significant portion of the medical community and medical organizations are opposed to DTC advertising, EthicAd® maintains a different position. We respect the pharmaceutical industry's long tradition of developing valuable and credible professional educational programs. We believe that if industry takes proactive responsible steps to develop voluntary goals, standards and best practices, DTC advertising has the potential to make a significant positive contribution to public health. We believe that the major concern of healthcare professionals is not the existence of DTC, but the informational depth, quality and focus of the current genre of DTC advertising.

As a result of our research, we offer the following observations about DTC advertising:

1. The Pharmaceutical Industry Has Become a *De Facto* Member of the Healthcare System

DTC represents a dramatic departure from the traditional relationship of the pharmaceutical industry to the healthcare professional and patient. Prior to DTC, industry communicated directly to the healthcare professional through the common language of scientific studies and clinical data. When industry sponsored patient education materials, these were distributed to patients only after being screened by "learned intermediaries." DTC fundamentally changed this dynamic by enabling industry to provide healthcare information directly to patients. Because no tradition or common language exists for industry to communicate complex medical information to consumers, by default the "language" used is predominantly one of merchandise advertising. This emphasizes product image and brand awareness more than education. While this mode of advertising is appropriate for most types of consumer goods, society holds medical practice to higher standards. EthicAd® believes that there is an important rationale for asking industry to adhere to similar high standards. *Through DTC, the pharmaceutical industry has become a healthcare provider and a de facto member of the healthcare community.* In all other instances, society requires that healthcare providers undergo extensive training and licensure as a prerequisite for the privilege of providing healthcare to the public. EthicAd® believes that, when industry exercises the privilege of becoming a provider of healthcare information, industry must take similar self-regulatory steps to assure that the information it develops, sponsors and/or pro-

vides adheres to ethical standards comparable to those of other healthcare providers.

2. DTC—The Tip of the Iceberg

While DTC advertising is the most visible form of industry involvement in the delivery of healthcare information, the scope of this new relationship between industry and consumers goes far beyond television and print advertising. In recent years, industry has been systematically extending the "reach" of its marketing into less apparent direct and indirect forms of healthcare information delivery to consumers. These activities take various forms, from creating and sponsoring disease-state Internet sites, to creating and sponsoring patient advocacy groups whose goal is to promote patient information in a manner that is consistent with product marketing strategy. These activities do not necessarily fall within the category of "direct-to-consumer" programs but under the headings of:

- Relationship marketing;
- Industry-funded patient support programs; and
- Direct-to-patient marketing.

The scope and extent of these alternate forms of healthcare information delivery to consumers are not necessarily reflected as DTC spending. They can fall into other less apparent categories. Industry's involvement in communicating directly with patients through these more ambiguous channels is likely to expand exponentially given the rate of industry's growing investment in consumer data mining sources such as healthcare Web sites, online patient medical record systems, and pharmacy benefits management databases. These forms of patient data sources provide industry with the opportunity to market directly to patients within a specific disease category in a manner that may not be recognized as commercial advertising by patients and patients' families.

3. The Consumers' Need for Trustworthy Information

Based upon discussions with consumers, we believe that the public may be uncertain and confused about the reliability and impartiality of DTC healthcare information. As alternate forms of advertising, such as "infomercials," expand, it will become increasingly difficult for consumers to separate valid and unbiased medical information from commercial product advertising. They are also confused about educational efforts represented as "independent" but actually funded by industry. Activities such as disease-state Web sites may be represented as "independent" but may not necessarily be unbiased. For example, an "independent" consumer Web site about a cholesterol-lowering treatment may discuss the relative benefits of a particular class of drug used to treat high cholesterol in a medically accurate manner. But while the materials may be factually correct, they may not provide sufficient emphasis upon the fact that lifestyle modification (proper diet and exercise) might entirely eliminate the need for medication. Thus, while consumers and patients have enormous need for healthcare information, they are uncertain about whether they can trust material developed though industry funding.

An important question is, if industry is going to play the role of healthcare information provider, how can consumers trust that the information provided is independent, unbiased, medically reliable, and represents the patients best interest . . . not just the commercial best interest of the sponsor.

4. The Need for Voluntary Best Practices for DTC

There is enormous variability in the methodologies used by different pharmaceutical companies in the development of DTC campaigns and materials. Some companies take extraordinary steps to assure that the DTC programs they sponsor provide significant public health benefits. Those companies take systematic steps to gain input and suggestions from independent medical experts, consumers, and patient advocacy groups. Some companies develop comprehensive DTC campaigns that include patient education and patient care materials developed in collaboration with reputable independent third-party organizations and institutions. Other companies have a more restrictive view of DTC. They limit DTC activities to product advertising and promotion. Currently, there is no set of standards or best practices, or even agreed upon goals for DTC. Moreover, the consumer has no way to differentiate programs developed using these "best practices" from those that employ only a narrow commercial bias.

5. FDA Regulations Represent the Legal Requirements, Not the Highest Ethical Standards

We recognize that the FDA has ultimate regulatory authority and commend DDMAC for its excellent performance in balancing the complex needs of its stakeholders. However, there are limitations to the FDAs role given limitations in its regulatory scope and its finite manpower. While current FDA regulations are *necessary* to protect the public, they are *not sufficient* to assure that DTC programs promote the public good. The FDA has no regulatory authority to require that industry develop DTC programs in a manner designed to promote public health. For example, FDA regulations require that sponsors include a "Brief Summary" to accompany a product advertisement. The term Brief Summary refers to complex, exhaustive labeling traditionally used to inform physicians about the myriad of potential side effects and complications associated with a given product. While the FDA "encourages" pharmaceutical companies to modify this Brief Summary into a form that is understandable to patients, FDA regulations do not "require" pharmaceutical companies to do so. This is but one example of how current FDA regulations protect the public interest but do not require industry to act according to optimum standards.

We believe that there is enormous and immediate need for industry to develop voluntary self-regulatory DTC goals, standards, and best practices that promote development of consumer healthcare information that is reliable, understandable and trustworthy.

Part 2

Goals and Standards in Direct-to-Consumer Advertising of Ethical Pharmaceutical Products

Background

Advertising prescription drug products to consumers is a relatively recent phenomenon. The most visible form of DTC advertising, television commercials for prescription products where the indicated use of the product was identified, has only been in existence since 1997 when the FDA released its draft Guidance to Industry. Because DTC advertising is so new, there has not been enough time to fully assess its impact upon public health, or to evolve standards and best practices for DTC advertising. EthicAd® has been studying this issue for more than a year. It has obtained input from representatives of the pharmaceutical industry, advertising industry, healthcare professionals, regulatory agencies, patient advocates and, most importantly, consumers. The ideas for DTC Standards described below are based upon this research.

The pharmaceutical industry has a long and honorable tradition of collaboration with the medical community and government agencies in the development of new therapies and sponsorship of educational programs designed to promote public health. DTC advertising represents a fundamental shift in the nature of the pharmaceutical industry's relationship to healthcare providers, patients, and the public ("consumers"). Prior to DTC, industry made information available to healthcare professionals who then served as learned intermediaries in educating patients with information they deemed relevant. By permitting industry to provide health information directly to consumers, DTC advertising allows industry to function in a role traditionally reserved to trained and licensed healthcare professionals.

EthicAd® is not opposed to DTC advertising. We believe that providing the public with reliable, balanced, and understandable information about diseases, treatments and prevention can result in consumers developing more responsibility for their own health and well-being. EthicAd® believes that it is possible for the American people to derive public health benefits from DTC advertising if industry takes positive, responsible, and constructive steps to reduce the potential for bias in DTC information. Such voluntary efforts would also reduce the need, or likelihood, of systematic government regulation.

The Need for DTC Best Practices

The FDA has sole regulatory authority for promotional materials involving prescription pharmaceuticals. However, FDA regulations represent the minimum legal requirements, not optimal behavior. Professional organizations, consumer groups and the legislative community have raised serious questions about whether the current form of DTC advertising contributes to public health and well-being or merely raises the cost of pharmaceutical products and contributes to public confusion. EthicAd® believes that it is critical for the pharmaceutical industry to take voluntary constructive steps to assure that DTC advertising develops in a responsible manner.

Just as all healthcare professionals are trained in a set of ethical standards and their behavior monitored for adherence to those standards, we believe that industry must take concrete positive steps to assure that DTC information is consistent with the ethics of good medical practice based upon the following principles:

- By virtue of providing the public with health information through DTC advertising, the pharmaceutical industry has become a *de facto* healthcare information provider. As with any other health care provider, this is a privilege and carries community responsibilities.
- In enjoying this privilege, industry must exercise social responsibility to ensure that the information they provide to patients and the public is honest, fair, balanced, and comprehensive.
- In addition, industry should accept responsibility for using DTC advertising as an opportunity to collaborate with the medical community, patient advocates and government agencies to improve public health by dedicating a significant portion of DTC budgets to providing the public with non-promotional educational materials.

A Vision for DTC

EthicAd® is committed to promoting constructive change in the field of DTC advertising. One of the first steps is to develop a clear vision for DTC advertising.

We envision the next generation of "ethical DTC advertising" to be Direct-to-Consumer programs developed by the pharmaceutical industry in collaboration with other stakeholders (the medical community, consumer groups, government agencies) that are designed to meet the needs of the public for reliable, relevant and trustworthy information while also meeting industry's need to build brand awareness and promote appropriate use of its products.

There are several important elements to this vision. First, it acknowledges the fact that the pharmaceutical industry is, and has long been, an active participant in the health care system. Second, it recognizes and accepts the fact that the pharmaceutical industry is a business and not a charity. Industry participates in DTC because it expects a return on investment. There is nothing inherently wrong with this, but by definition, it does mean that industry has an inherent bias. In order to create "socially responsible" DTC, it is important to recognize, accept and adjust for that bias. This is the third component, the need for collaboration and for systems of checks and balances.

In order for DTC to meet the consumers desire for reliable and trustworthy information, industry can correct its inherent bias through collaboration with outside and independent advisors or organizations willing to assure the credibility, reliability, and balance of the information being presented.

EthicAd® Recommended Goals for DTC Advertising

The EthicAd® goals for Direct-to-Consumer advertising of pharmaceutical products are:

1. To provide consumers with substantive and reliable information about pharmaceutical products and the diseases that they treat.
2. To provide materials that increase consumer awareness of the signs, symptoms and treatment options for medical conditions.
3. To provide a mechanism for industry to develop and deliver materials to patients/consumers that can be useful in the patients' care or improve consumers' ability to ask more informed questions of their healthcare provider.

Best Practices for Development of Quality DTC by Pharmaceutical Industry

EthicAd® has determined that many, but not all, pharmaceutical companies take constructive steps to develop socially responsible DTC. The following are industry best practices that some pharmaceutical companies are already successfully employing in the development of DTC programs:

1. Ethical DTC advertising should provide consumers with reliable and accurate pharmaceutical products available for the treatment of a disease or medical condition without creating misimpressions or unrealistic expectations regarding,
   a. The specific patient population for which the product is indicated,
   b. The availability of non-pharmacologic means of therapy,
   c. Results that patients can expect from treatment, and
   d. Possible negative consequences from treatment.

2. All materials developed through direct or indirect industry influence and/or financial support should explicitly state the nature of such support and the nature of influence exercised by industry over the subject matter.

3. When designing a DTC campaign, industry should develop an advisory board of independent health care professionals and patient advocates at the formative design stage of a DTC campaign. The goal of this advisory board is to help identify the needs of patients and to assure that the approach being developed is consistent with public health interests. This best practice helps industry to create DTC programs that balance the needs of the company with the needs of the public and the healthcare community.

4. In DTC campaign development, industry should conduct a formal needs assessment of the informational and educational requirements of individuals who have a particular disease. In essence, this is a step to define what specific benefits a DTC campaign can provide for consumers and patients.

5. Industry should formally test DTC materials with consumers in order to validate the materials educational efficacy. DTC materials go through a rigorous process of focus group testing to assess how well they convey the sponsor's message. This testing can be expanded to evaluate whether the advertisements are conveying medical information clearly and effectively, and to assure that the advertisement is not creating any misimpressions.

6. Industry should develop consumer-friendly versions of the current professional "Brief Summaries." Not only has the FDA allowed industry to revise this material, they have encouraged industry to do so. From a best practice perspective, there is no reason why industry cannot revise the Brief Summaries of each and every product that is promoted through DTC by the end of 2002. These revisions should also be tested to assure that they are understandable to the average consumer.

7. Recommendations for DTC Content Design

a. Content accuracy is more than just lack of factual errors. Often materials can be misleading by omission of information that can provide objectivity and balance. The review process established by industry should include outside independent advice from medical experts to look for such important omissions or potential areas of confusion.

b. Responsible DTC should include information about behavioral and non-pharmacologic approaches to treatment and/or prevention. In many common diseases and conditions, such as hypertension and Type II diabetes, diet and exercise are the first-line therapy. DTC materials have the responsibility to inform patients of these important public health measures.

c. The use of statistics or data in DTC advertisement can be inherently misleading and, if used, must be presented in a manner that assures accurate understanding by the target audience. For example, stating that a drug reduces risk of a disease by 50% may be factually correct. But, that benefit may only be a reduction from 2% risk to 1% risk. To simply state a "50% reduction" is inherently misleading unless accompanied by a full and understandable disclosure of the meaning of the data.

d. Industry typically assesses DTC advertising materials by means of field tests and focus groups. These tests should be expanded beyond just marketing efficacy to include questions that measure whether the content is understandable to consumers and to assure that the content does not create misimpressions. That data should be made available to the internal DTC reviewers and should be available for submission if requested by the FDA.

8. Recommendations For DTC Design and Visual Presentation

a. Industry must recognize that patients, especially those with serious or chronic medical conditions, may be emotionally vulnerable to information that can be interpreted as suggesting unrealistic hope for improvement.

b. Print advertisements and broadcast commercials are expensive to develop and disseminate. Obviously, industry has the right to make these materials visually attractive so that consumers will pay attention. However, there is a point where the application of visual design that appeals to consumers' "inner self" and "inner desires" may become misleading to consumers by creating unrealistic hope. While this area is admittedly subjective, the main area of concern relates to the selection and portrayal of "role model" patients and the activities they are represented as performing.

c. Industry should establish a process for including outside medical advice regarding the selection and characterization of actors cast to depict patients suf-

fering from a condition or disease. Every effort should be made to assure that actors portraying patients are appropriate in age, sex, race, national origin, body habitus, and physical characteristics. Actors portraying patients become "role models" for how patients see themselves. They should be shown with performance and activities that represent realistic expectations for individuals who suffer from the respective disease or condition.

Part 3

EthicAd®

EthicAd® is non-profit organization dedicated to helping to promote increased public health benefits from DTC information about prescription pharmaceutical products. EthicAd® is a coalition of leaders from academic medicine and the healthcare community who are committed to working as a neutral and impartial body in collaboration with regulatory agencies, professional organizations, consumer groups, advertising agencies, and the pharmaceutical industry. Dr. Michael E. DeBakey is Chairman Emeritus of EthicAd®.

Our goal is to maximize the public health benefits of DTC information by providing the consumer with *substantive, understandable* and *reliable* information about pharmaceutical products. We will achieve this goal through the development and continuous improvement of "Ethical DTC Standards" for the development of DTC material. EthicAd® will focus upon the educational quality of DTC material, while taking into account the concerns of manufacturers and regulators. The role of EthicAd® is not to judge or evaluate individual products, but to promote high ethical standards and effective educational techniques for communicating information about those products. In addition, EthicAd® will review DTC materials and provide an "EthicAd® Seal" for DTC pharmaceutical information that demonstrates use of the Ethical DTC Standards.

Senator DORGAN. Dr. Shaw, thank you very much.

Dr. Dolinar.

STATEMENT OF RICHARD DOLINAR, M.D., ENDOCRINOLOGIST, ENDOCRINOLOGIST ASSOCIATES

Dr. DOLINAR. Senator Dorgan, Senator Fitzgerald: Thank you for allowing me to testify today. I am an endocrinologist in private practice in Phoenix, Arizona. I specialize in the treatment of diabetes. I received my undergraduate degree at SUNY College in Albany, New York, I went to medical school at State University of New York at Buffalo, and I did my training in diabetes and endocrinology at Duke University down in North Carolina.

I am also a retired Air Force colonel, Vietnam veteran, former flight surgeon. I mention my flying experience for the following reason: I want to use it as an example to make the case for direct-to-consumer advertising and to show you the value thereof.

When you are flying in an airplane and you smell smoke in the cockpit, you have got to address that issue immediately and aggressively. Otherwise that plane is going to come down sooner than you planned, at a location other than an airport, and the wheels are not going to be the first thing to touch the ground.

Likewise with diabetes. High blood sugars indicate the smoke of diabetes in a patient. If that is not treated immediately and aggressively, that patient is going to crash, and the crash is going to be in the form of a heart attack, a stroke, kidney failure, amputation, blindness. What direct-to-consumer advertising is doing is bringing patients into my office early so that I can treat them, can intervene.

We know that by treating diabetes, bringing the blood sugars under control, we can decrease the complications down the road. When you look at diabetes, it is the complications that really cost.

For example, if you do not treat the sugars and they get a heart attack, then they come into the hospital with a heart attack or stroke, very expensive.

In fact, your diabetes patients, they represent 6 percent of the population; they consume 15 percent of the health care dollar. On the other hand, if we can get them early and treat them, I am confident we can decrease the amount of dollars spent on the diabetes patient.

Direct-to-consumer advertising brings these people in for treatment. The other thing it does, it helps to reach out to those who are not diagnosed. The ADA estimates there are 6 million people out there with diabetes that do not realize it. By getting the word out to them and reaching out to those people and bringing them in, we can significantly help them. They really represent smoke in the cockpit of our health care system. There is an avalanche of diabetes that is now affecting our population.

I also think direct-to-consumer advertising is critically important today, especially in light of managed care. Managed care has changed the doctor-patient relationship. I started medical school in 1968 and over the last 30 years I have seen the changes. The doctor is now often faced with the problem of attempting to meet the needs of two masters: on the one hand the patient, on the other hand the managed care plan, the HMO, the insurance company.

On the one hand, he is trying to provide care. On the other hand, incentives and disincentives are set up to withhold care. In a situation like this, the doctor-patient relationship becomes an adversarial one. We have drugs available to treat diabetes that can save money down the road, but unfortunately many of the managed care plans have incentives in place not to treat these patients. So consequently the patient is in a very difficult situation, in a situation where you are in an adversarial relationship with your physician, you need everything you can to help you. Information is critical. DTC provides information to those patients.

I personally do not think that advertising burdens the physicians or negatively impacts on the doctor-patient relationship. In fact, I find that patients who have seen these ads on diabetes, hypertension, etcetera, are easier to work with. They know the seriousness of the disease, they know there are treatments out there, and they come asking for help. So I have found it to be a benefit actually.

I do not think it puts pressure on me to order drugs that are not necessary. If that patient does not require the drug, I do not order it.

If any of us were to go out and buy a house or buy a car or buy a stereo set, would we not get information from various sources before we made that decision? Yet when it comes to health care we seem to keep the patient in the dark. I think knowledge is power. I think it is critically important that patients have that knowledge, have that power, because currently they are trapped in their health care systems. They do not have choice. They have to take their employer's health care system. So we have limited choice, and now if we limit direct-to-consumer advertising we limit knowledge, and if we limit choice and limit knowledge how is that patient going to

work their way through the health care maze to get the care that they need?

Direct-to-consumer advertising provides information that is filtered through the FDA. It is regulated by the FDA. It is a better source of information than on the unregulated Internet or whatever hearsay the patient picks up from somebody down the street.

For the sake of the patients, I would ask you to vote against ignorance. I think anyone against direct-to-consumer advertising is really in favor of ignorance. I would ask you to vote against ignorance. I would ask you not to place any further constraints on direct-to-consumer advertising.

Thank you. I would be happy to take any questions.

[The prepared statement of Dr. Dolinar follows:]

PREPARED STATEMENT OF RICHARD DOLINAR, M.D., ENDOCRINOLOGIST, ENDOCRINOLOGIST ASSOCIATES

Mr. Chairman and Members of the Committee:

I am Dr. Richard Dolinar, an endocrinologist in private practice in Phoenix, Arizona, specializing in the treatment of diabetes. I earned my undergraduate degree at Siena College in Albany, New York, and my medical degree from the State University of New York at Buffalo. I did a fellowship in endocrinology and diabetes at Duke University. I am co-author, with Betty Breckenridge, of a book entitled *Diabetes 101,* a patient-oriented guide to this disease. It is in its 3rd edition and has been published in several languages. I am also a retired Air Force Colonel, a Vietnam veteran, and a former flight surgeon.

I mention my flight experience because I want to use an airplane analogy to make the case for the value of direct to consumer advertising of prescription drugs.

When you're flying and you smell smoke in the cockpit, you know that this is something that has to be addressed immediately and aggressively. If this problem is not addressed, the plane is likely to come down sooner than planned, at a place other than an airport, and the wheels are not going to be the first things that touch the ground.

If a patient's blood sugar is high, that's the smoke that warns of diabetes. Unless the problem is addressed immediately and aggressively, there will certainly be a crash—in the form of a heart attack, a stroke, kidney failure, amputation or blindness, all of which are complications of diabetes.

In my experience as an endocrinologist, direct to consumer advertising of prescription medicines is getting patients with diabetes into my office sooner, so they can be treated with effective medicines and avoid the dire complications of this disease. According to the American Diabetes Association, an estimated six million Americans have undiagnosed diabetes. This constitutes smoke in the cockpit of our health care system that, unless addressed, will lead to deadly, and costly, crashes.

People with diabetes make up about 6 percent of the U.S. population but account for 15 percent of health care costs—15 cents out of every health care dollar. For Medicare, the percentage is even higher because 1 out of 5 people over age 65 has diabetes. Twenty-five percent of Medicare costs go toward diabetes. The majority of this expenditure goes to the complications of diabetes, complications that put patients in the hospital or on the surgery table and can make them disabled for life.

If we can get diabetes under control, we can avoid these complications, saving lives and money. That's why it's critical to diagnose diabetes promptly and treat it aggressively. Direct to consumer advertising is helping us reach this important goal.

Direct to consumer advertising is bringing diabetes to the attention of people who might have it. It's pointing out the seriousness and possible complications of the disease. It's prompting people who may have diabetes in the family or may be feeling unusually tired, to see their doctors and be checked out. For people who are already diagnosed, the ads reinforce the fact that this is a chronic disease and that patients need to stay on their medicines.

Direct to consumer advertising is particularly critical in this era of managed care. Sadly, in many cases, the physician can no longer act as the patient's advocate. In health maintenance organizations, or HMOs, the physician is often forced into the uncomfortable position of being an adversary rather than an advocate. The way the system works, the physician makes more money if he or she provides less care. Although medicines, by helping avoid complications from diabetes, can save money in

the long run, HMOs, unfortunately, focus on the short run, the bottom line for the current quarter. And, since patients tend to change insurers every two or three years, there is always the hope that when the patient crashes, it will be on another HMO's watch.

In this environment, the patient needs all the help he or she can get. Specifically, the patient needs information about disease and possible treatments. Armed with such information, a patient may be able to successfully navigate the HMO maze and get needed treatment. Direct to consumer advertising is an excellent source of information. Since it's regulated by the Food and Drug Administration, it's a far better source of information than the neighbor down the street or the unregulated Internet.

I dispute the notion that direct to consumer advertising burdens physicians. I find that patients who have seen ads for diabetes medicines are informed and easier to work with. They are aware of the disease, and they know that it can be treated. Perhaps more important, they know that treating the disease now can make a difference down the road. They're ahead of the game and willing to take new medicines that can help them avoid the complications of diabetes.

Nor do I feel that direct to consumer advertising puts pressure on doctors to prescribe unnecessary medicines. Quite often, patients with Type 1, or insulindependent, diabetes come in with an advertisement for a pill they hope will enable them to stop insulin injections. I simply level with these patients and tell them that these new medicines work only for Type 2 diabetes. They are disappointed, but accept the reality that these pills are not appropriate for them. I do not consider taking the time to explain this to patients an inconvenience, and I resent any implication that I would allow pressure from direct-to-consumer advertising to influence my prescribing decisions.

If any of the Members of this Committee were buying a car or a house or even a television, I'm sure you would gather information about the purchase from a variety of sources. When it comes to health care, a much more critical decision, however, we seem to want to keep consumers in the dark. We need educated and informed consumers of health care. It's not right to withhold information about health care from patients. Direct-to-consumer advertising is an easily accessible, user-friendly, and FDA-regulated source of information about diseases and possible treatments.

To be against direct to consumer advertising is, in my mind, to be in favor of ignorance. Knowledge is power. That's why we're at this hearing, so we'll gain the knowledge to make the right decisions. Don't take knowledge away from them, too. How are patients to defend themselves and get the best care possible, if we limit both choice and knowledge?

For the sake of patients, I ask that you vote against ignorance and refrain from placing further restrictions on direct to consumer advertising of prescription medicines.

Thank you very much. I would be happy to take any questions.

Senator DORGAN. Thank you very much. You have provided interesting and in some cases different testimony about the same issue.

I recall an ad that has been on television for some long while about a young man what lost I think 140 pounds eating Subway sandwiches. Do you recall that ad?

Dr. DOLINAR. I do not recall that one, no.

Senator DORGAN. Well, do you recall it? Some guy walking around holding up the pants he used to wear. He dropped I think 100, 140 pounds by eating a certain deli sandwich at a franchise store.

I was thinking about advertising. You know, I am smart enough to understand that the proper weight loss program does not include going to a fast food store. But it seems to me in advertising it is kind of let the buyer beware, you make whatever claims you can make and let people assess those claims.

It is different, however, with respect to prescription drugs. I expect or I would expect that all of you would agree that there are risks that one must be cognizant of, and that is the reason we have a regulatory regime with respect to prescription drug advertising.

We want to make sure that what people are representing about the drugs is accurate, number one, and number two that we are giving some basic information about the risk of the drugs and so on.

There has been testimony today that the regulatory responsibility is not being met, not sufficient resources exist at the FDA. You have heard some of that discussion. Mr. Cloutier, what is your impression of that?

Mr. CLOUTIER. I would echo the support of Sidney Wolfe and others saying that, given the volume and the rate of increase, we have not seen a commensurate increase in staff and resources at the FDA to oversee and regulate this.

Senator DORGAN. Dr. Shaw?

Dr. SHAW. We actually have a very good relationship with the FDA and it is interesting that a lot of times there is internal pressure placed on them not to come to the Hill and ask for additional funding. But I think that if one took the individuals aside within FDA they would almost uniformly say that they are in desperate need of additional funding and staff.

Senator DORGAN. Dr. Dolinar, as a practicing physician you may not deal with that question day to day, but what is your impression of that?

Dr. DOLINAR. I would be happy to respond to it. First of all, the Subway sandwiches, I will have to get the reference on that so I can start using it in my practice.

But think about it. If we had the same constraints on advertising for Subway sandwiches and hamburgers, probably at the end of the advertisement there would be a disclaimer: This food could cause obesity, heart attack, high cholesterol, et cetera.

Senator Fitzgerald I thought made a very good point earlier when he said he had a nine year old boy who saw an advertisement and wanted something. But actually Senator Fitzgerald, being the parent, had control over whether that child was going to get that or not. I have a nine year old boy, Mark, and Mark came to me. He wanted me to build him a pipeline. I said, a pipeline? That is one of those things where you go flying on your skateboard, you go up in the air and flip around. I am the parent. I am not going to do that.

But my point is these are prescription drugs. What DTC does, it brings the patient in, it starts the process. Then the physician evaluates, is this an appropriate drug, is it not appropriate, is there something else we should be using. So I think that is important.

Also, just to share with you, as I have been sitting here listening to the proceedings I just could not help but think back to the 1950's. I was a child in the 1950's and at that time polio was a very big problem, in the early 1950's. Then the vaccine came out. I wonder, if this were the 1950's, whether we would be sitting here today pointing out that the amount of money spent on vaccines is skyrocketing and that this is a very bad thing and that we should not be advertising about polio because it is bringing all these people in to ask for this vaccine, when in reality there would be another chart with the number of iron lungs going in the opposite direction.

I think drugs are the solution, not the problem. I think when it comes to the world of diabetes, high blood pressure, heart attack, and stroke, it is not as obvious as that polio example I just gave

you, but I can assure you by using these drugs I can decrease blood pressure, blood sugars, cholesterol. I can decrease the chance of complications coming down the road.

So I find this to be very important.

Senator DORGAN. I would just observe that in the 1950's they could not advertise prescription drugs, and of course in the 1950's when Dr. Salk gave us the vaccine it became a matter of public health for us to deliver that vaccine to virtually everyone, especially all children in this country.

Yes, Dr. Shaw.

Dr. SHAW. Mr. Chairman, if I could follow up on your Subway sandwich analogy, as long as you have offered it. I think that what I have heard here is almost universal agreement that DTC has the potential to do great good and the pharmaceutical industry in the United States and globally is one of the best assets for health care that exists, period. It is just a question of a squandered opportunity.

With your Subway analogy, there is an opportunity to talk to the American people, not just about which lipid-lowering drug is best, but the fact that if you went back to Subway and started using their low-fat sandwiches or other modifications that in fact you could reduce or eliminate the potential for heart disease or atherosclerotic that two-thirds of the American citizens are going to die from, approximately, and two-thirds of the world's population does not have this entity.

Why can this opportunity be used also, not just to promote drugs, but to promote public health?

Senator DORGAN. Let me just make one quick comment. I do not dispute at all that there is good that can be achieved by direct-to-consumer advertising. The issue we have not discussed in great detail because that is not what the hearing is about is the substantial increased cost and pricing of prescription drugs, which I think one could have a hearing or several hearings just on the question of pricing and whether that pricing is fair.

But let me call on my colleague Senator Fitzgerald.

Senator FITZGERALD. Thank you, Mr. Chairman.

Thank you, all of you, for your testimony. It is all very good. I wondered really if our tort system in your opinion does not provide a sufficient check on rogue behavior on the part of prescription drug advertisers. I do not know if either of the first two witnesses had any particular ads that they have seen for prescription drugs that they thought went too far. If you do, I would be interested, if there are any specific ads that you could cite that you thought went too far.

But also, does not our legal system in this country present some liability for any advertiser of pharmaceuticals or, for that matter, anything else that goes too far? Either of you, Mr. Cloutier and Dr. Shaw?

Mr. CLOUTIER. I would just actually draw your attention to the ads that the chairman showed at the beginning. Our concern is about the amount of risk information and the availability of that in terms of comprehension relative to other information that is being presented. I think it is a complicated picture.

We are about to release some research next week on use of drugs in the over 65 population. One of the things that we have found is that 10 percent of people over 65 use 8 therapeutic classes or more. That means that they are treating eight separate conditions simultaneously. What we know about that is there is a 100 percent probability of polypharmacy, in other words some adverse health consequence of using all those drugs.

As we see direct-to-consumer advertising driving up volume and usage, some of which is very appropriate, some of which is less clear, that consumers as we empower them to seek these prescription drugs need to have the information available to them. We believe that it is lacking and the voluntary regulations that are in place do not require appropriate disclosure of those risks.

Senator FITZGERALD. Dr. Shaw.

Dr. SHAW. Well, in our opinion the overwhelming majority of pharmaceutical companies are extremely responsible in the way they approach direct-to-consumer advertising. It is sort of the 80–20 rule, that perhaps 20 percent of the companies are causing 80 percent of the problems.

Earlier testimony by Dr. Wolfe cited the fact that in some instances companies have been cited 13 and 14 different times for essentially the same violation, with little or no consequences, and it has just become sort of a cost of doing business. In the mean time, it provides incremental revenue.

Senator FITZGERALD. How is this really any different than just about any other area? You have ads out there all over the place, say, to invest in a mutual fund and you are not going to have all the information you really need in the ad, which will probably show their last year's return or something like that, just as you are not going to have all the information on both sides of the story in an ad for a prescription drug. Why is this any different than any other area?

The consumers out there who undertake research on their own, try to get educated as best as possible, and view a variety of sources are always going to come out better, whatever the area.

Dr. SHAW. Senator, I think from our perspective the key is this: through direct-to-consumer advertising the pharmaceutical industry has become a de factor health care information provider. Frankly, I think the health care providers——

Senator FITZGERALD. What is wrong with that?

Dr. SHAW. Nothing necessarily. The issue is the essence of standards and are they going to assume the same ethical levels of behavior that we expect from other health care professionals. We think that they are capable of that, but we think that there is a need to push in that dimension.

Senator FITZGERALD. Back to my liability question, do they not have liability if they are misleading people?

Dr. SHAW. What behaviors would you expect from your physician? Would you expect your physician to merely act within the bounds of the law or do you expect something different? With due respect——

Senator FITZGERALD. I think they have a fiduciary duty. I expect them to take extra care, a physician. But they are always worried about their own liability for medical malpractice. I would think

that there would be many potential tort causes of action for misleading advertising for a prescription drug manufacturer. That is kind of a free market check on the whole system.

Mr. CLOUTIER. I would like to respond to that. I think there is a dimension of public health protection here that is being missed. To go back to my example of eight therapeutic classes being used by 10 percent of the over 65 population, there simply is no evidence of what three drugs or more does when someone is taking them. So part of it is that we actually lack the science, that the science is out of pace with the promotional activity of loading on all these pharmacologic agents in one person, that we need to pay attention to and that we need to be cautious about.

Senator FITZGERALD. Now, that patient who is taking eight or more pharmaceuticals at the same time—you said 10 percent of the seniors are doing that?

Mr. CLOUTIER. Yes.

Senator FITZGERALD. They are getting those prescriptions from doctors, are they not?

Mr. CLOUTIER. They are, and those doctors do not have information about any more than there of those drugs interacting with each other. So what will typically happen is that someone will be taking eight or nine drugs and they will come in they will have a number of moderate side effects—dizziness, nausea.

Senator FITZGERALD. That doctor could be liable for malpractice if he prescribes those conflicting medicines, could he not?

Mr. CLOUTIER. There is that potential, yes.

Senator FITZGERALD. I know Dr. Dolinar has been chomping at the bit. I do not know if I mangled your name there. If I did, I apologize.

Dr. DOLINAR. That is fine.

I am a doctor. I treat patients. Some of them require that many medications. In fact, in the over age 65 group one out of five has diabetes and they are taking up 25 percent of the Medicare budget.

The other point I would like to make, this issue of empowering the patient I think is critical. I touched on it in my introductory statement. Many times the doctor is in an adversarial relationship with the patient. In a setting like that, you need a patient who is educated.

Let me give you a quick example. A drug came out a few years ago that was a pill for the treatment of diabetes. It would allow people who were on insulin who had type 2 diabetes, it would allow them to come off the insulin shot. They could go on this pill. Many of them could go on this pill, stop the insulin.

There was an HMO, I spoke with the physicians there. They were happy with the drug. They could not use it. They could not use it because, the way their finances were structured, if the physician wrote for that drug the patient would get it, but the cost of that drug would come out of that physician's pay check that month. So if the drug costs, let us say, $100 for the month, that doctor's pay check would be $100 less that month.

In a situation like that, I doubt if there would be more than a handful of physicians who would offer to the patient, let us try this pill and take you off of insulin. On the other hand, an empowered

patient could go in there and say: I have seen this drug, I think this could help me; can we try it out.

I cannot emphasize enough how the doctor-patient relationship has changed. The doctor is in an adversarial role.

Senator FITZGERALD. Well, thank you. Thank you all for your testimony.

Senator DORGAN. Let me just observe, my colleague raises the question of tort liability. It is the case, I think, however, with respect to food safety and safety of prescription drugs and so on, there is a separate class. I was thinking to myself as you were asking those questions about Upton Sinclair's work in Chicago, as a matter of fact, where he was going into these meatpacking plants, and they had rat problems, so they were lacing slices of bread with poison and then the rates would eat the poison and die and they would throw the bread and the rats right down the same chute where the mystery meat came out the other end.

He wrote a book about it and of course that led to the Food and Drug Administration and dramatic standards about food safety.

There are some things where let the consumer beware and let the courts respond to it do not work. I think medicine is one of them, in the sense that you must have standards. I think the question you raise is important, what kind of standards should you have with respect to advertising, and that is less—that is a little less clear.

It is quite clear what standards you ought to have when you manufacturer prescription drugs in an FDA-approved plant. But it is a little less clear, and that is one of the reasons for the hearing, what the standards one must have to deal with advertising of prescription drugs. It is a most interesting discussion.

Senator FITZGERALD. By the way, the stockyards are no longer in Chicago. I think they moved them out West, your way.

Senator DORGAN. That is true.

I want to thank the panel. The testimony we have received has been most interesting and I think sheds different opinions and viewpoints on a very interesting question. As the price and the cost of prescription drugs continues to increase and as new and exciting prescription drugs are developed to deal with dread diseases and other conditions, I think all of these issues will continue to be ones that will be discussed in I hope a thoughtful and a serious way by the Congress.

This hearing is adjourned.

[Whereupon, at 4:33 p.m., the Subcommittee was adjourned.]

○